

**UNITED STATES  
SECURITIES AND EXCHANGE COMMISSION  
WASHINGTON, D.C. 20549**

**FORM 10-K**

(Mark One)

**ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**  
For the fiscal year ended December 31, 2021

**TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**  
OR  
For the transition period from \_\_\_\_\_ to \_\_\_\_\_  
Commission File Number 001-38662

**SUTRO BIOPHARMA, INC.**  
(Exact Name of Registrant as Specified in Its Charter)

Delaware  
(State or other jurisdiction of  
incorporation or organization)  
111 Oyster Point Blvd.  
South San Francisco, California  
(Address of principal executive offices)

47-0926186  
(I.R.S. Employer  
Identification No.)

94080  
(Zip Code)

(650) 881-6500  
(Registrant's telephone number, including area code)

**Securities registered pursuant to Section 12(b) of the Act:**

Title of each class  
Common stock, \$0.001 par value

Trading Symbol  
STRO

Name of each exchange on which registered  
The Nasdaq Stock Market LLC  
(Nasdaq Global Market)

**Securities registered pursuant to Section 12(g) of the Act:**

None

Indicate by check mark if the registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act. Yes  No

Indicate by check mark if the registrant is not required to file reports pursuant to Section 13 or Section 15(d) of the Act. Yes  No

Indicate by check mark whether the issuer (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes  No

Indicate by check mark whether the registrant has submitted electronically every Interactive Data File required to be submitted pursuant to Rule 405 of Regulation S-T (§232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit such files). Yes  No

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, a smaller reporting company or an emerging growth company. See the definitions of "large accelerated filer," "accelerated filer," "smaller reporting company" and "emerging growth company" in Rule 12b-2 of the Exchange Act.

Large accelerated filer   
Non-accelerated filer

Accelerated filer   
Smaller reporting company   
Emerging growth company

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act.

Indicate by check mark whether the registrant has filed a report on and attestation to its management's assessment of the effectiveness of its internal control over financial reporting under Section 404(b) of the Sarbanes-Oxley Act (15 U.S.C. 7262(b)) by the registered public accounting firm that prepared or issued its audit report.

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act). Yes  No

The aggregate market value of the voting and non-voting common equity held by non-affiliates of the Registrant on June 30, 2021 (the last business day of the Registrant's second fiscal quarter), based upon the closing price of \$18.59 of the Registrant's common stock as reported on The Nasdaq Global Market, was approximately \$849.9 million.

The number of shares of the registrant's common stock outstanding as of February 24, 2022, was 46,381,212.

**DOCUMENTS INCORPORATED BY REFERENCE**

Portions of the registrant's definitive proxy statement to be filed for its 2022 Annual Meeting of Stockholders are incorporated by reference into Part III hereof. Such proxy statement will be filed with the Securities and Exchange Commission within 120 days of the end of the fiscal year covered by this Annual Report on Form 10-K.

**Sutro Biopharma, Inc.**  
**ANNUAL REPORT ON FORM 10-K**  
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## Forward-Looking Statements

This Annual Report on Form 10-K, or Annual Report, contains forward-looking statements within the meaning of Section 21E of the Securities Exchange Act of 1934, as amended, or the Exchange Act, and section 27A of the Securities Act of 1933, as amended, or the Securities Act. All statements contained in this Annual Report other than statements of historical fact, including statements regarding our future results of operations and financial position, business strategy, market size for our product candidates, potential future milestone and royalty payments, the value of the our holdings of Vaxcyte common stock, potential growth opportunities, nonclinical and clinical development activities, efficacy and safety profile of our product candidates, our ability to maintain and recognize the benefits of certain designations received by product candidates, our ability to successfully leverage Fast Track designation, the timing and results of nonclinical studies and clinical trials, collaboration with third parties, the expected impact of the COVID-19 pandemic on our operations, and the receipt and timing of potential regulatory designations, approvals and commercialization of product candidates, are forward-looking statements. The words “believe,” “may,” “will,” “potentially,” “estimate,” “continue,” “anticipate,” “predict,” “target,” “intend,” “could,” “would,” “should,” “project,” “plan,” “expect,” and similar expressions that convey uncertainty of future events or outcomes are intended to identify forward-looking statements, although not all forward-looking statements contain these identifying words.

These forward-looking statements are subject to a number of risks, uncertainties and assumptions, including those described in Item 1A, “Risk Factors” and elsewhere in this Annual Report. Moreover, we operate in a very competitive and rapidly changing environment, and new risks emerge from time to time. It is not possible for our management to predict all risks, nor can we assess the impact of all factors on our business or the extent to which any factor, or combination of factors, may cause actual results to differ materially from those contained in any forward-looking statements we may make. In light of these risks, uncertainties, and assumptions, the forward-looking events and circumstances discussed in this Annual Report may not occur and actual results could differ materially and adversely from those anticipated or implied in the forward-looking statements.

You should not rely upon forward-looking statements as predictions of future events. Although we believe that the expectations reflected in the forward-looking statements are reasonable, we cannot guarantee that the future results, levels of activity, performance or events and circumstances reflected in the forward-looking statements will be achieved or occur. We undertake no obligation to update publicly any forward-looking statements for any reason after the date of this report to conform these statements to actual results or to changes in our expectations, except as required by law. You should read this Annual Report with the understanding that our actual future results, levels of activity, performance and events and circumstances may be materially different from what we expect.

Except where the context otherwise requires, in this Annual Report on Form 10-K, “we,” “us,” “our” and the “Company” refer to Sutro Biopharma, Inc.

## Trademarks

This Annual Report on Form 10-K includes trademarks, service marks and trade names owned by us or other companies. All trademarks, service marks and trade names included in this Annual Report on Form 10-K are the property of their respective owners. We do not intend our use or display of other companies’ trade names, trademarks or service marks to imply a relationship with, or endorsement or sponsorship of us by, these other companies.

## Summary of Risk Factors

Our business is subject to a number of risks and uncertainties, including those highlighted in the section titled “Risk Factors”. Some of these risks include:

- The COVID-19 pandemic is impacting the availability of routine materials for our business, which has caused us to spend significant effort in sourcing alternatives and otherwise modifying our activities, and it may have even more pronounced and significant impact on our activities in the future. For example, difficulties in sourcing filters used in our manufacturing operations have resulted in modified manufacturing schedules and additional development work to qualify alternatives, which has affected our manufacturing operations. While these effects have not yet impacted availability of preclinical or clinical materials, it is possible that further such difficulties may result in delays in initiating or conducting our clinical trials.
- We have a limited operating history, a history of significant losses and may never achieve or maintain profitability.
- We will need substantial additional funds to advance development of our product candidates and failure to obtain timely funding, may force us to delay, limit or terminate our product development programs, commercialization efforts or other operations.
- Our product candidates are in early stages of development and may fail or suffer delays that materially and adversely affect their commercial viability.
- Our business is dependent on the success of our product candidates based on our proprietary XpressCF® and XpressCF+®™ platforms and, in particular, our proprietary product candidates, STRO-001 and STRO-002.
- If we do not achieve our projected development goals in the time frames we announce and expect, the commercialization of our products may be delayed and, as a result, our stock price may decline.
- Security breaches, cyber-attacks, loss of data, and other disruptions at our facilities or at our third party CROs, CMOs, or other vendors could compromise sensitive information related to our business or other personal information or prevent us from accessing critical information and expose us to liability, which could adversely affect our business, reputation, results of operations, financial condition and prospects.
- Our failure to comply with privacy and data protection laws or to adequately secure the personal information we hold could result in significant liability or reputational harm and, in turn, a material adverse effect on our client base, member base and revenue.
- If our collaborations with third parties to develop and commercialize certain product candidates are not successful, we may not be able to capitalize on the market potential of our XpressCF® platform and the product candidates.
- We currently manufacture a portion of our product candidates internally and also rely on third-party manufacturing and supply partners to provide us with components of our product candidates. Our inability to manufacture sufficient quantities of our product candidates, or the loss of our third-party suppliers, or our or their failure to comply with applicable regulatory requirements or to supply sufficient quantities at acceptable quality levels or prices, or at all, would materially and adversely affect our business.
- We face competition from entities that have developed or may develop product candidates for cancer, including companies developing novel treatments and technology platforms. If these companies develop technologies or product candidates more rapidly than we do or their technologies are more effective, our ability to develop and successfully commercialize product candidates may be adversely affected.
- If we are not able to obtain and enforce patent protection for our technologies or product candidates, development and commercialization of our product candidates may be adversely affected.
- If we are unable to develop, obtain regulatory approval for or commercialize our product candidates, or experience significant delays in doing so, our business will be materially harmed.

## PART I

### Item 1. *Business*

#### Overview

We are a clinical stage drug discovery, development and manufacturing company focused on deploying our proprietary integrated cell-free protein synthesis platform, XpressCF<sup>®</sup>, and our site-specific conjugation platform, XpressCF+<sup>®</sup>™, to create a broad variety of optimally designed, next-generation protein therapeutics, initially for cancer. We aim to design therapeutics using the most relevant and potent modalities, including cytokine-based therapeutics, immunoncology, or I/O agents, antibody-drug conjugates, or ADCs, immunostimulatory ADCs, or iADCs, and bispecific antibodies that are directed primarily against clinically validated targets where the current standard of care is suboptimal. We believe our platform allows us to accelerate the discovery and development of potential first-in-class and best-in-class molecules by enabling the rapid and systematic evaluation of protein structure-activity relationships to create optimized homogeneous product candidates. Our mission is to transform the lives of patients by using our XpressCF<sup>®</sup> platform to create medicines with improved therapeutic profiles for areas of unmet need.

Our two most advanced product candidates are wholly owned: STRO-002, an ADC directed against folate receptor-alpha, or FolR $\alpha$ , for patients with FolR $\alpha$ -expressing cancers, such as ovarian and endometrial cancers, and STRO-001, an ADC directed against CD74, for patients with B-cell malignancies, such as multiple myeloma and non-Hodgkin lymphoma, or NHL. In March 2019, STRO-002 began enrolling patients in a Phase 1 trial focused on ovarian and endometrial cancers. The dose escalation portion of the STRO-002 Phase 1 trial has been completed and the dose expansion portion of the trial is ongoing to assess the efficacy, safety and tolerability of STRO-002 at dose levels of 4.3 and 5.2 mg/kg. In May 2021, we reported data from the dose-escalation cohort. Based on such reported data, STRO-002 exhibited a manageable safety profile and promising preliminary efficacy data, as discussed in more detail below. In January 2022, we released initial results of the dose expansion portion of the STRO-002 Phase 1 trial. These data suggested that STRO-002 exhibited a manageable safety profile together with promising preliminary efficacy data in the tested patient population, as discussed in more detail below. In August 2021, we were granted Fast Track designation for STRO-002 by the U.S. Food and Drug Administration, or FDA, for the treatment of patients with platinum-resistant epithelial ovarian, fallopian tube, or primary peritoneal cancer who have received one to three prior lines of systemic therapy. In December 2021, we entered into a licensing agreement with Tasly Biopharmaceuticals Co., Ltd, or Tasly, to grant Tasly an exclusive license to develop and commercialize STRO-002 in China, Hong Kong, Macau and Taiwan, referred to as Greater China (the "Tasly License Agreement").

Our second candidate, STRO-001, is currently enrolling patients in a Phase 1 trial, with updated data reported in December 2020, as discussed in more detail below. Based on such reported data, STRO-001 has been generally well-tolerated and, unlike certain other ADCs, no ocular toxicity signals have been observed, with no patients receiving prophylactic corticosteroid eye drops. Dose escalation in the STRO-001 Phase 1 trial is continuing, and the maximum tolerated dose has not yet been reached. In October 2018, we were granted Orphan Drug Designation by the FDA for STRO-001 for the treatment of multiple myeloma. In October 2021, we granted BioNova Pharmaceuticals Limited, or BioNova, an option to exclusively license the right to develop and commercialize STRO-001 in Greater China (the "BioNova Option Agreement").

Based on our proprietary XpressCF<sup>®</sup> and XpressCF+<sup>®</sup>™ platforms, we have also entered into multi-target, product-focused collaborations with leaders in the field of oncology, including a cytokine derivatives collaboration with Merck Sharp & Dohme Corp., a subsidiary of Merck & Co., Inc., Kenilworth, NJ, or Merck; a B Cell Maturation Antigen, or BCMA, ADC collaboration with Celgene Corporation, or Celgene, a wholly owned subsidiary of Bristol-Myers Squibb Company, New York, NY, or BMS; a MUC1-EGFR ADC collaboration with Merck KGaA, Darmstadt Germany (operating in the United States and Canada under the name "EMD Serono"); and license agreement to develop and commercialize STRO-002 in Greater China with Tasly. Our XpressCF<sup>®</sup> and XpressCF+<sup>®</sup>™ platforms have also supported a spin-out company, Vaxcyte Inc., or Vaxcyte, focused on discovery and development of vaccines for the treatment and prophylaxis of infectious disease.

We believe our XpressCF® platform is the first and only current Good Manufacturing Practices, or cGMP, compliant and scalable cell-free protein synthesis technology that has resulted in multiple product candidates in clinical development. We believe key advantages of our cell-free protein synthesis platform over conventional biologic drug discovery and development include:

- ability to rapidly produce a wide variety of protein structures in-house;
- ability to incorporate multiple, different non-natural amino acids in a single protein;
- faster cycle time;
- efficient drug discovery and early pharmacology and safety assessment; and
- rapid and predictable scalability.

We plan to leverage these capabilities to accelerate the discovery and development of potential first-in-class and best-in-class molecules.

The benefits of our XpressCF® and XpressCF+®™ platforms have resulted in collaborations with leaders in the field of oncology, including Merck, BMS and EMD Serono. As a result of discovery efforts enabled through our XpressCF® and XpressCF+®™ platforms, Merck has the right to develop two cytokine derivative candidate molecules. Additionally, BMS has the worldwide right to develop and commercialize a novel ADC therapeutic directed against BCMA, known as CC-99712. An IND submission was filed in connection with CC-99712 in the first half of 2019. CC-99712 is being studied in a Phase 1 trial, as a monotherapy and in combination with a gamma secretase inhibitor, and is currently enrolling patients with relapsed and refractory multiple myeloma. In February 2021, CC-99712 was granted orphan drug designation for the treatment of relapsed and refractory multiple myeloma. Finally, our collaboration with EMD Serono yielded a novel bispecific ADC product candidate targeting EGFR and MUC1, known as M1231, for which an IND submission was filed in the second half of 2020 and which is currently under investigation in a Phase 1 trial for the treatment of solid tumors, including metastatic non-small cell lung cancer and esophageal squamous cell carcinoma. Through December 31, 2021, we have received an aggregate of approximately \$446 million in payments from all of our collaborations, which includes approximately \$54 million in investments in our stock. We intend to selectively enter into additional collaborations with partners who are seeking efficient and effective drug discovery, preclinical development and manufacturing capabilities for the creation of novel therapeutics.

Our first internally developed product candidate is STRO-001, which we believe has the potential to be a first-in-class and best-in-class ADC directed against CD74, an antigen that is highly expressed in many B cell malignancies. In multiple preclinical models, STRO-001 has demonstrated potent anti-tumor activity. In addition, the properties of STRO-001 suggest a low likelihood of off-target toxicity and potential for an improved therapeutic index. STRO-001 is currently enrolling patients in a Phase 1 trial for multiple myeloma and NHL for which we reported updated data in December 2020. Based on such reported data, STRO-001 has been generally well-tolerated and no ocular toxicity signals have been observed, with no patients receiving prophylactic corticosteroid eye drops. Dose escalation in the STRO-001 Phase 1 trial is continuing, and the maximum tolerated dose has not yet been reached. We expect to identify a recommended Phase 2 dose for STRO-001 by the end of 2022.

In October 2021, we entered into the BioNova Option Agreement. We believe that our collaboration with BioNova extends the opportunity to realize the potential value of STRO-001 through clinical development and commercialization in Greater China.

We are also internally developing STRO-002, an ADC directed against FolR $\alpha$ , initially targeted for the treatment of ovarian and endometrial cancers. Our experiments show that FolR $\alpha$  expression can be detected in 90% or more of ovarian and endometrial cancers. In preclinical models, STRO-002 has demonstrated the potential for enhanced and selective activity against cells expressing FolR $\alpha$ , superior inhibition of tumor growth and greater linker stability, in comparison to experiments we conducted with a benchmark FolR $\alpha$ -targeting molecule. We began enrolling patients in a STRO-002 Phase 1 trial focused on ovarian and endometrial cancers in March 2019. We have completed the dose-escalation portion of the trial and reported updated data for STRO-002 in May 2021. The dose-expansion portion of the trial has been fully enrolled and is ongoing to assess the efficacy, safety and tolerability of STRO-002 at dose levels of 4.3 and 5.2 mg/kg. For the dose-expansion portion, we dosed the first patient in January 2021 and are enrolling less heavily pre-treated ovarian cancer patients. We reported initial dose-expansion data in January 2022. Additionally, a STRO-002 combination cohort in ovarian cancer opened for enrollment in December 2021, assessing the combination of STRO-002 with bevacizumab, and an expansion cohort for FolR $\alpha$ -selected endometrial cancer opened and began enrolling patients in the fourth quarter of 2021.

In December 2021, we entered into the Tasly License Agreement. We believe that our collaboration with Tasly extends the opportunity to realize the potential value of STRO-002 through clinical development and commercialization in Greater China.

Although we believe our product candidates have the potential to be first-in-class and/or best-in-class and to provide potent anti-tumor activity with reduced off-target toxicity, we will need to complete additional studies to determine the safety and efficacy of our product candidates. The results of these future studies may be different than the results of our earlier studies. We have not received regulatory approval for any of our product candidates, and in order to obtain regulatory approval and commercialize our product candidates, the FDA or foreign regulatory agencies will need to determine that our product candidates are safe and effective. We may not obtain regulatory approval on the timeline we currently expect, or at all, and competing therapies and products may ultimately reach the market faster or have more favorable safety and efficacy profiles than our product candidates.

Beyond these wholly owned programs and collaborations, we are developing a broader pipeline of next-generation protein therapeutics using our XpressCF<sup>®</sup> and XpressCF+<sup>™</sup> platforms. Our protein engineering and chemistry efforts are focused on maximizing therapeutic indices, and our technology allows us to rapidly test our therapeutic hypothesis in significantly more product candidates than conventional protein synthesis allows in order to identify the best molecule to advance to the clinic. Our drug discovery teams are exploring novel immuno-oncology therapies, including cytokine-based therapies. We are also actively pursuing the discovery and development of other novel ADCs, including tumor targeting immunostimulant-ADCs, or iADCs and bispecific antibodies, including T cell-engager discovery programs.

### Our Strategy

Our goal is to use our proprietary XpressCF<sup>®</sup> platform to create product candidates primarily against clinically validated targets. Key elements of our strategy are to:

•**Advance STRO-001 and STRO-002 through clinical development.** We are currently evaluating STRO-001 in a Phase 1 trial for patients with advanced and/or refractory multiple myeloma and NHL. Based on our preclinical data, we believe STRO-001 has the potential to be a first-in-class and best-in-class ADC directed against CD74, which is highly expressed in many B cell malignancies. We reported updated data in December 2020, expect to establish a recommended Phase 2 dose in 2022, and thereafter may begin the dose expansion portion of the Phase 1 trial. In October 2018, we were granted Orphan Drug Designation by the FDA for STRO-001 for the treatment of multiple myeloma. In October 2021, we entered into the BioNova Option Agreement for STRO-001 in Greater China. We began enrolling patients in a STRO-002 Phase 1 trial focused on ovarian and endometrial cancers in March 2019 and dosed the first patient in the dose expansion portion of the Phase 1 trial in January 2021, enrolling less heavily pre-treated ovarian cancer patients. We reported updated dose-escalation data in December 2020 and May 2021 and reported initial dose-expansion data in January 2022. In December 2021, we entered into the Tasly License Agreement for STRO-002 in Greater China. Given that FolR $\alpha$  is a clinically validated target for ovarian cancer, along with STRO-002's homogeneous design, we believe it

has the potential to be a best-in-class FolR $\alpha$ -targeted ADC and provide greater activity, stability and safety as compared to other investigational agents in development.

**•Maintain worldwide rights to our core product candidates to the extent possible and collaborate with partners to develop and commercialize our core product candidates in certain territories.** We own the worldwide commercial rights to our most advanced product candidates, STRO-001 and STRO-002, except for the rights granted to BioNova and Tasly, respectively, in certain territories. We have assembled a management team with extensive experience in the biopharmaceutical industry, including drug discovery and development through commercialization, and our plan is to independently pursue the development and commercialization of our product candidates. As we continue to advance our products, we may opportunistically pursue additional strategic partnerships that maximize the value of our pipeline.

**•Develop a diverse pipeline of novel product candidates with optimal therapeutic profiles.** We intend to build a broad pipeline of optimally designed, next-generation protein therapeutics, initially for cancer, using our XpressCF<sup>®</sup> platform. Our cell-free-based protein synthesis system enables the rapid and systematic evaluation of protein structure-activity relationships, which we believe will accelerate the discovery and development of molecules. We aim to take advantage of the most potent modalities, including cytokines, ADCs, iADCs and bispecific antibodies, to create drugs that are directed primarily against clinically validated targets where the current standard of care is suboptimal.

**•Strategically pursue additional collaborations to broaden the reach of our XpressCF<sup>®</sup> platform.** To maximize the value of our XpressCF<sup>®</sup> platform technology, we have entered into multi-target, product-focused collaborations with leaders in the field of oncology, including a cytokine derivatives collaboration with Merck, a BCMA ADC collaboration with Celgene (now BMS) and a MUC1-EGFR ADC collaboration with EMD Serono. We intend to selectively enter into additional collaborations with partners who are seeking efficient and effective drug discovery and manufacturing capabilities for the development of novel therapeutics. We intend to retain certain development and commercial rights to maximize the future potential value of product candidates discovered and developed using our XpressCF<sup>®</sup> platform.

**•Selectively expand the scope of our XpressCF<sup>®</sup> platform into other therapeutic areas.** Due to the versatility of our platform, we can explore additional therapeutic areas outside of oncology. We intend to make further investment in the development of our XpressCF<sup>®</sup> platform to expand our pipeline of product candidates.

### **Cancer Remains a Major Unmet Medical Need**

Cancer is the second leading cause of mortality in the United States, and is the leading cause of death for those under 65 years of age. The American Cancer Society estimated that there would be roughly 1.9 million new cases of cancer diagnosed and approximately 609,000 people would die of cancer in the United States in 2021.

#### ***Traditional Cancer Therapeutics***

Cancer treatment has traditionally included chemotherapy, radiation, surgery or a combination of these approaches. Chemotherapy agents and other small molecule targeted therapies can be effective in certain types of cancer, but they can also cause toxicities that may lead to life-threatening consequences, lower quality of life or early termination of treatment. Furthermore, these agents offer limited efficacy in many types of cancer.

Over the last twenty years, new paradigms of cancer research and treatment have emerged to address the limitations of existing treatments. Some of the most promising new approaches involve biologic therapies, including monoclonal antibodies. Monoclonal antibodies are proteins that bind to antigen targets on tumor cells and inhibit tumor growth, or block processes that provide nourishment for the tumor. As a drug class, monoclonal antibodies have transformed the treatment of oncology and represent some of the top selling therapies on the market, resulting in more than \$65 billion in sales in 2020 across all oncology indications.

Despite the success of conventional monoclonal antibodies, they still have limitations. For example, the response seen with monoclonal antibodies can be variable, with some patients responding, while others do not. In addition, the response is often not durable and many patients relapse or become refractory to treatment. Also, safety and tolerability concerns often limit the use of higher, potentially more efficacious doses. We believe our



XpressCF® platform will provide enhanced therapeutic approaches for treating cancer to address these unmet needs. A new generation of biologics is emerging, including cytokine-based therapeutics, immuno-oncology agents, ADCs, iADCs and bispecific antibodies. The expectation is that multiple therapeutic modalities will be used in novel combinations to treat patients and provide the most potent anti-cancer effect.

### **Immuno-Oncology**

The immune system is capable of recognizing and eliminating tumor cells. However, some cancer cells over express proteins, called immune checkpoints, which suppress the immune system, and enable the tumor cells to evade destruction. Immuno-oncology has emerged as a promising new therapeutic approach that aims to enhance anti-tumor immune responses by using monoclonal antibodies to overcome these immune checkpoint blockades.

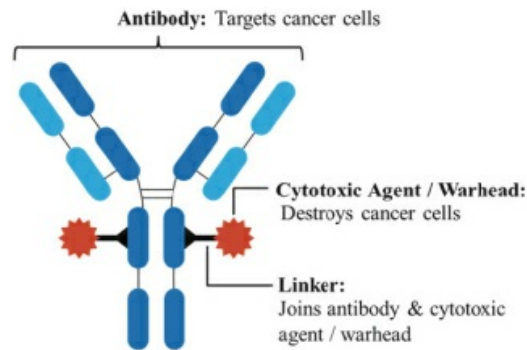
Six monoclonal antibody immune checkpoint inhibitors are approved in the United States for the treatment of cancer indications, such as melanoma, non-small cell lung cancer, or NSCLC, renal cancer and bladder cancer. Checkpoint inhibitors are among the leading cancer drugs, with Keytruda and Opdivo alone generating more than \$22 billion in worldwide sales in 2020.

#### *Limitations to Current Immuno-Oncology Approaches*

The effectiveness of any cancer immunotherapy is dependent on the status of an individual patient's immune system. While many single-agent immunotherapies have resulted in remarkable clinical results, only a minority of patients have realized durable benefits from these treatments. An immunotherapy cannot succeed if a patient's immune cells are too impaired to benefit from a particular checkpoint inhibitor or cytokine-based therapeutic. As a result, combination therapies have been explored clinically and are designed to provide an additional boost to revive a patient's ability to mount an immune response against their tumor. However, combination therapies will likely have to provide a significant risk-benefit advantage to justify the cumulative costs of combining two separate immunotherapies. New single agent approaches to achieving combinatorial stimulation of a patient's immune system may therefore create the preferred option for many patients and physicians.

### **Antibody-Drug Conjugates**

After more than two decades of industry efforts, several new modalities of highly potent monoclonal antibody-based therapies have emerged, including ADCs. The key components of ADCs include an antibody, a stable linker and a cytotoxic agent (warhead). The antibody is used to target and deliver the cytotoxic agent to tumor cells. ADCs can be mono, bispecific or multi-specific. The intended result of this powerful and targeted approach is greater tumor cell death and less systemic tolerability issues as compared to traditional chemotherapy. The following diagram shows the component parts of an ADC.

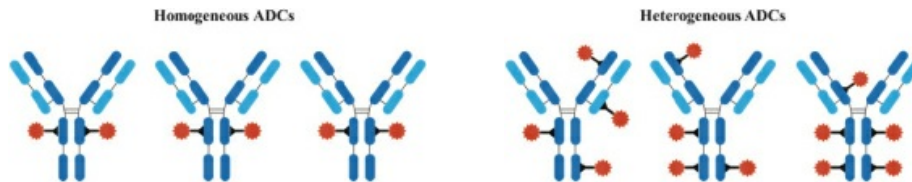


Currently, there are more than 100 ADCs being explored in clinical development. Kadcyla and Adcetris were the first of the new generation of ADCs to be approved for the treatment of specific subsets of breast cancer and lymphoma, respectively. Since the approval of Kadcyla, ten more ADCs entered or re-entered the market, as Besponsa, Mylotarg, Lumoxiti, Polivy, and Zynlonta were approved for the treatment of specific subsets of leukemia and lymphoma; Padcev was approved for the treatment of bladder and urinary tract cancers; Enhertu and Trodelvy were approved for the treatment of breast cancer; Blenrep was approved for the treatment of multiple myeloma; and Tivdak was approved for the treatment of cervical cancer. All twelve of these approved therapies demonstrate that ADCs have an emerging role in the armamentarium of cancer therapeutics.

#### *Limitations to Current ADC Approaches*

Despite the approvals of these ADCs, there have been challenges in achieving the full clinical potential of this modality. We believe these challenges are directly related to the following:

•*Heterogeneity as a Result of Imprecise and Variable Conjugation.* The approved ADCs and many that are in development use imprecise technologies that opportunistically attach the cytotoxic payload to naturally occurring amino acids within the antibody and result in a heterogeneous mixture. In these mixtures, the number and site location of the linker-warhead can vary significantly from antibody to antibody within the single ADC product. These many different forms in the final product are likely to perform differently, with some forms carrying insufficient cytotoxin to kill the tumor, and some forms carrying too high a load resulting in unintended toxicities. The overall performance of the heterogeneous ADC is therefore the average activity of the different species within the ADC mixture, which may limit both efficacy and tolerability. For these reasons, we believe this current class of ADCs, which are heterogeneous mixtures, are suboptimal for effective cancer treatment. The figure below compares homogeneous and heterogeneous ADCs.

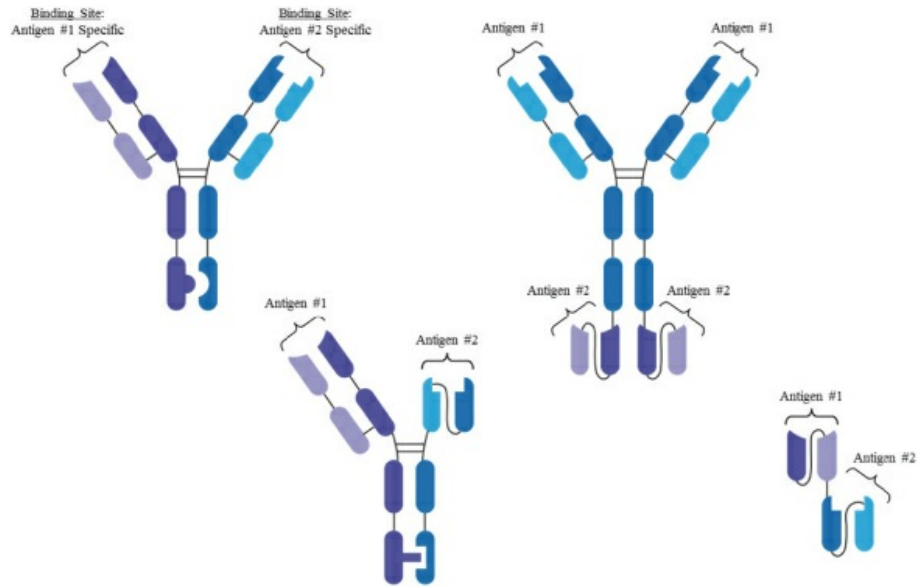


•*Suboptimal Linker-Warhead Positioning.* Conventional ADC technologies use conjugation chemistry to attach linker-warheads to naturally occurring amino acids within an antibody; therefore, the position is dictated by the pre-existing amino acid sequence. Published research studies have demonstrated that linker-warhead positioning along an antibody can have significant effect on the ability of an ADC to kill tumor cells, with some positions resulting in suboptimal killing. This position effect also contributes to the challenge of a heterogeneous ADC mixture. We believe that superior ADCs can be developed using technologies that allow linker-warhead positioning to be fine-tuned to empirically determined sites for maximal therapeutic benefit.

•*Instability Due to Linker Design.* One of the major challenges in ADC technology has been to develop linking chemistries that ensure that warheads are only released from the antibody within a tumor cell, and not released within the blood or healthy tissue as the ADC is delivered systemically and travels through the body. We believe that safer ADCs can be developed by utilizing non-natural amino acids that enable state-of-the-art chemistries to ensure that the warhead is not prematurely released.

## Bispecific Antibodies

Bispecific antibodies are engineered proteins that can simultaneously bind to two different types of antigens. Targeting two individual antigens simultaneously is expected to drive a larger clinical impact than conventional monoclonal antibodies. As a class, there are currently approximately 45 bispecific antibodies in clinical development for oncology indications. Bispecific antibodies can be engineered in a variety of different formats as shown below.



Bispecific antibodies come in a wide variety of structural formats that can be used in multiple therapeutic modalities, including dual blocking bispecific antibodies, T cell-engaging bispecific antibodies and dual antigen targeting bispecific antibodies. Given the potential synergistic nature of these approaches, they have the potential to provide a similar, if not improved, therapeutic benefit as compared to a traditional combination approach. In addition, they may also demonstrate an improved safety and tolerability profile. These characteristics could allow for a wider therapeutic index as compared to the comparable combination therapy approach. Additionally, combining two mechanisms in a single bispecific antibody could have advantages in manufacturing, clinical development and patient convenience.

### Limitations to Current Bispecific Antibody Approaches

Bispecific antibodies are highly engineered proteins with structural features not found in nature. The generation of these molecules therefore presents significant design and development challenges, especially when using conventional cell-based technologies. These challenges include:

- Optimization Challenges.** Bispecific antibodies simultaneously engage two different targets and therefore have precise requirements for the binding properties and spatial orientation of each domain in order to have pharmacologic activity. Combinatorial pairing of antibody binding arms to identify an optimized bispecific antibody requires many distinct cell lines that must be engineered during the discovery process, a cumbersome process when using conventional cell-based technologies.
- Challenges to T Cell-Engagers.** Discovery of bispecific T cell-engagers is further limited by the challenge of designing bispecific pairs that can safely activate T cells specifically in the tumor environment without activating peripheral T cells, which would result in severe toxicities.

•*Difficulties in Protein Expression and Manufacturing.* Because bispecific antibodies are highly engineered proteins, conventional cell-based systems have significant difficulties in protein expression, particularly at a larger scale.

We believe that new protein engineering technologies will enable significantly broader design opportunities to discover new bispecific antibodies optimized for therapeutic activity, safety and manufacturability.

### ***Cytokine-Based Immuno-Oncology Therapeutics***

Cytokines are small biologically active proteins that play an essential role in immune cell function. Cytokines are important for cell-to-cell communication and are responsible for controlling immune cell growth and differentiation. Recombinant human cytokines were among the first biotechnology products engineered for therapeutic use and, in the field of oncology, cytokines that stimulate the immune system to attack cancer cells have been viewed as a potential new approach.

Certain cytokines play a central role in T cell function, contributing to the careful balance between helpful and harmful immune responses. These can be powerful activators of the immune system but can also suppress immune responses through certain specialized T cells that have suppressive functions. A previously approved cytokine therapeutic Proleukin had shown therapeutic benefit in a small number of cancer patients, but its therapeutic use was limited due to toxicity. Scientists at other companies have focused research on finding ways to modify cytokines so as to reduce toxicity while maintaining therapeutic benefit. The observed efficacy of a modified cytokine, in combination with an immune checkpoint inhibitor, indicates the potential of this new approach. In light of these data and our prior research into cytokines, we commenced a cytokine-based research program using our XpressCF® and XpressCF+®™ platform technologies and are now collaborating with Merck on developing cytokine derivatives. We believe that recent advances in immuno-oncology combined with new protein engineering technologies create opportunities to identify novel cytokine-based therapeutics with superior therapeutic indexes.

### **Our Proprietary XpressCF® Platform**

While cytokine-based immuno-oncology therapeutics, ADCs, iADCs and bispecific antibodies hold significant promise, drug developers working with these complex biologics face significant design and development challenges. Optimizing these complex biological structures is a challenging, trial and error process that requires the refinement of several properties in tandem. This iterative process is cumbersome and fraught with significant limitations. As a result, the drug candidate nominated for development is often plagued by inefficient design properties, which then translates to a suboptimal therapeutic index when investigated in the clinic.

Our XpressCF® platform seeks to address these significant shortcomings. We believe our cell-free-based protein synthesis technology allows for efficient and proper design exploration to be conducted prior to nominating a lead drug candidate. In addition, we believe we can optimally design these types of complex biologics in a manner that is ideal for subsequent production at relevant scale and manufacture. We believe we are the only company with products in clinical development that has the capability to produce cell-free-based protein synthesis at scale. We believe we have a significant advantage over other development approaches in this space.

### ***Limitations of Current Cell-Based Synthesis Approaches***

All existing therapeutic proteins rely on cell-based design, production and manufacturing technologies. The conventional biotechnology approach for the production of these complex biologics relies primarily on CHO cell lines. This first requires low yield transient production from cells that enable characterization of a new protein over several months. This is then followed by development of stable cell lines over several months to a year to enable larger scale preclinical, clinical and commercial production. The characterization process has to be reproduced for every minor variant of the therapeutic protein, which may or may not result in improved properties. Each change requires development of new cell-based methods to generate protein of sufficient quality and quantity to evaluate. Therefore, it is extremely laborious and resource intensive to elucidate principles of structure-activity relationship, and drug discovery is limited by the number of cell lines that can be practically managed in parallel. In addition, they have limited ability to introduce non-natural amino acids into proteins. We believe these limitations hinder the efficiency of drug discovery and often result in suboptimal protein selection.

## **Overview of Our XpressCF® Platform**

Our XpressCF® platform is fundamentally different from the conventional cell-based protein synthesis approach in that we separate the production of the cell mass from the production of the protein.

We first generate a cellular mass from our proprietary cell line from which we harvest the inner cellular machinery for making proteins. The cellular mass is generated from our highly engineered variant of *Escherichia coli*, or *E. coli* bacteria, and has been optimized to make extract that produces complex mammalian proteins. These cells are grown over the course of several days, harvested, broken apart, clarified and stored as a cell mass for future production of our protein therapeutics. We refer to this proprietary cell mass as extract, or XtractCF®. The extract includes necessary components for energy production, transcription and translation and can be used to support cell-free protein synthesis. This extract can then be used agnostically to manufacture a wide variety of therapeutic proteins and protein fragments without the need to generate further cell lines.

As a result, protein synthesis then becomes a predictable and reproducible biochemical reaction, independent of the constraints of a cell. A specific DNA sequence is added to the extract, which results in the coding and expression of the desired protein in less than 24 hours. Using this process, we express hundreds or thousands of DNA sequences simultaneously within the same cell-free extract system and therefore can make and purify hundreds or thousands of unique proteins at the same time. This allows us to perform rapid expression, testing and characterization of many variants early in discovery to elucidate structure-activity relationships. Structure-activity relationship refers to how changes to the structure of a protein can lead to improvements in a molecule's properties, such as binding, internalization, functional activity and stability, which are properties that are key to the therapeutic protein's efficacy and tolerability in the patient. We are thereby able to optimize many properties with high specificity, including: binding efficiency to each antigen target, spatial orientation, linker design, target killing efficiency, immunological activity, protein expression, and folding efficiency and stability.

## **Advantages of Our XpressCF® Platform**

We believe our drug discovery platform provides significant advantages over conventional cell-based protein synthesis approaches and has the ability to produce a large number of variants during the development stage, while preserving the ability to design and test large families of molecules for optimized efficacy and safety features. As a result, we believe that our drug discovery platform can accelerate time to IND by nine to fifteen months compared to conventional technologies.

We believe the advantages of our cell-free-based protein synthesis technology platform include:

•**Ability to Rapidly Produce and Evaluate a Wide Variety of Protein Structures In-house.** By decoupling the production of the cell-free extract from the production of the protein, we are able to stockpile large quantities of cell-free extract from which we are able to manufacture a wide variety of proteins without the need to generate individual cell lines, including cytokine-based immuno-oncology therapeutics, ADCs, iADCs and bispecific antibodies.

•**Ability to Incorporate Non-Natural Amino Acids.** Our technology allows for efficient incorporation of a non-natural amino acid in any location in an antibody or protein with high precision and fidelity, which we believe allows for the design of optimized protein conjugates. Further, our non-natural amino acid conjugation technology permits complete and rapid stable linkage between our linker components and the non-natural amino acid, resulting in a single species without loss of efficiency as the conjugates become increasingly complex.

•**Faster Cycle Time.** Our ability to produce thousands of protein variants in parallel overnight allows us to rapidly express, test and characterize many variants early in discovery to elucidate structure-activity relationships and identify opportunities for superior therapeutic profiles, as well as new intellectual property. We are therefore able to efficiently optimize many properties with high specificity in parallel.

•*Efficient Drug Discovery and Early Pharmacology and Safety Assessment.* Our cell-free technology creates the opportunity for accelerated pharmacology and safety assessments during the design and discovery phase of product development. This approach allows us to generate optimized proteins early in our discovery process, which can be transitioned seamlessly to clinical scale production using the same cell-free process.

•*Rapid and Predictable Scalability.* Our cell-free extract does not need to be modified in any manner as we scale from research to preclinical to clinical to commercial production. This enables us to move more rapidly to the clinic by eliminating master cell banking activities and significantly de-risks scale-up to manufacturing.

*Our XpressCF® Solution for Cytokine, ADCs, iADCs and Bispecific Antibody-Based Drug Therapeutics*

As a result, we believe our technology enables new approaches to cytokine, ADCs, iADCs and bispecific antibody-based drug discovery, development and manufacturing. Key attributes are:

•*Homogeneous Design.* Our XpressCF+™ platform enables precise and specific placement of non-natural amino acids in defined numbers and positions within our engineered proteins. These non-natural amino acids then serve as highly stable attachment sites, also known as conjugation sites, for chemical functional groups. For example, we attach linker-warheads to non-natural amino acids within our antibodies to create single-species, tumor-killing ADCs. Similarly, we can attach polyethylene glycol polymers onto non-natural amino acids within our cytokine-based therapeutics to create single-species immunotherapies designed for extended pharmacokinetics and safety.

•*Experimentally Defined Structure-Activity Relationships.* Our cell-free technology enables rational design of protein therapeutics through a rapid, reiterative process that experimentally defines structure-activity relationship for cytokine-based therapeutics, ADCs, iADCs and bispecific antibodies. This approach allows us to explore a wide variety of structural features and formats in parallel as we optimize therapeutic candidates. For example, the precise location of chemical conjugation sites directly affects the activity of both ADCs and cytokine-based therapeutics. Our proprietary technology is key to our ability to define the best number and positions of non-natural amino acids for conjugation based on: conjugation efficiency; functional activity/pharmacological properties; and pharmacokinetics and safety. This design flexibility is also an important aspect of our discovery approach to other protein therapeutics. For example, we are able to make and directly compare a variety of pairings and structural formats for our immuno-oncology bispecific antibody and bispecific T cell-engager programs. This allows us to identify antibody pairs and formats with the best binding properties, spatial orientations and structural stability to create the optimal balance of therapeutic activity and safety.

•*Rapid and Efficient Transition from Discovery to the Clinic.* Protein therapeutics can encounter obstacles, or even fail, during the transition from research-grade cell lines to cGMP cell lines appropriate for clinical development and commercialization. Our XpressCF® platform can rapidly produce different protein types from a single proprietary extract, which can be scaled for discovery, development and ultimately, we believe, commercialization of cytokine-based immuno-oncology therapeutics, ADCs, iADCs and bispecific antibodies and bispecific T cell-engagers.

Accordingly, we use our XpressCF® platform to discover and develop cancer therapeutics by empirically determining the optimum structure-activity relationships for cytokine-based immuno-oncology therapeutics, ADCs, IADCs, bispecific antibodies, and transitioning those products to cGMP compliant manufacturing. The following chart illustrates the applicability of these attributes across the range of modalities we are developing.

#### XpressCF® Attributes for Various Therapeutic Modalities

XpressCF® Attribute	ADCs	Bispecific I/O, Bispecific ADCs and Bispecific T cell-engagers	Cytokine-based therapeutics
<b>Homogeneous Design</b>			
Stable, site-specific attachment of chemical functionality	✓	✓ (if needed)	✓
<b>Experimentally Defined Structure-Activity Relationships</b>			
Rapid, direct comparison of a wide variety of protein variants	✓	✓	✓
<b>Rapid and Efficient Transition from Discovery to the Clinic</b>			
Single-source scalability from discovery to clinical / commercial	✓	✓	✓

#### Our Collaborations Demonstrate our Capabilities

Our XpressCF® platform has garnered the attention of leading pharmaceutical and biopharmaceutical companies and resulted in collaborations to discover and develop novel therapeutics. We have leveraged these strategic partnerships to extend our own capabilities and broaden the scope of our XpressCF® platform. Through December 31, 2021, all of our collaborations have provided us with an aggregate of approximately \$446 million in payments, which includes approximately \$54 million in investments in our stock. Our collaborations include:

- Merck Programs.** We have granted Merck the right to develop two cytokine derivative candidate molecules.
- BMS Programs.** We have granted BMS the right to develop a novel ADC therapeutic directed against the target BCMA, known as CC-99712, which is currently under investigation in a Phase 1 trial focused on patients with relapsed and refractory multiple myeloma.
- EMD Serono Programs.** We have granted EMD Serono the right to develop the novel bispecific ADC targeting EGFR and MUC1, known as M1231, which is currently under investigation for the treatment of solid tumors, including metastatic non-small cell lung cancer and esophageal squamous cell carcinoma in a Phase 1 trial.
- Vaxcyte Relationship.** We have granted Vaxcyte the right to discover and develop vaccines for the prophylaxis and treatment of infectious diseases. Vaxcyte's IND for its lead product candidate, a 24-valent pneumococcal conjugate vaccine, was cleared by the FDA in January 2022.
- Tasly Relationship.** We have granted Tasly an exclusive license to the right to develop and commercialize STRO-002 in Greater China.
- BioNova Relationship.** We have granted BioNova an option to exclusively license the right to develop and commercialize STRO-001 in Greater China.

## •Our Pipeline of Product Candidates and Discovery/Preclinical Programs

Our current product candidates and Discovery and Preclinical stage programs, all based on our proprietary XpressCF® platform, are summarized in the chart below:



(1) We have granted Tasly an exclusive license to the right to develop and commercialize STRO-002 in Greater China.

(2) We have granted BioNova an option to exclusively license the right to develop and commercialize STRO-001 in Greater China.

(3) EMD Serono is the biopharmaceutical business of Merck KGaA, Darmstadt Germany in the US.

(4) Cytokine derivative program with Merck includes two molecules derived from one undisclosed target.

(5) We are eligible to receive 4% royalties on net sales of VAX-24.

### Our Product Candidates

#### STRO-001, an ADC Directed Against the Cancer Target CD74

##### Overview

We are developing STRO-001, an optimally designed ADC directed against the cancer target CD74, for multiple myeloma and NHL. STRO-001 was designed and optimized for maximal therapeutic index by placing linker-warheads at specific locations within the antibody using our proprietary XpressCF+™ platform. We are currently enrolling patients in a STRO-001 Phase 1 trial and presented updated data in December 2020. Based on such reported data, STRO-001 has been generally well-tolerated and no ocular toxicity signals have been observed, with no patients receiving prophylactic corticosteroid eye drops. Dose escalation in the STRO-001 Phase 1 trial is continuing, and the maximum tolerated dose has not yet been reached. We expect to establish a recommended Phase 2 dose in 2022 and thereafter may begin the dose expansion portion of the Phase 1 trial. In October 2018, we were granted Orphan Drug Designation by the FDA, for STRO-001 for the treatment of multiple myeloma. In October 2021, we entered into the BioNova Option Agreement.



## *CD74 Overview and Current Limitations*

CD74 is a transmembrane glycoprotein, or a protein with an attached sugar that spans the inside and outside of a cell. While normal tissues appear to have minimal CD74 expression levels, CD74 is an important B cell target for multiple myelomas and lymphomas. CD74 is expressed in approximately 90% of B cell cancers, including multiple myeloma and lymphoma.

Currently, there are no approved therapeutics that specifically target CD74 for treatment of B cell malignancies. We believe earlier ADCs being developed against the target CD74 were ineffective either because they failed to achieve sufficient killing of malignant B cells or they were unable to achieve a sufficient therapeutic benefit before toxicities limited further dose escalations.

## *B Cell Malignancies Overview and Current Limitations*

B cell malignancy tumor subtypes include multiple myeloma and NHL, which includes mantle cell lymphoma, diffuse large B cell lymphoma, or DLBCL, and follicular lymphoma. In the United States alone in 2017, the prevalence of multiple myeloma and NHL was estimated at more than 800,000 cases, and the American Cancer Society estimated that there would be more than 116,000 new cases of multiple myeloma and NHL in 2021. Although several therapeutics have recently been approved for the treatment of specific B cell malignancies, including immunotherapies, targeted kinase inhibitors, ADC and CAR-T cell therapies, unmet need persists. Many of these therapeutics are typically used in combination with other agents to provide the most potent anti-cancer effect. While these new therapies have demonstrated improvements in survival, the majority of these patients ultimately relapse during treatment and some experience a resistance to therapy.

## *Our Solution, STRO-001*

Our first internally developed product candidate is STRO-001, which we believe has the potential to be a first-in-class and best-in-class ADC directed against the cancer target CD74, an antigen that is highly expressed in many B cell malignancies and is an attractive target for an ADC therapeutic, given its rapid internalization by the cell. STRO-001 is an ADC targeting the CD74 protein antigen that was developed using our proprietary XpressCF® and XpressCF+™ platforms. STRO-001 is composed of an antibody stably conjugated to a highly potent cytotoxic drug, a maytansinoid derivative, at two specific sites on the antibody using a non-cleavable linker. STRO-001 degrades inside of tumor cells to release very potent intracellular catabolites whose hydrophilic nature results in poor permeability into surrounding cells. We believe this decreases the potential of off-target effect in normal tissues. From a safety perspective, we designed STRO-001 to have an optimal potency to toxicity ratio. We rationally selected a homogeneous ADC with a drug-antibody ratio, or DAR, of two. Heterogeneous ADCs typically have DARs that range from zero to eight, with lower DARs generally being associated with less potency and higher DARs generally being associated with a negative impact on pharmacokinetics and toxicity. We chose a DAR of two after demonstrating that DARs of four or six did not increase the efficacy of STRO-001. In October 2018, we were granted orphan drug designation by the FDA, for STRO-001 for the treatment of multiple myeloma.

## *Phase 1 Clinical Trial*

The Phase 1 trial for STRO-001 is an open-label study that is evaluating STRO-001 as a monotherapy for patients with multiple myeloma and NHL. The trial is being conducted in two parts: dose escalation and dose expansion. The primary objectives of the trial are to determine the safety and tolerability profile of STRO-001, determine the recommended Phase 2 dose and interval and evaluate preliminary anti-tumor activity. The secondary objectives are to characterize the human pharmacokinetics of STRO-001 and additional safety, tolerability and efficacy measures.

Our Phase 1 trial of STRO-001 is enrolling adult patients with advanced and/or refractory multiple myeloma and NHL (including DLBCL, mantle cell lymphoma and follicular lymphoma) who are refractory to, or intolerant of, all established therapies known to provide clinical benefit for their condition. Multiple myeloma and NHL patients are being enrolled in two separate dose escalation cohorts, starting initially with an accelerated dose titration design. We estimate that there will be approximately 35-40 patients in each cohort. Treatment is currently scheduled on day one of a 21-day cycle.

After the recommended Phase 2 dose level is determined, patients could be enrolled in up to four dose expansion cohorts (myeloma, DLBCL, mantle cell lymphoma and follicular lymphoma) if anti-tumor activity is observed during the dose escalation phase. We may enroll up to 40 patients in each of the four dose expansion cohorts.

We submitted our IND for STRO-001 in December 2017 and the first patient was dosed in April 2018. In October 2018, we were granted Orphan Drug Designation by the FDA for STRO-001 for the treatment of multiple myeloma.

In December 2020, we reported data from the NHL cohort from the dose escalation portion of the Phase 1 trial as of October 30, 2020:

- Most (90%) treatment emergent adverse events were Grade 1 or 2 events of nausea, fatigue, chills, anemia, headache, dyspnea, abdominal pain, vomiting, decreased appetite and pyrexia, and no ocular or neuropathy toxicity signals have been observed.
- Subsequent to a previously announced protocol amendment in 2019 requiring pre-treatment screening imaging for patients at risk for thromboses, no thromboembolic events have been observed.
- In the seven patients with diffuse large B-cell lymphoma, one complete response and two partial responses were observed.
- Out of other NHL types, two patients with follicular lymphoma had stable disease, of which one is still on treatment at nine weeks. One patient with marginal zone lymphoma had stable disease and is still on treatment at 39 weeks.
- In addition, the maximum tolerated dose was not reached at 4.2 mg/kg. Active enrollment in the NHL cohort continues at the 5.0 mg/kg dose level and additional higher dose levels may be explored.

The maximum tolerated dose for the multiple myeloma dose escalation cohort has not been reached. Active enrollment in that cohort continues at the 5.0 mg/kg dose level and additional higher dose levels may be explored.

The trial, registered with [clinicaltrials.gov](https://clinicaltrials.gov) identifier NCT03424603, continues to enroll patients in dose escalation in both multiple myeloma and NHL cohorts.

We expect to determine the recommended Phase 2 dose for STRO-001 by the end of 2022.

In October 2021, we entered into the BioNova Option Agreement to confer BioNova the option to obtain exclusive rights to develop and commercialize STRO-001 in Greater China. BioNova will pursue the clinical development, regulatory approval, and commercialization of STRO-001 in multiple indications, including NHL, multiple myeloma, and leukemia in the licensed territory. We will retain development and commercial rights of STRO-001 globally outside of Greater China, including the United States.

## **STRO-002, an ADC Directed Against the Target Folate Receptor-Alpha (FolRα)**

### *Overview*

We are developing STRO-002, an optimally designed ADC directed against the cancer target FolRα, initially targeted for ovarian and endometrial cancers. STRO-002 was designed and optimized for an improved therapeutic index by placing a precise number of linker-warheads at four specific locations within the antibody using our proprietary XpressCF+<sup>®</sup> platform. We began enrolling patients in a STRO-002 Phase 1 trial focused on ovarian and endometrial cancers in March 2019 and presented updated dose-escalation data in December 2020 and May 2021. Based on such reported data, STRO-002 exhibited a manageable safety profile and promising preliminary efficacy data. Dose escalation in the STRO-002 Phase 1 trial has been fully enrolled and the dose-expansion portion of the trial is ongoing to assess the efficacy, safety and tolerability of STRO-002 at dose levels of 4.3 and 5.2 mg/kg. For the dose-expansion portion of the Phase 1 trial, we dosed the first patient in January 2021 and have enrolled less heavily pre-treated ovarian cancer patients. We reported initial dose-expansion data in January 2022. Based on the reported data, STRO-002 demonstrated a manageable safety profile and promising preliminary efficacy data. Additionally, a STRO-002 combination cohort in ovarian cancer, assessing the combination of STRO-002 with bevacizumab, opened for enrollment in December 2021, and an expansion cohort for FolRα-selected endometrial cancer opened and began enrolling patients in the fourth quarter of 2021. In August 2021, we were granted Fast Track designation for STRO-002 by the FDA for the treatment of patients with platinum-resistant epithelial ovarian, fallopian tube, or primary peritoneal cancer who have received one to three prior lines of systemic therapy. In December 2021, we entered into a collaboration and exclusive license agreement with Tasly to develop and commercialize STRO-002 in Greater China.

### *FolRα Overview*

FolRα is a cell-surface glycoprotein, which is believed to be important for supporting DNA synthesis in rapidly dividing cancer cells. FolRα exhibits limited expression and distribution in normal tissues.

High levels of FolRα have been found in multiple cancer types, including epithelial ovarian cancer, endometrial adenocarcinoma, triple negative breast cancer and non-small cell lung cancer. Expression appears to correlate with disease progression in ovarian cancer and continues to be expressed following chemotherapy treatment.

### *Ovarian Cancer Overview*

Ovarian cancer is the most common cause of cancer death from gynecologic tumors in the United States, and the fifth most common cause of cancer death in women. In the United States alone, the American Cancer Society estimates that 21,000 new cases of ovarian cancer would be diagnosed in 2021, and approximately 14,000 women would die of this disease. Given that early stages of the disease cause minimal, nonspecific symptoms or is asymptomatic, approximately 75% of patients with ovarian cancer are diagnosed are stage III and IV, for which the prognosis is poor. Standard pre- or post-operative chemotherapy for ovarian cancer is combination therapy with a platinum compound and a taxane, for example, carboplatin and paclitaxel, with or without bevacizumab which achieves a complete or partial response in between 70% to 80% of patients. Increasingly, PARP inhibitors are being used in the maintenance setting. Patients who are refractory or resistant to platinum-based treatments are then treated with a host of additional palliative chemotherapeutic agents, each showing only marginal benefit with response rates to single agent chemotherapy of 10-12% and progression free survival of 3-4 months. This represents a significant unmet need.

## *Endometrial Cancer Overview*

There is also a significant unmet need in the treatment of recurrent or metastatic endometrial cancer. In the United States alone, the American Cancer Society estimated that there would be more than 66,000 new cases of endometrial cancer in 2021, and that approximately 13,000 women would die of this disease. First-line treatment for stage III/IV disease is commonly paclitaxel/carboplatin. Recently, the combination of lenvatinib and pembrolizumab was approved for the treatment of patients with advanced, metastatic endometrial cancer who have disease progression following prior systemic therapy with a platinum doublet. With the lack of available therapies for patients who progress after standard of care therapies, long-term survival prospects are poor and novel treatments offering even a modest improvement in progression-free survival or overall survival may be considered for expedited regulatory approval.

### *Limitations to Current FolR $\alpha$ -Targeted Therapeutics*

There have been a number of folate- or FolR $\alpha$ -targeted therapies in development, including naked antibodies, small molecule drug conjugates, ADCs and T cell retargeting molecules. The most advanced clinically active agent targeting FolR $\alpha$  to date has been Immunogen's mirvetuximab soravtansine (IMGN853), an ADC composed of a FolR $\alpha$ -binding antibody linked to the tubulin-disrupting maytansinoid, DM4, via a cleavable linker.

Immunogen announced in December 2019 that the FDA has provided guidance for potential accelerated approval of its mirvetuximab soravtansine (mirvetuximab) monotherapy, demonstrating that FolR $\alpha$  remains an attractive target. In November 2021, Immunogen reported positive top-line data in its SORAYA trial evaluating the safety and efficacy of mirvetuximab soravtansine monotherapy in patients with high FR $\alpha$ -expressing platinum-resistant ovarian cancer who have been previously treated with Avastin<sup>®</sup> (bevacizumab). Mirvetuximab soravtansine is currently being evaluated in a Phase 3 randomized confirmatory trial, and in multiple combination studies.

### *Our Solution, STRO-002*

STRO-002 is directed against the cancer target FolR $\alpha$ , which is highly expressed in multiple cancer types, including ovarian cancer and endometrial cancer. This property, together with the highly restricted expression of FolR $\alpha$  on normal tissues, make FolR $\alpha$  a promising ADC approach.

STRO-002 employs a cleavable linker that releases a cytotoxic drug inside of tumor cells, while being stable and resistant to cleavage in general circulation. The cytotoxic drug used is our proprietary hemisterlin moiety. From a safety perspective, we designed STRO-002 to have the optimal potency-to-safety ratio. We rationally selected a homogenous ADC with an optimized DAR of four.

Based on preclinical findings, we believe our efficient homogeneous design of STRO-002 could provide anti-tumor activity, stability and safety with the potential to minimize off-target damage and improve clinical impact by reducing dose-limiting toxicities. We believe an improved therapeutic index could differentiate STRO-002 from conventional technology for the treatment of ovarian cancer and endometrial cancer. To test this, we have created a benchmark FolR $\alpha$ -targeting surrogate molecule based on conventional technology that has a heterogeneous ADC, with a similar DAR utilizing a DM4 linker-warhead. We have tested this benchmark molecule against STRO-002 in multiple preclinical models. However, additional preclinical and clinical testing will be needed to determine the safety and efficacy of STRO-002 and to obtain regulatory approval, if ever. STRO-002 may not ultimately provide a greater therapeutic benefit than the current standard of care.

### *Clinical Development Plan*

Our first Phase 1 trial for STRO-002 is an open-label study evaluating STRO-002 as a monotherapy for patients with ovarian and endometrial cancers. This trial is being conducted in two-parts, dose escalation and dose expansion. We began enrolling ovarian cancer patients in March 2019, with updated data for the dose escalation cohort reported in December 2020 and May 2021. The primary objectives of the STRO-002 clinical trial are to determine the safety and tolerability profile, to define the recommended Phase 2 dose level and interval and to evaluate preliminary anti-tumor activity. Our secondary objectives are to characterize the human pharmacokinetics and additional safety, tolerability and efficacy measures.

We initially enrolled adult patients with advanced and/or refractory ovarian cancer, for whom no suitable treatment exists. These patients are considered to have incurable disease and need repeated courses of life-prolonging and palliative treatment. The initial STRO-002 Phase 1 trial enrolled ovarian cancer patients regardless of their FolR $\alpha$  expression levels. These ovarian cancer patients were enrolled in a dose escalation cohort, with STRO-002 administered on day one of a 21-day cycle. Since anti-tumor activity was observed during the dose escalation portion of the Phase 1 trial, we initiated enrollment of patients in the dose expansion portion of this clinical study in January 2021 and are treating less heavily pre-treated ovarian cancer patients. Enrollment of the dose-expansion portion of the Phase 1 study is complete and the study is currently ongoing.

In May 2021, we announced updated data from the dose-escalation portion of our ongoing Phase 1 clinical trial of STRO-002 in patients with ovarian cancer.

The dose-escalation portion of the trial was fully enrolled with 39 patients in August 2020. Patients were heavily pre-treated and had a median of six prior lines of therapy, including standard of care platinum-based regimens, bevacizumab, PARP inhibitors, and checkpoint inhibitors.

The dose-escalation portion of the Phase 1 trial included 34 patients treated with clinically active dose levels, 2.9 mg/kg or higher, of which 31 patients had post-baseline scans and were evaluable for RECIST response. At the data cutoff of April 23, 2021, results out of 31 evaluable patients included:

- 10 patients (32%) met RECIST criteria for response, of which, one patient achieved a complete response and nine patients achieved a partial response (four confirmed partial responses and five unconfirmed partial responses).
- For the five confirmed responders (1 complete response, or CR, and 4 confirmed partial responses, or cPRs), the median duration of response, or DOR, was 5.8 months (95% CI: 2.0, not evaluable).
- Median study follow-up was 8.4 months and median progression-free survival (PFS) was 7.2 months (95% CI: 4.5, 10.8).
- 86% of treatment-emergent adverse events, or TEAEs, were Grade 1 or 2. The most common Grade 3 and 4 AEs were neutropenia (64%), arthralgia (13%), fatigue (10%), neuropathy (8%), and abdominal pain (8%), all of which were managed with standard medical treatment, dose reductions, or dose delays.
- Dose limiting toxicities, or DLTs, were observed at higher dose levels in two patients – at 6.0 mg/kg (Grade 2 neuropathy/Grade 3 arthralgia) and at 6.4 mg/kg (Grade 3 bone pain).

Based on the results of the dose escalation portion of the Phase 1 trial discussed above, we identified dose levels of 4.3 and 5.2 mg/kg to study in the dose-expansion portion of the Phase 1 trial. For the dose-expansion portion, we dosed the first patient in January 2021 and are treating less heavily pre-treated ovarian cancer patients. We reported initial dose-expansion data in January 2022.

The dose-expansion cohort for ovarian cancer enrolled 44 patients, who had experienced up to three prior lines of therapy. As of the interim data cutoff date of November 8, 2021, 43 patients had been randomized into dose levels starting at 4.3 mg/kg and 5.2 mg/kg, and one patient had not yet been dosed. 81% of the patients were platinum-resistant, and 63% and 65% of the patients had been treated previously with bevacizumab and PARP inhibitors, respectively. Of the 43 patients, 33 had at least one post-baseline scan, and therefore were evaluable for RECIST v1.1 responses. As of the interim data cutoff date, the Best Overall Response for evaluable patients were as follows (N=33):

- Seven patients had achieved partial responses, or PR, which were confirmed with at least two post-baseline scans.
- Five patients had unconfirmed partial responses, or PRus, based on having received only one post-baseline scan as of the interim data cutoff date. Their next scheduled scan, subsequent to the interim data cutoff date, revealed the following: Four PRs were confirmed and one patient was in stable disease, or SD.

- An Objective Response Rate, or ORR, of 33% (11 confirmed PRs out of 33 patients) was demonstrated in all evaluable patients, unenriched for FolRα-expression levels at both dose levels.

- 14 total patients experienced SD and 8 patients had progressive disease, or PD.

Dose response was observed, with an ORR of 47% (8 PRs out of 17 patients) for patients who started at the 5.2 mg/kg dose level, unenriched for biomarker status.

Higher FolRα expression levels calculated using tumor proportion scores, or TPS, correlated with higher response rates. We have identified TPS as a potentially appropriate scoring algorithm for STRO-002 with respect to the biomarker enrichment strategy. Based on an exploratory cut-off of TPS > 25%, we observed a 40% ORR (10 PRs out of 25 patients) irrespective of initial dose. TPS ≤25% demonstrated a 13% ORR. In a limited number of patients with TPS > 25% and who were treated with an initial dose of 5.2 mg/kg, we further observed a 53.8% ORR (7 PRs out of 13 patients). Based on the population statistics in our Phase 1 trial, an enrichment approach of TPS > 25% FolRα expression may enable treatment of about 70% of the advanced ovarian cancer patient population.

Safety signals from the 43 safety evaluable patients, at the 5.2 mg/kg and 4.3 mg/kg starting dose levels, were consistent with data from the dose-escalation cohort, including:

- No qualitatively new safety signals were observed in the dose-expansion cohort, including the absence of keratopathy.

- 85.5% TEAEs were Grade 1-2.

- Neutropenia was the leading TEAE, resulting in treatment delay or dose reduction. The majority of the cases of neutropenia were generally asymptomatic and resolved with a one-week dose delay or, in other cases, with standard medical treatment, including the use of G-CSF.

- There were limited observed cases of febrile neutropenia, including one Grade 5 event at the 5.2 mg/kg starting dose level and one Grade 3 event at the 4.3 mg/kg starting dose level. The trial protocol was subsequently updated to require dose reduction for Grade 4 neutropenia.

Data from the STRO-002 dose-expansion cohort are expected to provide further information to inform regulatory discussions and a global registration strategy.

Additionally, a Phase 1 trial to assess the combination of STRO-002 and bevacizumab for treatment of ovarian cancer was opened for enrollment in December 2021. We expect to present initial results from this study in the first half of 2023. Moreover, an expansion cohort for FolRα-selected endometrial cancer began enrolling patients in the fourth quarter of 2021. We expect to present initial results from this study in the first half of 2023. Finally, we plan to initiate a pilot study to assess STRO-002 for the treatment of NSCLC and other non-gynecologic cancers in the second half of 2022.

#### ***Additional Discovery Efforts***

Our technology allows us to rapidly incorporate non-natural amino acids in varying numbers and positions, to identify the best cytokine modification for pharmacological activity, pharmacokinetics and safety. Furthermore, our technology enables rapid preclinical development and transition to cGMP manufacturing, ensuring speed to clinic in a promising field. Our drug discovery teams are exploring novel immuno-oncology therapies, including cytokine-based therapies.

We are also actively researching to identify new ADCs to add to our pipeline. We have multiple ADC discovery programs ongoing using our XpressCF+<sup>®</sup>™ platform. Our protein engineering and chemistry efforts are focused on maximizing therapeutic indices, and our technology allows us to rapidly test our therapeutic hypothesis in significantly more product candidates than conventional protein synthesis allows in order to identify the best molecule to advance to the clinic. We have also expanded our ADC technology platform to include iADCs. Our XpressCF+<sup>®</sup>™ platform has enabled a groundbreaking technology to engineer homogeneous, dually conjugated immunostimulant and cytotoxic warheads on a single ADC molecule. Our novel iADC design is intended to deliver two different drugs directly to the tumor, and not only kill tumor cells but also locally prime an immune response to the patient's particular tumor cells. We believe that our iADC approach creates a new therapeutic opportunity by combining the best features of an ADC with the biology of a personalized vaccine.

Our bispecific antibody drug discovery programs are focused on T cell-engagers. We are using our technology to find the optimum protein structure and T cell-engaging properties to maximize safety and efficacy for this promising class of cancer therapeutics.

## **Collaboration and License Agreements**

### ***Merck Collaboration***

In July 2018, we entered into an Exclusive Patent License and Research Collaboration Agreement (the "2018 Merck Agreement") with Merck to jointly develop up to three research programs focusing on cytokine derivatives for cancer and autoimmune disorders.

Under the 2018 Merck Agreement, we received from Merck a non-refundable, non-creditable, upfront payment of \$60.0 million in August 2018 for access to our technology and the identification and preclinical research and development of two target programs, with an option for Merck to engage us to continue these activities for a third program upon the payment of an additional amount. The option to expand activities to a third program expired in January 2021. In December 2021, Merck did not extend the research term for the second research program of the collaboration and that research program reverted to us. The first program of the collaboration is focused on two distinct cytokine derivative molecules for the treatment of cancer.

In March 2020, Merck exercised its option to extend the research term of the collaboration's first cytokine-derivative program by one year, which, pursuant to the terms of the 2018 Merck Agreement, triggered a payment of \$5.0 million to us. In the second quarter of 2021, we earned a \$15.0 million contingent payment for the initiation by Merck of the first IND-enabling toxicology study under the first cytokine-derivative program in the collaboration. In September 2021, Merck agreed to extend the research term of this program for an additional two years to facilitate completion of preclinical research and development activities for a second candidate molecule in the program, which has a novel design and approach. In connection with the extension, we received an initial \$2.5 million payment and are eligible for additional payments of up to \$7.5 million.

In August 2020, we entered into a Pre-Clinical and Clinical Supply Agreement with Merck, wherein Merck requested us to provide manufacturing services, including clinical product supply, upon completion of the research programs under the 2018 Merck Agreement. The consideration for the services is based on an agreed-upon level of FTE personnel effort and related reimbursement rate in addition to agreed-upon pricing for the clinical product supply.

We are also eligible to receive aggregate contingent payments of up to approximately \$0.5 billion for the target program selected by Merck, assuming the development and sale of the related therapeutic candidates and all possible indications identified under the collaboration. If one or more products from the target program is developed for non-oncology or a single indication, we will be eligible for reduced aggregate milestone payments. In addition, we are eligible to receive tiered royalties ranging from mid-single digit to low teen percentages on the worldwide sales of any commercial products that may result from the collaboration.

Merck may terminate the 2018 Merck Agreement at any time with 60 days' prior written notice. Either we or Merck has the right to terminate the 2018 Merck Agreement based on the other party's uncured material breach or bankruptcy.

## **BMS Collaboration**

In November 2019, BMS acquired Celgene, and Celgene became a wholly owned subsidiary of BMS. In connection with such acquisition, BMS assumed the rights and obligations of the 2014 Celgene Agreement, 2017 Celgene Agreement and 2018 Celgene Master Services Agreement. Throughout this Annual Report, we refer to Celgene as BMS and our agreements with Celgene as the BMS Agreement and the 2018 BMS Master Services Agreement.

In September 2014, we signed a Collaboration and License Agreement with BMS to discover and develop bispecific antibodies and/or "ADCs", focused primarily on the field of immuno-oncology, using our proprietary integrated cell-free protein synthesis platform, XpressCF®. In August 2017, we entered into an amended and restated collaboration and license agreement with BMS to refocus the collaboration on four programs that were advancing through preclinical development, including an ADC program targeting B cell maturation antigen, or the BCMA ADC.

Upon signing the BMS Agreement in 2014, we received an upfront, nonrefundable payment totaling \$83.1 million.

In March 2015, we received a \$15.0 million contingent payment from BMS that provided BMS a right to access certain of our technology for use in conjunction with certain BMS intellectual property. In June 2016, we received a \$25.0 million milestone upon completion of certain preclinical activities. Additionally, in June 2016, we earned a \$10.0 million substantive milestone for certain manufacturing accomplishments.

In August 2017, we received an option fee payment of \$12.5 million from BMS. In each of October 2017 and December 2018, we received a \$10.0 million milestone for certain manufacturing accomplishments.

In 2019, BMS initiated the Phase 1 clinical trial for CC-99712, a BCMA ADC which was discovered and is being manufactured by us. In the second half of 2021, BMS expanded their Phase 1 trial to include combination treatment with a gamma secretase inhibitor. BMS has worldwide development and commercialization rights with respect to CC-99712. We will continue to be responsible for clinical supply manufacturing and certain development services for the BCMA ADC and are eligible to receive from BMS aggregate development and regulatory contingent payments of up to \$275.0 million, if approved in multiple indications, and tiered royalties ranging from mid to high single digit percentages on worldwide sales of any resulting commercial products.

In March 2018, we entered into a Master Development and Clinical Manufacturing Services Agreement, or the 2018 BMS Master Services Agreement, with BMS, wherein BMS requested us to provide development, manufacturing and supply chain management services, including clinical product supply. The consideration for the services is based on an agreed-upon level of FTE personnel effort and related reimbursement rate in addition to agreed-upon pricing for clinical product supply for use in Phase 1 clinical trials.

BMS may terminate the BMS Agreement at any time with 120 days' prior written notice. Either we or BMS has the right to terminate the BMS Agreement based on the other party's uncured material breach, challenge of the validity and enforceability of intellectual property, or bankruptcy.

## ***EMD Serono Collaboration***

We signed a Collaboration Agreement and a License Agreement with EMD Serono in May 2014 and September 2014, respectively, which were entered into in contemplation of each other. The Collaboration Agreement was subsumed into the License Agreement (the "MDA Agreement"), which agreement is to develop ADCs for multiple cancer targets. Our collaboration with EMD Serono has yielded a novel bispecific ADC product candidate targeting EGFR and MUC1, known as M1231, for which an IND submission was filed in the second half of 2020 and which is currently under investigation in a Phase 1 trial for the treatment of solid tumors, including metastatic non-small cell lung cancer and esophageal squamous cell carcinoma.

Upon signing the Collaboration Agreement, we received an upfront, nonrefundable, non-creditable payment totaling \$10.0 million. Upon signing the MDA Agreement, we received an additional upfront, nonrefundable, non-creditable payment totaling \$10.0 million and will receive financial support for research and development services to be provided by us, based on an agreed-upon level of FTE personnel effort and related reimbursement rate. Under a supply agreement with EMD Serono, we provide them with product candidate materials for IND-enabling



and Phase 1 clinical studies. The consideration for any related services is based on an agreed-upon level of FTE personnel effort and related reimbursement rate in addition to agreed-upon pricing for providing the materials.

We are eligible to receive up to \$52.5 million for M1231 under the MDA Agreement, primarily from pre-commercial contingent payments, of which we have earned and received a \$1.5 million payment, a \$1.0 million payment, and a \$2.0 million payment in 2019, 2020 and 2021, respectively. In addition, we are eligible to receive tiered royalties ranging from low-to-mid single digit percentages, along with certain additional one-time royalties, on worldwide sales of any commercial products that may result from the MDA Agreement. The MDA Agreement term expires on a product-by-product and country-by-country basis. Upon expiration, EMD Serono will have a fully paid-up, royalty-free, perpetual, and irrevocable non-exclusive license, with the right to grant sublicenses, under certain of our intellectual property rights. EMD Serono may terminate the MDA Agreement at any time with 90 days' prior written notice or upon the inability of us to provide EMD Serono access to a specified number of cancer drug targets. Either we or EMD Serono has the right to terminate the MDA Agreement based on the other party's uncured material breach or bankruptcy.

#### ***Stanford License***

In October 2007, we entered into an Amended and Restated Exclusive Agreement, or the Stanford License, with the Board of Trustees of the Leland Stanford Junior University (Stanford), that grants us an exclusive license, with the right to sublicense, under the patent rights owned by Stanford covering certain technology rights related to our XpressCF®™ expression system.

We were required to make milestone payments to Stanford of approximately \$930,000 on the accomplishment of certain development and regulatory milestones, which total amount has been paid as of December 31, 2021. No additional milestone payments are due under the Stanford License. Additionally, we owe Stanford annual license maintenance fees of \$75,000, which may be creditable against earned royalties in such year and are required to reimburse Stanford for ongoing patent-related costs. We are also required to pay to Stanford low single digit royalties on net sales and to share any sublicensing income received related to the licensed technology. We may terminate the agreement at any time upon 30 days' written notice.

#### ***Vaxcyte (formerly known as SutroVax) Relationship***

In 2013, we and Johnson & Johnson Innovation, through the Johnson & Johnson Development Corporation, provided initial co-funding for Vaxcyte, Inc., or Vaxcyte, with which we have a license agreement and a supply agreement. Under the license agreement, Vaxcyte has the right to use the XpressCF® and XpressCF+®™ platforms to discover and develop vaccine candidates for the treatment or prophylaxis of infectious diseases. The lead program for Vaxcyte is a broad-spectrum pneumococcal conjugate vaccine. Vaxcyte is responsible for performing all research and development activities, and we provide technical support and supply XtractCF® and other materials to Vaxcyte. Vaxcyte has announced that the IND for its first clinical product, VAX-24, a 24-valent pneumococcal conjugate vaccine, was cleared by the FDA in January 2022 and announced in February 2022 that the first participants had been dosed in a Phase 1/2 clinical study.

In May 2018, we entered into a Supply Agreement with Vaxcyte, wherein Vaxcyte engaged us to supply extracts and custom reagents, as requested by Vaxcyte. The pricing is based on an agreed upon cost plus arrangement.

We hold 1.6 million shares of common stock of Vaxcyte and are eligible for four percent royalties on worldwide net sales of any vaccine candidates for human health use under the license agreement. Also, we retain the right to discover and develop vaccines for the treatment or prophylaxis of any disease that is not caused by an infectious pathogen, including cancer.

Vaxcyte has the right to terminate the Vaxcyte license agreement for convenience upon prior written notice. Either party may terminate for the other party's material uncured breach.

### ***Tasly Relationship***

In December 2021, we entered into the Tasly License Agreement with Tasly to grant an exclusive license to develop and commercialize STRO-002 in Greater China. Tasly will pursue the clinical development, regulatory approval, and commercialization of STRO-002 in multiple indications, including ovarian cancer, non-small cell lung cancer, triple-negative breast cancer, and other indications in Greater China. We retained development and commercial rights of STRO-002 globally outside of Greater China, including the United States.

Under the Tasly License Agreement, Tasly is obligated to make an initial payment to us of \$40.0 million, with additional potential payments totaling up to \$345.0 million related to development, regulatory and commercialization contingent payments and milestones. We will provide STRO-002 to Tasly under appropriate clinical and commercial supply service agreements. Upon commercialization, we will receive tiered royalties, ranging from low- to mid-teen percentages based on annual net sales of STRO-002 in Greater China for at least ten years following the first commercial sale of STRO-002 in Greater China. In February 2022, Tasly indicated that it would like to discuss and renegotiate the terms of the Tasly License Agreement. Based on the currently ongoing discussions, we believe substantial uncertainty exists as to whether Tasly will timely deliver the initial payment of \$40.0 million to us in accordance with the terms of the Tasly License Agreement. We believe that we have performed all our material obligations under the Tasly License Agreement and are considering all remedies available under the Tasly License Agreement. Of note, no new or updated clinical data has been shared by us with Tasly subsequent to our STRO-002 initial dose-expansion data release in January 2022.

Tasly has the right to terminate the Tasly License Agreement for convenience or other reasons specified in the Tasly License Agreement, upon prior written notice.

### ***BioNova Relationship***

In October 2021, we entered into the BioNova Option Agreement to confer BioNova the right to obtain exclusive rights to develop and commercialize STRO-001 in Greater China. BioNova will pursue the clinical development, regulatory approval, and commercialization of STRO-001 in multiple indications, including NHL, multiple myeloma, and leukemia in the licensed territory. We retain development and commercial rights of STRO-001 globally outside of Greater China, including the United States.

Under the BioNova Option Agreement, BioNova paid the Company an initial licensing option payment of \$4.0 million, with potential payments totaling up to \$200.0 million related to option exercise, development, regulatory, and commercial milestones. We will provide STRO-001 to BioNova under appropriate clinical and commercial supply service agreements. Upon commercialization, we will receive tiered royalties ranging from low- to mid-teen percentages based on annual net sales of STRO-001 in Greater China for at least ten years following the first commercial sale of STRO-001 in Greater China.

BioNova has the right to terminate the BioNova Option Agreement for convenience or other reasons specified in the BioNova Option Agreement, upon prior written notice.

### ***Manufacturing***

We have significant expertise in the production of therapeutic biologics. Our proprietary XpressCF® platform is a cell-free protein synthesis technology that enables rapid and systematic process development, streamlined scale-up and cGMP manufacturing.

### ***Extract and Reagents***

We manufacture our cell-free extract and related reagents in our cGMP manufacturing facility in San Carlos, California for our clinical trials and supply commitments. If we are successful in developing an effective strategic relationship with a contract manufacturing organization, or CMO, we would consider supplementing our manufacturing capacity by outsourcing the production of cell-free extract and related reagents to one or more such CMO(s) to cover our needs during product launch and for long-term commercial supply.

## **Drug Substance and Drug Product**

Our process development and manufacturing strategies are tailored to rapidly advance our product candidates, including the use of a supply chain of established CMOs to ensure successful execution. The production of antibodies will be done by either us or CMOs, depending on our internal cGMP production capacity. The production of all other necessary elements for the manufacture of our ADC product candidates, and the final manufacture of the ADC drug product, will be handled entirely by CMOs. Our XpressCF+<sup>®</sup>™ platform has been successfully used for manufacturing several antibodies containing non-natural amino acids and requires minimal process optimization to support early clinical phase manufacturing. We utilize industry established production steps for the purification of our antibodies. The CMOs we have selected have strong track records in cGMP manufacturing with expertise in clinical or commercial drug manufacturing for the cytotoxic agent, conjugation and fill-finish of the therapeutic biologics. All activities from cell-free extract production to formulated drug product are performed to maintain aggressive timelines and minimize delays.

### **Competition**

The biotechnology and biopharmaceutical industries, and the immuno-oncology subsector, are characterized by rapid evolution of technologies, fierce competition and strong defense of intellectual property. Any product candidates that we successfully develop and commercialize will have to compete with existing therapies and new therapies that may become available in the future. While we believe that our proprietary XpressCF<sup>®</sup> platform and scientific expertise in the field of biologics and immuno-oncology provide us with competitive advantages, a wide variety of institutions, including large biopharmaceutical companies, specialty biotechnology companies, academic research departments and public and private research institutions, are actively developing potentially competitive products and technologies. We face substantial competition from biotechnology and biopharmaceutical companies developing products in immuno-oncology. Our competitors include larger and better funded biopharmaceutical, biotechnological and therapeutics companies, including companies focused on cancer immunotherapies, such as AstraZeneca PLC, BMS, GlaxoSmithKline PLC, Merck, Novartis AG, Pfizer Inc., or Pfizer, Roche Holding Ltd, Sanofi S.A and companies focused on ADCs, such as Pfizer, GlaxoSmithKline PLC, Daiichi Sankyo Company, Limited, ImmunoGen, Inc., Mersana Therapeutics, Inc., or Mersana, Seagen, Inc., Genentech, Inc., or Genentech, Gilead Sciences, Inc., or Gilead, and ADC Therapeutics SA, as well as numerous small companies. Moreover, we also compete with current and future therapeutics developed at universities and other research institutions.

If our most advanced product candidates are approved, they will compete with a range of therapeutic treatments that are either in development or currently marketed. Currently marketed oncology drugs and therapeutics range from monoclonal antibodies, such as Genentech's Herceptin; to ADCs, such as Genentech's Kadcyla; to immune checkpoint inhibitors, such as BMS's Opdivo; to T cell-engager immunotherapies, such as Amgen, Inc.'s Blincyto; and to CAR-T cell therapies, such as Gilead's Yescarta. In addition, numerous compounds are in clinical development for cancer treatment. With respect to B cell-based malignancies, such as multiple myeloma, the most common treatments are chemotherapeutic compounds, radiation therapy, stem cell transplantation, corticosteroids, immunotherapy and targeted therapy. The clinical development pipeline for cancer includes small molecules, antibodies, vaccines, cell therapies and immunotherapies from a variety of companies and institutions.

Many of our competitors, either alone or with strategic partners, have substantially greater financial, technical, manufacturing, marketing, sales, supply and human resources or experience than we have. Accordingly, our competitors may be more successful than us in obtaining approval for treatments and achieving widespread market acceptance, rendering our treatments obsolete or non-competitive. Accelerated merger and acquisition activity in the biotechnology and biopharmaceutical industries may result in even more resources being concentrated among a smaller number of our competitors. These companies also compete with us in recruiting and retaining qualified scientific and management personnel, establishing clinical trial sites and patient registration for clinical trials, and acquiring technologies complementary to, or necessary for, our programs. Smaller or early-stage companies may also prove to be significant competitors, particularly through collaborative arrangements with large and established companies. Our commercial opportunity could be substantially limited in the event that our competitors develop and commercialize products that are more effective, safer, less toxic, more convenient or less expensive than our comparable products. In geographies that are critical to our commercial success, competitors may also obtain regulatory approvals before us, resulting in our competitors building a strong market position in advance of the entry of our products. We believe the factors determining the success of our programs will be the efficacy, safety and convenience of our product candidates.

## **Reimbursement**

The regulations that govern pricing and reimbursement for new drugs and therapeutic biologics vary widely from country to country. Some countries require approval of the sale price of a drug or therapeutic biologic before it can be marketed. In many countries, the pricing review period begins after marketing approval is granted. In some foreign markets, prescription biopharmaceutical pricing remains subject to continuing governmental control even after initial approval is granted. As a result, a drug company can obtain regulatory approval for a product in a particular country, but then be subject to price regulations that delay commercial launch of that product.

A drug company's ability to commercialize any products successfully will also depend in part on the extent to which coverage and adequate reimbursement for these products and related treatments will be available from government authorities, private health insurers and other organizations. Even if one or more products are successfully brought to the market, these products may not be considered cost-effective, and the amount reimbursed for such products may be insufficient to allow them to be sold on a competitive basis. Increasingly, third-party payors who reimburse patients or healthcare providers, such as government and private insurance plans, are requiring that drug companies provide them with predetermined discounts from list prices, and are seeking to reduce the prices charged or the amounts reimbursed for biopharmaceutical products.

Significant delays can occur in obtaining reimbursement for newly-approved drugs or therapeutic biologics, and coverage may be more limited than the purposes for which the drug or therapeutic biologic is approved by the FDA or similar foreign regulatory authorities. Moreover, eligibility for reimbursement does not imply that any drug or therapeutic biologic will be reimbursed in all cases or at a rate that covers a drug company's costs, including research, development, manufacture, sale and distribution.

Interim reimbursement levels for new drugs or therapeutic biologics, if applicable, may also be insufficient to cover a drug company's costs and may not be made permanent. Reimbursement rates may be based on payments allowed for lower cost drugs or therapeutic biologics that are already reimbursed, may be incorporated into existing payments for other services and may reflect budgetary constraints or imperfections in Medicare data. Net prices for drugs or therapeutic biologics may be reduced by mandatory discounts or rebates required by government healthcare programs or private payors and by any future relaxation of laws that presently restrict imports of drugs or therapeutic biologics from countries where they may be sold at lower prices than in the United States. Further, no uniform policy for coverage and reimbursement exists in the United States. Third-party payors often rely upon Medicare coverage policy and payment limitations in setting their own reimbursement rates, but also have their own methods and approval processes apart from Medicare determinations. Therefore, coverage and reimbursement can differ significantly from payor to payor.

## Intellectual Property

We strive to protect and enhance the proprietary technology, inventions, and improvements that are commercially important to our business, including seeking, maintaining, and defending patent rights, whether developed internally or licensed from third parties. Our policy is to seek to protect our proprietary position by, among other methods, pursuing and obtaining patent protection in the United States and in jurisdictions outside of the United States related to our proprietary technology, inventions, improvements, platforms and product candidates that are important to the development and implementation of our business. Our patent portfolio is intended to cover, but is not limited to, our technology platforms, our product candidates and components thereof, their methods of use and processes for their manufacture, our proprietary reagents and assays, and any other inventions that are commercially important to our business. We also rely on trade secret protection of our confidential information and know-how relating to our proprietary technology, platforms and product candidates, continuing innovation, and in-licensing opportunities to develop, strengthen, and maintain our proprietary position in our XpressCF® platform and product candidates. We expect to rely on data exclusivity, market exclusivity, patent term adjustment and patent term extensions when available. Our commercial success may depend in part on our ability to obtain and maintain patent and other proprietary protection for our technology, inventions, and improvements; to preserve the confidentiality of our trade secrets; to maintain our licenses to use intellectual property owned or controlled by third parties; to defend and enforce our proprietary rights, including our patents; to defend against and challenge the assertion by third parties of their purported intellectual property rights; and to operate without the unauthorized infringement on the valid and enforceable patents and other proprietary rights of third parties.

We believe that we have a strong global intellectual property position and substantial know-how and trade secrets relating to our XpressCF® platform technology, platform and product candidates. Our patent portfolio as of December 31, 2021 contained 22 U.S. issued patents and 186 patents issued in ex-U.S. jurisdictions, including Europe, China, Japan, Australia and Singapore, and 33 U.S. pending applications, as well as 83 patent applications pending in ex-U.S. jurisdictions, including Europe, China, Japan, Australia and Singapore owned solely by us. These patents and patent applications include claims relating to:

- bacterial strains, and extracts prepared therefrom, comprising an engineered Release Factor 1 protein, which facilitates incorporation of non-natural amino acids into proteins;
- bacterial strains, and extracts prepared therefrom, comprising combinations of chaperone proteins, which facilitate expression of complex eukaryotic proteins in bacterial extracts;
- bacterial strains having an oxidative cytoplasm;
- non-natural amino acid tRNA synthetases;
- antibodies with engineered CH2 domains;
- antibodies with site-specific glutamine tags;
- PEGylated linkers for conjugation;
- antibodies and antibody fragments containing one or more non-natural amino acids at defined positions in their amino acid sequences;
- antibodies targeting receptors of interest, including CD74, FolR $\alpha$ , BCMA, and EpCAM, and methods of treating therewith;
- ADCs targeting receptors of interest, including CD74, FolR $\alpha$  and BCMA, and methods of treating therewith;
- combination therapies with anti-Fol $\alpha$  ADCs, and methods of treating therewith;
- iADCs, and TLR7 and TLR7/8 agonists, and methods of treating therewith;

- hemiasterlin, both as a cytotoxin and as a linker-warhead, which is used in our STRO-002 product candidate; and

- para-azidomethylphenylalanine, or pAMF, and proteins comprising pAMF, our workhorse non-natural amino acid which is primarily used when we conjugate molecules to proteins produced with our XpressCF+<sup>®</sup>™ platform.

Our issued patents, and any patents that may issue from our pending patent applications, in our solely owned patent portfolio are expected to expire between January 2030 and December 2042, absent any patent term adjustments or extensions.

In addition, we have exclusively licensed the following patent portfolio from Stanford: 11 U.S. issued patents and 35 patents issued in ex-U.S. jurisdictions, including Europe, China, Canada, India, Australia, South Korea, Eurasia and Singapore. This patent portfolio includes claims relating to methods related to *in vitro* protein synthesis that we use in our XpressCF<sup>®</sup> platform when discovering, developing and manufacturing our product candidates.

Remaining patents in our patent portfolio licensed from Stanford are expected to expire between August 2023 and January 2028, absent any patent term adjustments or extensions.

As for the XpressCF<sup>®</sup> platform, product candidates and processes we develop and commercialize, in the normal course of business, we intend to pursue, where appropriate, patent protection or trade secret protection relating to compositions, methods of manufacture, assay methods, methods of use, treatment of indications, dosing and formulations. We may also pursue patent protection with respect to product development processes and technology.

The following table describes the material patents and patent applications owned or licensed by us.

Patent Relevance	Ownership	Type of Patent Protection	Expiration or Anticipated Expiration (absent patent term extension or adjustment)	Pending Jurisdictions	Issued Jurisdictions
XpressCF® platform	In licensed from Stanford	Utility	2023	None	US, AU, CA, EP, JP
XpressCF® platform	Owned by Sutro	Utility	2033	US, CA, JP	US, AU, CN, EP, IL, IN, JP, KR, SG
XpressCF® platform	Owned by Sutro	Utility	2034	US, CA, EP, HK, IN, SG	US, AU, CN, IL, JP, KR
XpressCF® platform	Owned by Sutro	Utility	2034	None	US, EP
XpressCF® platform	Owned by Sutro	Utility	2035	EP	US
XpressCF® platform	Owned by Sutro	Utility	2041	US, TW, PCT	None
STRO-001 and STRO-002	Owned by Sutro	Utility	2033	US, BR, CA, EP, IN	US, AU, CN, EP, HK, IL, JP, KR, SG
STRO-001 and STRO-002	Owned by Sutro	Utility	2033	US, BR, CA, EP	US, AU, EP, CN, HK, IL, IN, JP, KR, SG
STRO-001	Owned by Sutro	Utility	2035	US, EP	US, EP
STRO-001	Owned by Sutro	Utility	2037	US, EP, HK	None
STRO-001	Owned by Sutro	Utility	2037	AU, BR, CA, CN, IN, IL, JP, KR, MX, NZ, RU, SG, ZA	None
STRO-001	Owned by Sutro	Utility	2038	US, EP	None
STRO-002	Owned by Sutro	Utility	2037	US, EP	None
STRO-002	Owned by Sutro	Utility	2038	US, AU, BR, CA, CN, EP, HK, IL, IN, JP, KR, MX, NZ, RU, SG, ZA	US
STRO-002	Owned by Sutro	Utility	2036	US, BR, CA, CN, EP, IL, IN, KR	US, AU, JP, SG
STRO-002	Owned by Sutro	Utility	2039	US, EP, JP	None
STRO-002	Owned by Sutro	Provisional	2042	US	None
STRO-002	Owned by Sutro	Provisional	2042	US	None

We continually assess and refine our intellectual property strategy as we develop new platform technologies and product candidates. To that end, we are prepared to file additional patent applications if our intellectual property strategy requires such filings, or where we seek to adapt to competition or seize business opportunities. Further, we are prepared to file patent applications, as we consider appropriate under the circumstances, relating to the new technologies that we develop. In addition to filing and prosecuting patent applications in the United States, we often file counterpart patent applications in the European Union and in additional countries where we believe such foreign filing is likely to be beneficial, including but not limited to any or all of Australia, Brazil, Canada, China, Hong Kong, India, Israel, Japan, Mexico, New Zealand, Singapore, South Africa, South Korea and Taiwan.

The term of individual patents depends upon the laws of the countries in which they are obtained. In most countries in which we file, the patent term is 20 years from the earliest date of filing of a non-provisional patent application. However, the term of United States patents may be extended for delays incurred due to compliance with the FDA requirements or by delays encountered during prosecution that are caused by the United States Patent and Trademark Office, or the USPTO. For example, the Hatch-Waxman Act permits a patent term extension for FDA-approved drugs of up to five years beyond the expiration of the patent. The length of the patent term extension is related to the length of time the drug is under regulatory review. Patent extension cannot extend the remaining term of a patent beyond a total of 14 years from the date of product approval, and only one patent applicable to an approved drug may be extended. Similar provisions are available in Europe and other jurisdictions to extend the term of a patent that covers an approved drug. In the future, if and when our biopharmaceutical product candidates receive FDA approval, we expect to apply for patent term extensions on patents covering those product candidates. We intend to seek patent term extensions to any of our issued patents in any jurisdiction where these are available; however, there is no guarantee that the applicable authorities, including the USPTO and FDA, will agree with our assessment of whether such extensions should be granted, and even if granted, the length of such extensions. Our currently issued patents will likely expire on dates ranging from 2030 to 2038, unless we receive patent term extension or patent term adjustment, or both. If patents are issued on our pending patent applications, the resulting patents are projected to expire on dates ranging from 2033 to 2042, unless we receive patent term extension or patent term adjustment, or both. However, the actual protection afforded by a patent varies on a product-by-product basis, from country-to-country, and depends upon many factors, including the type of patent, the scope of its coverage, the availability of regulatory-related extensions, the availability of legal remedies in a particular country and the validity and enforceability of the patent.

The patent positions of companies like ours are generally uncertain and involve complex legal and factual questions. No consistent policy regarding the scope of claims allowable in patents in the field of immunotherapy has emerged in the United States. The patent situation outside of the United States is even more uncertain. Changes in the patent laws and rules, either by legislation, judicial decisions, or regulatory interpretation in the United States and other countries may diminish our ability to protect our inventions and enforce our intellectual property rights, and more generally could affect the value of our intellectual property. In particular, our ability to stop third parties from making, using, selling, offering to sell, or importing any of our patented inventions, either directly or indirectly, will depend in part on our success in obtaining, defending, and enforcing patent claims that cover our technology, inventions, and improvements. With respect to both licensed and company-owned intellectual property, we cannot be sure that patents will be granted with respect to any of our pending patent applications or with respect to any patent applications filed by us in the future, nor can we be sure that any of our existing patents or any patents that may be granted to us in the future will be commercially useful in protecting our platforms and product candidates and the methods used to manufacture those platforms and product candidates. Moreover, even our issued patents do not guarantee us the right to practice our technology in relation to the commercialization of our platform's product candidates. However, the area of patent and other intellectual property rights in biotechnology is an evolving one with many risks and uncertainties, and third parties may have blocking patents that could be used to prevent us from commercializing our patented XpressCF® technology, platforms and product candidates and practicing our proprietary technology. Our issued patents and those that may issue in the future may be challenged, invalidated, or circumvented, which could limit our ability to stop competitors from marketing related platforms or product candidates or limit the length of the term of patent protection that we may have for our XpressCF® technology, platforms and product candidates. In addition, the rights granted under any issued patents may not provide us with protection or competitive advantages against competitors with similar technology. Furthermore, our competitors may independently develop similar technologies. For these reasons, we may have competition for our XpressCF® technology, platforms and product candidates. Moreover, because of the extensive time required for development, testing and regulatory review of a



potential product, it is possible that, before any particular product candidate can be commercialized, any related patent may expire or remain in force for only a short period following commercialization, thereby reducing any advantage of the patent. For this and more comprehensive risks related to our proprietary technology, inventions, improvements, platforms and product candidates, please see the section entitled "Risk Factors—Risks Related to Intellectual Property."

We intend to file applications for trademark registrations in connection with our product candidates in various jurisdictions, including the United States. We have filed for trademark protection of the Sutro Biopharma marks, the XpressCF® mark and the XpressCF+®™ mark with the USPTO. Additionally, we filed for trademark protection of the ProteinSAR™ mark, XpressPDF™ mark, XpressRNAP™ mark, XpressRS™ mark, XpressRNA™ mark and XtractCF® mark with the USPTO. XpressCF® refers to our cell-free protein synthesis technology as a whole, and XpressCF+®™ refers specifically to cell-free protein synthesis incorporating one or more non-natural amino acids. The Sutro Biopharma marks were registered by the USPTO in 2014 and 2018, the XpressCF® mark was registered by the USPTO in 2017, and XpressCF+®™ mark was registered by the USPTO in 2017.

We also rely on trade secret protection for our confidential and proprietary information. Although we take steps to protect our confidential and proprietary information as trade secrets, including through contractual means with our employees and consultants, third parties may independently develop substantially equivalent proprietary information and techniques or otherwise gain access to our trade secrets or disclose our technology. Thus, we may not be able to meaningfully protect our trade secrets. It is our policy to require our employees, consultants, outside scientific collaborators, sponsored researchers and other advisors to execute confidentiality agreements upon the commencement of employment or consulting relationships with us. These agreements provide that all confidential information concerning our business or financial affairs developed or made known to the individual during the course of the individual's relationship with us is to be kept confidential and not disclosed to third parties except in specific circumstances. In the case of employees, the agreements provide that all inventions conceived by the individual, and which are related to our current or planned business or research and development or made during normal working hours, on our premises or using our equipment or proprietary information, are our exclusive property. In many cases our confidentiality and other agreements with consultants, outside scientific collaborators, sponsored researchers and other advisors require them to assign or grant us licenses to inventions they invent as a result of the work or services they render under such agreements or grant us an option to negotiate a license to use such inventions.

We also seek to preserve the integrity and confidentiality of our proprietary technology and processes by maintaining physical security of our premises and physical and electronic security of our information technology systems. Although we have confidence in these individuals, organizations, and systems, agreements or security measures may be breached, and we may not have adequate remedies for any breach. To the extent that our employees, contractors, consultants, collaborators, and advisors use intellectual property owned by others in their work for us, disputes may arise as to the rights in related or resulting know-how and inventions.

### **Government Regulation**

Government authorities in the United States, at the federal, state and local level, and in other countries and jurisdictions extensively regulate, among other things, the research, development, testing, manufacture, quality control, approval, packaging, storage, recordkeeping, labeling, advertising, promotion, distribution, marketing, post-approval monitoring and reporting, and import and export of pharmaceutical products. The processes for obtaining regulatory approvals in the United States and in foreign countries and jurisdictions, along with subsequent compliance with applicable statutes and regulations and other regulatory authorities, require the expenditure of substantial time and financial resources.

### **FDA Approval Process**

In the United States, pharmaceutical products are subject to extensive regulation by the FDA. The Federal Food, Drug, and Cosmetic Act, or the FDC Act, and other federal and state statutes and regulations, govern, among other things, the research, development, testing, manufacture, storage, recordkeeping, approval, labeling, promotion and marketing, distribution, post-approval monitoring and reporting, sampling, and import and export of pharmaceutical products. Biological products used for the prevention, treatment, or cure of a disease or condition of a human being are subject to regulation under the FDC Act, except the section of the FDC Act which governs the approval of new drug applications, or NDAs. Biological products are approved for marketing under provisions

of the Public Health Service Act, or PHS Act, via a Biologics License Application, or BLA. However, the application process and requirements for approval of BLAs are very similar to those for NDAs, and biologics are associated with similar approval risks and costs as drugs. Failure to comply with applicable U.S. requirements may subject a company to a variety of administrative or judicial sanctions, such as clinical hold, FDA refusal to approve pending BLAs, warning or untitled letters, product recalls, product seizures, total or partial suspension of production or distribution, injunctions, fines, civil penalties, and criminal prosecution.

Biological product development for a new product or certain changes to an approved product in the United States typically involves preclinical laboratory and animal tests, the submission to the FDA of an investigational new drug application, or IND, which must become effective before clinical testing may commence, and adequate and well-controlled clinical trials to establish the safety and effectiveness of the biologic for each indication for which FDA approval is sought. Satisfaction of FDA pre-market approval requirements typically takes many years and the actual time required may vary substantially based upon the type, complexity, and novelty of the product or disease.

Preclinical tests include laboratory evaluation of product chemistry, formulation, and toxicity, as well as animal trials to assess the characteristics and potential safety and efficacy of the product. The conduct of the preclinical tests must comply with federal regulations and requirements, including good laboratory practices. The results of preclinical testing are submitted to the FDA as part of an IND along with other information, including information about product chemistry, manufacturing and controls, and a proposed clinical trial protocol. Long-term preclinical tests, such as animal tests of reproductive toxicity and carcinogenicity, may continue after the IND is submitted. A 30-day waiting period after the submission of each IND is required prior to the commencement of clinical testing in humans. If the FDA has neither commented on nor questioned the IND within this 30-day period, the clinical trial proposed in the IND may begin. Clinical trials involve the administration of the investigational biologic to healthy volunteers or patients under the supervision of a qualified investigator. Clinical trials must be conducted: (i) in compliance with federal regulations; (ii) in compliance with good clinical practice, or GCP, an international standard meant to protect the rights and health of patients and to define the roles of clinical trial sponsors, administrators, and monitors; as well as (iii) under protocols detailing the objectives of the trial, the parameters to be used in monitoring safety, and the effectiveness criteria to be evaluated. Each protocol involving testing on U.S. patients and subsequent protocol amendments must be submitted to the FDA as part of the IND.

The FDA may order the temporary, or permanent, discontinuation of a clinical trial at any time, or impose other sanctions, if it believes that the clinical trial either is not being conducted in accordance with FDA requirements or presents an unacceptable risk to the clinical trial patients. The trial protocol and informed consent information for patients in clinical trials must also be submitted to an institutional review board, or IRB, for approval. An IRB may also require the clinical trial at the site to be halted, either temporarily or permanently, for failure to comply with the IRB's requirements, or may impose other conditions.

Clinical trials to support BLAs for marketing approval are typically conducted in three sequential phases, but the phases may overlap. In Phase 1, the initial introduction of the biologic into healthy human subjects or patients, the product is tested to assess metabolism, pharmacokinetics, pharmacological actions, side effects associated with increasing doses, and, if possible, early evidence on effectiveness. In oncology clinical trials, efficacy endpoints are also often explored in Phase 1. Phase 2 usually involves trials in a limited patient population to determine the effectiveness of the drug or biologic for a particular indication, dosage tolerance, and optimum dosage, and to identify common adverse effects and safety risks. If a compound demonstrates evidence of effectiveness and an acceptable safety profile in Phase 2 evaluations, Phase 3 trials are undertaken to obtain the additional information about clinical efficacy and safety in a larger number of patients, typically at geographically dispersed clinical trial sites, to permit the FDA to evaluate the overall benefit-risk relationship of the drug or biologic and to provide adequate information for the labeling of the product. In some instances, trial phases may be truncated or combined into one or more combined-phase or adaptive design trials. In most cases, the FDA requires two adequate and well-controlled Phase 3 clinical trials to demonstrate the efficacy of the biologic. A single Phase 3 trial with other confirmatory evidence may be sufficient in certain oncological conditions where the trial is a large multicenter trial demonstrating internal consistency and a statistically very persuasive finding of a clinically meaningful effect on mortality, irreversible morbidity or prevention of a disease with a potentially serious outcome and confirmation of the result in a second trial would be practically or ethically impossible.

The manufacturer of an investigational drug in a Phase 2 or 3 clinical trial for a serious or life-threatening disease is required to make available, such as by posting on its website, its policy on evaluating and responding to requests for expanded access.

After completion of the required clinical testing, a BLA is prepared and submitted to the FDA. FDA approval of the BLA is required before marketing of the product may begin in the United States. The BLA must include the results of all preclinical, clinical, and other testing and a compilation of data relating to the product's pharmacology, chemistry, manufacture, and controls. The cost of preparing and submitting a BLA is substantial. The submission of most BLAs is additionally subject to a substantial application user fee, currently exceeding \$3,115,000 for Fiscal Year 2022. The applicant under an approved BLA is also subject to an annual program fee, currently exceeding \$369,000 per prescription drug product for Fiscal Year 2022. These fees are typically increased annually. The FDA has 60 days from its receipt of a BLA to determine whether the application will be filed based on the agency's threshold determination that it is sufficiently complete to permit substantive review. Once the submission is filed, the FDA begins an in-depth review. The FDA has agreed to certain performance goals in the review of BLAs. Most such applications for standard review biologic products are reviewed within 10 months of the date the FDA files the BLA; most applications for priority review biologics are reviewed within six months of the date the FDA files the BLA. Priority review can be applied to a biologic that the FDA determines has the potential to treat a serious or life-threatening condition and, if approved, would be a significant improvement in safety or effectiveness compared to available therapies. The review process for both standard and priority review may be extended by the FDA for three additional months to consider certain late-submitted information, or information intended to clarify information already provided in the submission.

The FDA may also refer applications for novel biologic products, or biologic products that present difficult questions of safety or efficacy, to an advisory committee—typically a panel that includes clinicians and other experts—for review, evaluation, and a recommendation as to whether the application should be approved. The FDA is not bound by the recommendation of an advisory committee, but it generally follows such recommendations. Before approving a BLA, the FDA will typically inspect one or more clinical sites to assure compliance with GCP. Additionally, the FDA will inspect the facility or the facilities at which the biologic product is manufactured. The FDA will not approve the product unless compliance with current Good Manufacturing Practices, or cGMPs, is satisfactory and the BLA contains data that provide substantial evidence that the biologic is safe, pure, potent and effective in the indication studied.

After the FDA evaluates the BLA and the manufacturing facilities, it issues either an approval letter or a complete response letter. A complete response letter generally outlines the deficiencies in the submission and may require substantial additional testing, or information, in order for the FDA to reconsider the application. If, or when, those deficiencies have been addressed to the FDA's satisfaction in a resubmission of the BLA, the FDA will issue an approval letter. The FDA has committed to reviewing such resubmissions in two or six months depending on the type of information included. An approval letter authorizes commercial marketing of the biologic with specific prescribing information for specific indications. As a condition of BLA approval, the FDA may require a risk evaluation and mitigation strategy, or REMS, to help ensure that the benefits of the biologic outweigh the potential risks. REMS can include medication guides, communication plans for healthcare professionals, and elements to assure safe use, or ETASU. ETASU can include, but are not limited to, special training or certification for prescribing or dispensing, dispensing only under certain circumstances, special monitoring, and the use of patient registries. The requirement for a REMS can materially affect the potential market and profitability of the product. Moreover, product approval may require substantial post-approval testing and surveillance to monitor the product's safety or efficacy.

Once granted, product approvals may be withdrawn if compliance with regulatory standards is not maintained or problems are identified following initial marketing. Changes to some of the conditions established in an approved application, including changes in indications, labeling, or manufacturing processes or facilities, require submission and FDA approval of a new BLA or BLA supplement before the change can be implemented. A BLA supplement for a new indication typically requires clinical data similar to that in the original application, and the FDA uses the same procedures and actions in reviewing BLA supplements as it does in reviewing BLAs.

### ***Fast Track Designation and Accelerated Approval***

The FDA is required to facilitate the development, and expedite the review, of biologics that are intended for the treatment of a serious or life-threatening disease or condition for which there is no effective treatment and which demonstrate the potential to address unmet medical needs for the condition. Under the fast track program, the sponsor of a new biologic candidate may request that the FDA designate the candidate for a specific indication as a fast track biologic concurrent with, or after, the filing of the IND for the candidate. The FDA must determine if the biologic candidate qualifies for fast track designation within 60 days of receipt of the sponsor's request. In addition to other benefits, such as the ability to engage in more frequent interactions with the FDA, the FDA may initiate review of sections of a fast track product's BLA before the application is complete. This rolling review is available if the applicant provides, and the FDA approves, a schedule for the submission of the remaining information and the applicant pays applicable user fees. However, the FDA's time period goal for reviewing an application does not begin until the last section of the BLA is submitted. Additionally, the fast track designation may be withdrawn by the FDA if the FDA believes that the designation is no longer supported by data emerging in the clinical trial process.

Under the FDA's accelerated approval regulations, the FDA may approve a biologic for a serious or life-threatening illness that provides meaningful therapeutic benefit to patients over existing treatments based upon a surrogate endpoint that is reasonably likely to predict clinical benefit, or on a clinical endpoint that can be measured earlier than irreversible morbidity or mortality, that is reasonably likely to predict an effect on irreversible morbidity or mortality or other clinical benefit, taking into account the severity, rarity, or prevalence of the condition and the availability or lack of alternative treatments.

In clinical trials, a surrogate endpoint is a measurement of laboratory or clinical signs of a disease or condition that substitutes for a direct measurement of how a patient feels, functions, or survives. Surrogate endpoints can often be measured more easily or more rapidly than clinical endpoints. A biologic candidate approved on this basis is subject to rigorous post-marketing compliance requirements, including the completion of Phase 4 or post-approval clinical trials to confirm the effect on the clinical endpoint. Failure to conduct required post-approval trials, or confirm a clinical benefit during post-marketing trials, will allow the FDA to withdraw the biologic from the market on an expedited basis. All promotional materials for biologic candidates approved under accelerated regulations are subject to prior review by the FDA.

### ***Orphan Drug Designation***

Under the Orphan Drug Act, the FDA may grant orphan drug designation to biological products intended to treat a rare disease or condition—generally a disease or condition that affects fewer than 200,000 individuals in the United States, or if it affects more than 200,000 individuals in the United States, there is no reasonable expectation that the cost of developing and making a product available in the United States for such disease or condition will be recovered from sales of the product.

Orphan drug designation must be requested before submitting a BLA. After the FDA grants orphan drug designation, the generic identity of the biological product and its potential orphan use are disclosed publicly by the FDA. Orphan drug designation does not convey any advantage in, or shorten the duration of, the regulatory review and approval process. The first BLA applicant to receive FDA approval for a product with particular principal molecular structural features to treat a particular disease with FDA orphan drug designation is entitled to a seven-year exclusive marketing period in the United States for that product for that indication. During the seven-year exclusivity period, the FDA may not approve any other applications to market a biological product containing the same active moiety for the same disease, except in limited circumstances, such as a showing of clinical superiority to the product with orphan drug exclusivity. A product is clinically superior if it is safer, more effective or makes a major contribution to patient care. Orphan drug exclusivity does not prevent the FDA from approving a different drug or biological product for the same disease or condition, or the same biological product for a different disease or condition. Among the other benefits of orphan drug designation are tax credits for certain research and a waiver of the BLA user fee.

### ***Disclosure of Clinical Trial Information***

Sponsors of clinical trials of FDA-regulated products, including biological products, are required to register and disclose certain clinical trial information. Information related to the product, patient population, phase of investigation, trial sites and investigators, and other aspects of the clinical trial are then made public as part of the registration. Sponsors are also obligated to discuss the results of their clinical trials after completion. Disclosure of the results of these trials can be delayed in certain circumstances for up to two years after the date of completion of the trial. Competitors may use this publicly available information to gain knowledge regarding the progress of development programs.

### ***Pediatric Information***

Under the Pediatric Research Equity Act, or PREA, BLAs or supplements to BLAs must contain data to assess the safety and effectiveness of the biological product for the claimed indications in all relevant pediatric subpopulations and to support dosing and administration for each pediatric subpopulation for which the biological product is safe and effective. The FDA may grant full or partial waivers, or deferrals, for submission of data. Unless otherwise required by regulation, PREA does not apply to any biological product for an indication for which orphan designation has been granted, except a product with a new active ingredient that is molecularly targeted cancer product intended for the treatment of an adult cancer and directed at a molecular target determined by FDA to be substantially relevant to the growth or progression of a pediatric cancer.

### ***Additional Controls for Biologics***

To help reduce the increased risk of the introduction of adventitious agents, the PHS Act emphasizes the importance of manufacturing controls for products whose attributes cannot be precisely defined. The PHS Act also provides authority to the FDA to immediately suspend licenses in situations where there exists a danger to public health, to prepare or procure products in the event of shortages and critical public health needs, and to authorize the creation and enforcement of regulations to prevent the introduction or spread of communicable diseases in the United States and between states.

After a BLA is approved, the product may also be subject to official lot release as a condition of approval. As part of the manufacturing process, the manufacturer is required to perform certain tests on each lot of the product before it is released for distribution. If the product is subject to official release by the FDA, the manufacturer submits samples of each lot of product to the FDA together with a release protocol showing a summary of the history of manufacture of the lot and the results of all of the manufacturer's tests performed on the lot. The FDA may also perform certain confirmatory tests on lots of some products, such as viral vaccines, before releasing the lots for distribution by the manufacturer. In addition, the FDA conducts laboratory research related to the regulatory standards on the safety, purity, potency, and effectiveness of biological products. As with drugs, after approval of biologics, manufacturers must address any safety issues that arise, are subject to recalls or a halt in manufacturing, and are subject to periodic inspection after approval.

### ***Post-Approval Requirements***

Once a BLA is approved, a product will be subject to certain post-approval requirements. For instance, the FDA closely regulates the post-approval marketing and promotion of biologics, including standards and regulations for direct-to-consumer advertising, off-label promotion, industry-sponsored scientific and educational activities and promotional activities involving the internet. Biologics may be marketed only for the approved indications and in accordance with the provisions of the approved labeling.

Adverse event reporting and submission of periodic reports is required following FDA approval of a BLA. The FDA also may require post-marketing testing, known as Phase 4 testing, REMS, and surveillance to monitor the effects of an approved product, or the FDA may place conditions on an approval that could restrict the distribution or use of the product. In addition, quality control, biological product manufacture, packaging, and labeling procedures must continue to conform to cGMPs after approval. Biologic manufacturers and certain of their subcontractors are required to register their establishments with the FDA and certain state agencies. Registration with the FDA subjects entities to periodic unannounced inspections by the FDA, during which the agency inspects manufacturing facilities to assess compliance with cGMPs. Accordingly, manufacturers must continue to expend time, money, and effort in the areas of production and quality-control to maintain compliance with cGMPs. Regulatory authorities may withdraw product approvals or request product recalls if a company fails to comply with regulatory standards, if it encounters problems following initial marketing, or if previously unrecognized problems are subsequently discovered.

#### **FDA Regulation of Companion Diagnostics**

A biologic product may rely upon an *in vitro* companion diagnostic for use in selecting the patients that will respond to a therapy. If an *in vitro* diagnostic is essential to the safe and effective use of the therapeutic product, then the FDA generally will require approval or clearance of the diagnostic at the same time that FDA approves the therapeutic product.

Pursuing FDA approval of an *in vitro* companion diagnostic usually would require a pre-market approval, or PMA, for that diagnostic. Based on a final FDA guidance document, and the FDA's past treatment of companion diagnostics, the FDA will likely require PMA approval of an *in vitro* companion diagnostics to identify patient populations suitable for a cancer therapy. The review of these *in vitro* companion diagnostics involves coordination of review by the FDA's Center for Biologics Evaluation and Research and by the FDA's Center for Devices and Radiological Health. Approval of a companion diagnostic is generally required at the time of new drug approval.

The PMA process, including the gathering of clinical and nonclinical data and the submission to and review by the FDA, can take several years or longer. The applicant must prepare and provide the FDA with reasonable assurance of the device's safety and effectiveness, including information about the device and its components regarding, among other things, device design, manufacturing and labeling. PMA applications are subject to an application fee, which exceeds \$374,000 for most PMAs for Fiscal Year 2022. In addition, PMAs for devices must generally include the results from extensive preclinical and adequate and well-controlled clinical trials to establish the safety and effectiveness of the device for each indication for which FDA approval is sought. In particular, for a diagnostic, the applicant must demonstrate that the diagnostic produces reproducible results between multiple users at multiple laboratories. As part of the PMA review, the FDA will typically inspect the manufacturer's facilities for compliance with the Quality System Regulation, or QSR, which imposes elaborate testing, control, documentation and other quality assurance requirements.

PMA approval is not guaranteed, and the FDA may ultimately respond to a PMA submission with a not approvable determination based on deficiencies in the application and require additional clinical trial or other data that may be expensive and time consuming to generate and that can substantially delay or prevent approval. If the FDA concludes that the applicable criteria have been met, the FDA will issue a PMA for the approved indications, which can be more limited than those originally sought by the applicant. The PMA can include post-approval conditions that the FDA believes necessary to ensure the safety and effectiveness of the device, including, among other things, restrictions on labeling, promotion, sale and distribution.

After a device is placed on the market, it remains subject to significant regulatory requirements. Medical devices may be marketed only for the uses and indications for which they are cleared or approved. Device manufacturers must also register with FDA and list their devices. A medical device manufacturer's manufacturing processes are required to comply with the applicable portions of the QSR, which cover the methods and documentation of the design, testing, production, processes, controls, quality assurance, labeling, packaging and shipping of medical devices. Domestic facility records and manufacturing processes are subject to periodic inspections by the FDA.

Failure to comply with applicable regulatory requirements can result in enforcement action by the FDA, which may include any of the following sanctions: warning or untitled letters, fines, injunctions, civil or criminal penalties, recall or seizure of current or future products, operating restrictions, partial suspension or total shutdown of production, denial of submissions for new products, or withdrawal of PMA approvals.

### **Other Healthcare Laws**

In addition to FDA restrictions on marketing of pharmaceutical products, several other types of state and federal laws have been applied to restrict certain general business and marketing practices in the pharmaceutical industry in recent years. These laws include anti-kickback statutes, false claims statutes and other healthcare laws and regulations.

The federal Anti-Kickback Statute prohibits, among other things, knowingly and willfully offering, paying, soliciting or receiving remuneration to induce, or in return for, purchasing, leasing, ordering or arranging for the purchase, lease or order of any healthcare item or service reimbursable under Medicare, Medicaid, or other federally financed healthcare programs. The Patient Protection and Affordable Care Act as amended by the Health Care and Education Reconciliation Act, collectively, the ACA, amended the intent element of the federal statute so that a person or entity no longer needs to have actual knowledge of the statute or specific intent to violate it in order to commit a violation. This statute has been interpreted to apply to arrangements between pharmaceutical manufacturers on the one hand and prescribers, purchasers and formulary managers on the other. Although there are a number of statutory exceptions and regulatory safe harbors protecting certain common activities from prosecution or other regulatory sanctions, the exceptions and safe harbors are drawn narrowly, and practices that involve remuneration intended to induce prescribing, purchases or recommendations may be subject to scrutiny if they do not qualify for an exception or safe harbor.

Federal civil and criminal false claims laws, including the federal civil False Claims Act, prohibit any person or entity from knowingly presenting, or causing to be presented, a false claim for payment to the federal government, or knowingly making, or causing to be made, a false statement to have a false claim paid. This includes claims made to programs where the federal government reimburses, such as Medicaid, as well as programs where the federal government is a direct purchaser, such as when it purchases off the Federal Supply Schedule. Recently, several pharmaceutical and other healthcare companies have been prosecuted under these laws for allegedly inflating drug prices they report to pricing services, which in turn were used by the government to set Medicare and Medicaid reimbursement rates, and for allegedly providing free product to customers with the expectation that the customers would bill federal programs for the product. In addition, certain marketing practices, including off-label promotion, may also violate false claims laws. Additionally, the ACA amended the federal Anti-Kickback Statute such that a violation of that statute can serve as a basis for liability under the federal False Claims Act. The majority of states also have statutes or regulations similar to the federal Anti-Kickback Statute and False Claims Act, which apply to items and services reimbursed under Medicaid and other state programs, or, in several states, apply regardless of the payor.

Other federal statutes pertaining to healthcare fraud and abuse include the civil monetary penalties statute, which prohibits, among other things, the offer or payment of remuneration to a Medicaid or Medicare beneficiary that the offeror or payor knows or should know is likely to influence the beneficiary to order a receive a reimbursable item or service from a particular supplier, and the additional federal criminal statutes created by the Health Insurance Portability and Accountability Act of 1996, or HIPAA, which prohibits, among other things, knowingly and willfully executing or attempting to execute a scheme to defraud any healthcare benefit program or obtain by means of false or fraudulent pretenses, representations or promises any money or property owned by or under the control of any healthcare benefit program in connection with the delivery of or payment for healthcare benefits, items or services.

In addition, HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act of 2009, or HITECH, imposes obligations on certain healthcare providers, health plans, and healthcare clearinghouses, known as covered entities, as well as their business associates that perform certain services involving the storage, use or disclosure of individually identifiable health information, including mandatory contractual terms, with respect to safeguarding the privacy, security, and transmission of individually identifiable health information, and require notification to affected individuals and regulatory authorities of certain breaches of security of individually identifiable health information.

Further, pursuant to the ACA, the Centers for Medicare & Medicaid Services, or CMS, has issued a final rule that requires manufacturers of prescription drugs to collect and report information on certain payments or transfers of value to physicians, physician assistants, certain types of advanced practice nurses and teaching hospitals, as well as investment interests held by physicians and their immediate family members. The reports must be submitted on an annual basis and the reported data are posted in searchable form on a public website on an annual basis. Failure to submit required information may result in civil monetary penalties.

In addition, several states now require prescription drug companies to report certain expenses relating to the marketing and promotion of drug products and to report gifts and payments to individual healthcare practitioners in these states. Other states prohibit various marketing-related activities, such as the provision of certain kinds of gifts or meals. Still other states require the posting of information relating to clinical studies and their outcomes. Some states require the reporting of certain pricing information, including information pertaining to and justifying price increases. In addition, certain states require pharmaceutical companies to implement compliance programs and/or marketing codes. Additional jurisdictions, such as the City of Chicago and the District of Columbia, require pharmaceutical sales representatives to be licensed and meet continuing education requirements. Certain states and local jurisdictions also require the registration of pharmaceutical sales representatives. Compliance with these laws is difficult and time consuming, and companies that do not comply with these state laws face civil penalties.

Efforts to ensure that business arrangements with third parties comply with applicable healthcare laws and regulations involve substantial costs. If a drug company's operations are found to be in violation of any such requirements, it may be subject to significant penalties, including civil, criminal and administrative penalties, damages, fines, disgorgement, imprisonment, the curtailment or restructuring of its operations, loss of eligibility to obtain approvals from the FDA, exclusion from participation in government contracting, healthcare reimbursement or other government programs, including Medicare and Medicaid, integrity oversight and reporting obligations and reputational harm. Although effective compliance programs can mitigate the risk of investigation and prosecution for violations of these laws, these risks cannot be entirely eliminated. Any action for an alleged or suspected violation can cause a drug company to incur significant legal expenses and divert management's attention from the operation of the business, even if such action is successfully defended.

### **Healthcare Reform**

Healthcare reforms that have been adopted, and that may be adopted in the future, could result in further reductions in coverage and levels of reimbursement for pharmaceutical products, increases in rebates payable under U.S. government rebate programs and additional downward pressure on pharmaceutical product prices. On September 9, 2021, the Biden administration published a wide-ranging list of policy proposals, most of which would need to be carried out by Congress, to reduce drug prices and drug payment. The HHS plan includes, among other reform measures, proposals to lower prescription drug prices, including by allowing Medicare to negotiate prices and disincentivizing price increases, and to support market changes that strengthen supply chains, promote biosimilars and generic drugs, and increase price transparency. Many similar proposals, including the plans to give Medicare Part D authority to negotiate drug prices, require drug manufacturers to pay rebates on drugs whose prices increase greater than the rate of inflation, and cap out-of-pocket costs, have already been included in policy statements and legislation currently being considered by Congress. It is unclear to what extent these and other statutory, regulatory, and administrative initiatives will be enacted and implemented.

### **Human Capital Resources**

As of December 31, 2021, we had 224 full-time employees and 15 full-time contract employees. Of these employees, 56 have an M.D. or a Ph.D. None of our employees are represented by a labor union or covered by collective bargaining agreements, and we believe our relationship with our employees is good.

We recognize that attracting, motivating, and retaining talent at all levels is vital to continuing our success. We invest in our employees in many ways, including through high-quality benefits and various health and wellness initiatives and offer competitive compensation packages (base salary and incentive plans), ensuring fairness in internal compensation practices. The principal purposes of our incentive plans (bonus and equity) are to provide retention incentives that align with the long-term interests of our stakeholders and stockholders.



To further engage and incentivize our workforce, we also offer a range of opportunities to support professional development and growth. We support ongoing education by providing an appropriate level of reimbursement for courses which are related to an individual's current or future position, we support our scientific team through encouraging their in-person and/or virtual attendance at conferences and symposia which further their development and we have a robust internal transfer practice to engage our current talent in growth opportunities within and outside of their functional areas. We embarked upon a Company-wide leadership development program which offered the opportunity for every employee to continue to build upon their learning. For our talent pipeline assessment and development, we work closely with individual scientific and business functional leaders to identify our high-performing and high-potential employees, by conducting a company-wide talent assessment and calibration. This assessment is completed annually to ensure we tie together our incentives, development, and recognition to retain and attract the people we need to drive our success.

We provide our team with ongoing resources aimed at both mental and physical health. We work closely with our Employee Assistance Plan which provides important mental health services and resources. We have a health and wellness initiative which encourages healthy behaviors aimed at creating positive life-long habits. We have a culture of collaboration and collaborative principles which we are intentional about fostering. Our initiatives on Diversity, Equity, Inclusion and Belonging aim to learn, listen and act in support of these principles. We are actively involved in our community through, among other things, mentoring underserved communities and supporting the philanthropic interests of our employees and patients.

#### **Corporate Information**

We were incorporated under the laws of the State of Delaware in April 2003 under the name Fundamental Applied Biology, Inc. We subsequently changed our name to Sutro Biopharma, Inc. Our principal executive offices are located at 111 Oyster Point Boulevard, South San Francisco, California 94080, and our telephone number is (650) 881-6500. Our website address is [www.sutrobio.com](http://www.sutrobio.com). The information contained on, or that can be accessed through, our website is not part of, and is not incorporated by reference into, this report.

#### **Available Information**

We file annual, quarterly and current reports, proxy statements and other documents with the Securities and Exchange Commission, or SEC, under the Securities Exchange Act of 1934, as amended, or Exchange Act. The SEC maintains an Internet website that contains reports, proxy and information statements, and other information regarding issuers, including us, that file electronically with the SEC. The public can obtain any documents that we file with the SEC at [www.sec.gov](http://www.sec.gov). Copies of each of our filings with the SEC can also be viewed and downloaded free of charge at our website, [ir.sutrobio.com](http://ir.sutrobio.com), after the reports and amendments are electronically filed with or furnished to the SEC.

## Item 1A. Risk Factors

### RISK FACTORS

*Investing in our common stock involves a high degree of risk. Before making your decision to invest in shares of our common stock, you should carefully consider the risks described below, together with the other information contained in this annual report, including our financial statements and the related notes and "Management's Discussion and Analysis of Financial Condition and Results of Operations." The risks and uncertainties described below are not the only ones we face. Additional risks and uncertainties that we are unaware of, or that we currently believe are not material, may also become important factors that affect us. We cannot assure you that any of the events discussed below will not occur. These events could have a material and adverse impact on our business, financial condition, results of operations and prospects. If that were to happen, the trading price of our common stock could decline, and you could lose all or part of your investment.*

#### Risks Related to Our Business

***We are a clinical stage biopharmaceutical company with a limited operating history and no products approved for commercial sale. We have a history of significant losses, expect to continue to incur significant losses for the foreseeable future and may never achieve or maintain profitability, which could result in a decline in the market value of our common stock.***

We are a clinical stage biopharmaceutical company with a limited operating history on which to base your investment decision. Biotechnology product development is a highly speculative undertaking and involves a substantial degree of risk.

To date, we have enrolled a limited number of patients in our initial clinical trials, have no products approved for commercial sale, have not generated any revenue from commercial product sales and, as of December 31, 2021, had an accumulated deficit of \$333.4 million. For the years ended December 31, 2021 and December 31, 2020, our net loss was \$105.5 million and \$32.1 million, respectively. Substantially all of our losses have resulted from expenses incurred in connection with our research and development programs and from general and administrative costs associated with our operations. The net loss for the year ended December 31, 2021 included the impact of the non-operating, unrealized loss of \$4.5 million related to our holdings of Vaxcyte common stock. The net loss for the year ended December 31, 2020 included the impact of the non-operating, unrealized gain of \$41.5 million related to our holdings of Vaxcyte common stock. Our technologies and product candidates are in early stages of development, and we are subject to the risks of failure inherent in the development of product candidates based on novel technologies. In addition, we have limited experience as a clinical stage company and have not yet demonstrated an ability to successfully overcome many of the risks and uncertainties frequently encountered by companies in new and rapidly evolving fields, particularly in the biotechnology industry. Furthermore, we do not expect to generate any revenue from commercial product sales for the foreseeable future, and we expect to continue to incur significant operating losses for the foreseeable future due to the cost of research and development, preclinical studies and clinical trials and the regulatory approval process for our product candidates. We expect our net losses to increase substantially as we progress further into clinical development of our lead programs and create additional infrastructure to support operations as a public company. However, the amount of our future losses is uncertain. Our ability to achieve profitability, if ever, will depend on, among other things, our, or our existing or future collaborators', successful development of product candidates, evaluating the related commercial opportunities, obtaining regulatory approvals to market and commercialize product candidates, manufacturing any approved products on commercially reasonable terms, establishing a sales and marketing organization or suitable third-party alternatives for any approved product, and raising sufficient funds to finance business activities. If we, or our existing or future collaborators, are unable to develop our technologies and commercialize one or more of our product candidates or if sales revenue from any product candidate that receives approval is insufficient, we will not achieve profitability, which could have a material and adverse effect on our business, financial condition, results of operations and prospects. Even if we achieve profitability in the future, we may not be able to sustain profitability in subsequent periods.

***The COVID-19 pandemic is having and may continue to have an impact on our business, which has caused us to spend significant effort in sourcing alternatives and otherwise modifying our activities.***

Public health crises such as pandemics or similar outbreaks could adversely impact our business. A pandemic, including COVID-19, or other public health epidemic poses the risk that we or our employees, contractors, suppliers, and other partners may be prevented from conducting business activities in whole or in part for an indefinite period of time, including due to spread of the disease within these groups or due to shutdowns that may be requested or mandated by governmental authorities. The COVID-19 pandemic has had, and is expected to continue to have, an adverse impact on our operations, particularly as a result of preventive and precautionary measures that we, other businesses, and governments are taking. In response to the spread of COVID-19, we initially modified operations in our executive offices with our administrative employees primarily continuing their work outside of those offices, restricted on-site research, development and manufacturing staff to only those required to execute their job responsibilities on-site for prioritized activities, limited the number and proximity of staff in any given laboratory or in our manufacturing facility (except as necessary for particular activities), and implemented multiple work place safety, social distancing and disinfection protocols.

Following the guidance of the CDC, OSHA, and applicable state regulations and orders, we have relaxed these safeguards and largely have returned to on-site work. We continue to closely monitor the state of the ongoing pandemic and the guidance provided by applicable governmental authorities and will modify our policies accordingly. To the extent that any governmental authority imposes additional regulatory requirements or changes existing laws, regulations, and policies that apply to our business and operations, such as additional workplace safety measures, our product development plans may be delayed, and we may incur further costs in bringing our business and operations into compliance with changing or new laws, regulations, and policies.

In addition, the COVID-19 pandemic has resulted in a significant percentage of our employees working remotely from time to time which has amplified certain risks to our business. For example, the increase in remote work has increased demand on our information technology resources and systems, increased phishing and other malicious activity as cybercriminals try to exploit the uncertainty surrounding the COVID-19 pandemic, which has led to an increase in the number of points of potential exposure, such as laptops and mobile devices, that need to be secured. Any failure to effectively manage these risks, including to timely identify and appropriately respond to any security incidents, may adversely affect our business. The COVID-19 pandemic has also had an adverse effect on our ability to attract, recruit, interview and hire at the pace we would typically expect to support our rapidly expanding operations. Additionally, we have incurred increased costs as a result of COVID-19, including increased expenses to implement additional measures to ensure the health and safety of our workforce, such as reimbursing for periodic COVID-19 testing and providing face masks.

We continue to experience the impact of the COVID-19 pandemic on our business, including increased costs and delays in the availability of materials routinely used in biologic therapeutic development and manufacturing, which may cause delays in our research, development and/or manufacturing activities, but overall patient enrollment and treatment remains on track. Most notably, certain consumables used in our development and manufacturing processes have been allocated, based on the Defense Priorities and Allocations System, or DPAS, rules currently in effect, first to production of COVID-19 therapeutic and prophylactic products and then next to production of approved products, with production of products under clinical investigation taking last priority. For example, we have not been able to procure certain filters used for GMP manufacture of our and our partners' product candidates in the time frame we were expecting, placing the timeline for manufacture of such product candidates at risk. Further, routine materials such as disposable bags, filters, and chromatography resins have become limited in supply and placed the timeline for development of the process to manufacture another one of our partners' projects at risk. We are attempting to mitigate these risks by ordering sufficient materials to provide a safety stock in reserve and by sourcing some of these materials from our partners' safety stock. We are also exploring developing new manufacturing processes to replace certain materials subject to reallocation under DPAS with equivalent materials that are not subject to reallocation. If these efforts are unsuccessful, or consumable shortages become more pronounced as the pandemic continues, we may experience delays in discovery, development and/or manufacture of our or our partners' products, which could delay our clinical and non-clinical programs. As such, these impacts and any potential future impacts from the COVID-19 pandemic may adversely affect our or our partners' research, development and/or manufacturing activities, which could negatively impact our business, financial condition, and operations.

As a result of the COVID-19 pandemic, or similar pandemics, we may experience disruptions that could severely impact our business, clinical trials and preclinical studies, including:

- delays or difficulties in enrolling and retaining patients in our clinical trials;
- delays or difficulties in clinical site initiation, including difficulties in recruiting clinical site investigators and clinical site staff;
- changes in protocol-specified procedures that lead to missing data (e.g., reduced or postponed patient visits, missed lab tests and scans, and patient discontinuation);
- increased rates of patients withdrawing from our clinical trials following enrollment as a result of contracting COVID-19, being forced to quarantine, losing insurance coverage or not accepting home health visits;
- diversion of healthcare resources away from the conduct of clinical trials, including the diversion of hospitals serving as our clinical trial sites and hospital staff supporting the conduct of our clinical trials;
- interruption of key clinical trial activities, such as clinical assessments at pre-specified timepoints during the trial and clinical trial site data monitoring, due to limitations on travel imposed or recommended by federal or state governments, employers and others, or interruption of clinical trial subject visits and study procedures (particularly any procedures that may be deemed non-essential), which may impact the integrity of subject data and clinical study endpoints;
- interruption or delays in the operations of the U.S. Food and Drug Administration, or FDA, and comparable foreign regulatory agencies, which may impact approval timelines;
- delays or disruptions in non-clinical experiments and investigational new drug application-enabling good laboratory practice standard toxicology studies;
- limitations on employee resources that would otherwise be focused on the conduct of our research, preclinical studies, clinical trials and manufacturing operations, including because of sickness of employees or their families, the desire of employees to avoid contact with large groups of people, an increased reliance on working from home or mass transit disruptions;
- interruption of, or delays in receiving, supplies of our product candidates or precursor molecules or other raw materials and the manufacture or shipment of both drug substance and finished drug product for our product candidates from either us or contract manufacturing organizations due to staffing shortages, production slowdowns, stoppages and disruptions in delivery systems or reallocation of global manufacturing resources to therapeutic or prophylactic treatments for COVID-19 resulting in reduced manufacturing capacity or shortages of raw materials; and
- reduced ability to engage with the medical and investor communities, including due to the cancellation of conferences scheduled throughout the year.

These and other factors arising from the COVID-19 pandemic could worsen in countries that are already afflicted with COVID-19, could continue to spread to additional countries, or could return to countries where the pandemic has been partially contained, each of which could further adversely impact our ability to conduct clinical trials and our business generally, and could have a material adverse impact on our operations and financial condition and results.

While the potential economic impact brought by, and the duration of, the COVID-19 pandemic is difficult to assess or predict, the COVID-19 pandemic has resulted in, and may continue to result in, extreme volatility and disruptions in the capital and credit markets, potentially reducing our ability to raise additional capital through equity, equity-linked or debt financings on acceptable terms, or at all, which could negatively impact our short-term and long-term liquidity and our ability to operate in accordance with our operating plan, or at all.

The ultimate impact of the COVID-19 pandemic is highly uncertain and subject to sudden change. The COVID-19 pandemic continues to evolve. The extent to which the pandemic may impact our business, clinical trials, research activities, preclinical studies and manufacturing activities will depend on future developments, which are highly uncertain and cannot be predicted with confidence, such as the ultimate geographic spread of COVID-19, the frequency of viral mutations and severity of the variants, the duration of the pandemic, the speed and breadth of mass vaccinations for COVID-19 and the efficacy of such vaccines, travel restrictions and actions to contain the outbreak or treat its impact, such as social distancing and quarantines or lock-downs in the United States and other countries, business closures or business disruptions and the effectiveness of actions taken in the United States and other countries to contain and treat the disease. While we do not yet know the full extent of current or future impacts on our business, any of these occurrences could significantly harm our business, financial condition, results of operations and prospects.

***We will need substantial additional funds to advance development of our product candidates. This additional financing may not be available on acceptable terms, or at all. Failure to obtain this necessary capital when needed may force us to delay, limit or terminate our product development programs, commercialization efforts or other operations.***

The development of biopharmaceutical product candidates is capital-intensive. If our product candidates enter and advance through preclinical studies and clinical trials, we will need substantial additional funds to expand our development, regulatory, manufacturing, marketing and sales capabilities. We have used substantial funds to develop our technology and product candidates and will require significant funds to conduct further research and development and preclinical testing and clinical trials of our product candidates, to seek regulatory approvals for our product candidates and to manufacture and market products, if any, which are approved for commercial sale. In addition, we expect to incur additional costs associated with operating as a public company.

Since our inception, we have invested a significant portion of our efforts and financial resources in research and development activities for our two proprietary clinical-stage product candidates STRO-001 and STRO-002, and the development of our technology platform, including our in-house manufacturing capabilities. Clinical trials for our product candidates will require substantial funds to complete. As of December 31, 2021, we had \$229.5 million in cash, cash equivalents and marketable securities. We expect to incur substantial expenditures in the foreseeable future as we seek to advance STRO-001 and STRO-002 and any future product candidates through clinical development, manufacturing, the regulatory approval process and, if approved, commercial launch activities, as well as in connection with the continued development of our technology platform and manufacturing capabilities. Based on our current operating plan, we believe that our available cash, cash equivalents and marketable securities will be sufficient to fund our operations through at least the next 12 months. However, our future capital requirements and the period for which we expect our existing resources to support our operations may vary significantly from what we expect, and we may need to seek additional funds sooner than planned. Our monthly spending levels vary based on new and ongoing research and development and other corporate activities. Because the length of time and activities associated with successful research and development of our product candidates is highly uncertain, we are unable to estimate the actual funds we will require for development and any marketing and commercialization activities for approved products. The timing and amount of our operating expenditures will depend largely on:

- the timing and progress of preclinical and clinical development activities;
- the costs associated with the development of our internal manufacturing and research and development facilities and processes;
- the number and scope of preclinical and clinical programs we decide to pursue;
- the progress of the development efforts of parties with whom we have entered or may in the future enter into collaborations and research and development agreements;
- the timing and amount of milestone and other payments we may receive under our collaboration agreements;
- our ability to maintain our current licenses and research and development programs and to establish new collaboration arrangements;

- the costs involved in prosecuting, defending and enforcing patent and other intellectual property claims;
- the costs of manufacturing our product candidates and those of our collaborators using our proprietary XpressCF® and XpressCF+®™ platforms;
- the cost and timing of regulatory approvals;
- the cost of commercialization activities if our product candidates or any future product candidates are approved for sale, including marketing, sales and distribution costs; and
- our efforts to enhance operational systems and hire additional personnel, including personnel to support development of our product candidates and satisfy our obligations as a public company.

If we are unable to obtain funding on a timely basis or on acceptable terms, we may have to delay, reduce or terminate our research and development programs and preclinical studies or clinical trials, limit strategic opportunities or undergo reductions in our workforce or other corporate restructuring activities. We also could be required to seek funds through arrangements with collaborators or others that may require us to relinquish rights to some of our technologies or product candidates that we would otherwise pursue on our own. We do not expect to realize revenue from sales of commercial products or royalties from licensed products in the foreseeable future, if at all, and, in no event, before our product candidates are clinically tested, approved for commercialization and successfully marketed. To date, we have primarily financed our operations through payments received under our collaboration agreements, the sale of equity securities and debt financing. We will be required to seek additional funding in the future and currently intend to do so through additional collaborations and/or licensing agreements, public or private equity offerings or debt financings, credit or loan facilities, or a combination of one or more of these funding sources. Our ability to raise additional funds will depend on financial, economic and other factors, many of which are beyond our control. Additional funds may not be available to us on acceptable terms or at all. Subject to limited exceptions, our Loan and Security Agreement with Oxford and SVB prohibits us from incurring indebtedness without the prior written consent of Oxford and SVB. If we raise additional funds by issuing equity securities, our stockholders will suffer dilution and the terms of any financing may adversely affect the rights of our stockholders. If we raise additional funds through licensing or collaboration arrangements with third parties, we may have to relinquish valuable rights to our product candidates, or grant licenses on terms that are not favorable to us. In addition, as a condition to providing additional funds to us, future investors may demand, and may be granted, rights superior to those of existing stockholders. Our current debt financing involves, and future debt financings, if available, are likely to involve, restrictive covenants limiting our flexibility in conducting future business activities, and, in the event of insolvency, debt holders would be repaid before holders of our equity securities receive any distribution of our corporate assets. Failure to obtain capital when needed on acceptable terms may force us to delay, limit or terminate our product development and commercialization of our current or future product candidates, which could have a material and adverse effect on our business, financial condition, results of operations and prospects.

***Our product candidates are in early stages of development and may fail in development or suffer delays that materially and adversely affect their commercial viability. If we or our collaborators are unable to complete development of or commercialize our product candidates or experience significant delays in doing so, our business will be materially harmed.***

We have no products on the market and all of our product candidates for cancer therapy are in early stages of development. In particular, our product candidates, STRO-001 is in the dose escalation phase and STRO-002 is in the dose expansion phase of their respective Phase 1 clinical trials. Also, enrollment began in the second half of 2019 for patients in the Phase 1 clinical trial for CC-99712, a BCMA ADC candidate resulting from our BMS collaboration; and a Phase 1 clinical trial was initiated in the first quarter of 2021 for M1231, a MUC1-EGFR bispecific ADC resulting from our EMD Serono collaboration. Further, Vaxcyte's investigational new drug application, or IND for its lead product candidate, VAX-24, a 24-valent pneumococcal conjugate vaccine, was cleared by the FDA in January 2022. Additionally, we have programs that are in earlier stages of discovery and preclinical development and may never advance to clinical-stage development. Our ability to achieve and sustain profitability depends on obtaining regulatory approvals for and successfully commercializing our product candidates, either alone or with third parties, and we cannot guarantee you that we will ever obtain regulatory approval for any of our product candidates. We have limited experience in conducting and managing the clinical trials necessary to obtain regulatory approvals, including approval by the FDA. Before obtaining regulatory approval for the commercial distribution of our product candidates, we or an existing or future collaborator must conduct extensive preclinical tests and clinical trials to demonstrate the safety and efficacy in humans of our product candidates.

We may not have the financial resources to continue development of, or to modify existing or enter into new collaborations for, a product candidate if we experience any issues that delay or prevent regulatory approval of, or our ability to commercialize, product candidates, including:

- negative or inconclusive results from our clinical trials or the clinical trials of others for product candidates similar to ours, leading to a decision or requirement to conduct additional preclinical testing or clinical trials or abandon a program;
- product-related side effects experienced by patients in our clinical trials or by individuals using drugs or therapeutic biologics similar to our product candidates;
- difficulty achieving successful continued development of our internal manufacturing processes, including process development and scale-up activities to supply products for preclinical studies, clinical trials and commercial sale;
- our inability to successfully transfer our manufacturing expertise and techniques to third-party contract manufacturers;
- inability of us or any third-party contract manufacturer to scale up manufacturing of our product candidates and those of our collaborators to supply the needs of clinical trials and commercial sales, and to manufacture such products in conformity with regulatory requirements using our proprietary XpressCF® and XpressCF+™ platforms;
- delays in submitting INDs or comparable foreign applications or delays or failures in obtaining the necessary approvals from regulators to commence a clinical trial, or a suspension or termination of a clinical trial once commenced;
- conditions imposed by the FDA or comparable foreign authorities regarding the scope or design of our clinical trials;
- delays in enrolling patients in our clinical trials;
- high drop-out rates of our clinical trial patients;
- inadequate supply or quality of product candidate components or materials or other supplies necessary for the conduct of our clinical trials;

- inability to obtain alternative sources of supply for which we have a single source for product candidate components or materials;
- occurrence of epidemics, pandemics or contagious diseases, such as the novel strain of coronavirus, and potential effects on our business, clinical trial sites, supply chain and manufacturing facilities;
- greater than anticipated costs of our clinical trials;
- harmful side effects or inability of our product candidates to meet efficacy endpoints during clinical trials;
- failure to demonstrate in our clinical trials a sufficient response rate or duration of response;
- failure to demonstrate a benefit-risk profile acceptable to the FDA or other regulatory agencies;
- unfavorable FDA or other regulatory agency inspection and review of one or more of our clinical trial sites or manufacturing facilities;
- failure of our third-party contractors or investigators to comply with regulatory requirements or otherwise meet their contractual obligations in a timely manner, or at all;
- delays and changes in regulatory requirements, policy and guidelines, including the imposition of additional regulatory oversight around clinical testing generally or with respect to our technology in particular; and
- varying interpretations of our data by the FDA and similar foreign regulatory agencies.

We or our collaborators' inability to complete development of or commercialize our product candidates or significant delays in doing so due to one or more of these factors, could have a material and adverse effect on our business, financial condition, results of operations and prospects.

***Our business is dependent on the success of our product candidates based on our proprietary XpressCF® and XpressCF+®™ platforms and, in particular, our proprietary product candidates, STRO-001 and STRO-002. Existing and future preclinical studies and clinical trials of our product candidates may not be successful. If we are unable to commercialize our product candidates or experience significant delays in doing so, our business will be materially harmed.***

We have invested a significant portion of our efforts and financial resources in the development of our proprietary XpressCF® platform and our proprietary product candidates, STRO-001 and STRO-002. Our ability to generate commercial product revenues, which we do not expect will occur for many years, if ever, will depend heavily on the successful development and eventual commercialization of STRO-001 and STRO-002. We have not previously submitted a new drug application, or NDA, or a biologics license application, or BLA, to the FDA, or similar regulatory approval filings to comparable foreign authorities, for any product candidate, and we cannot be certain that our product candidates will be successful in clinical trials or receive regulatory approval. Further, our product candidates may not receive regulatory approval even if they are successful in clinical trials. If we do not receive regulatory approvals for our product candidates, we may not be able to continue our operations. Even if we successfully obtain regulatory approvals to market our product candidates, our revenues will be dependent, in part, upon the size of the markets in the territories for which we gain regulatory approval and have commercial rights. If the markets for patient subsets that we are targeting are not as significant as we estimate, we may not generate significant revenues from sales of such products, if approved.



We plan to seek regulatory approval to commercialize our product candidates both in the United States and in selected foreign countries. While the scope of regulatory approvals generally is similar in other countries, in order to obtain separate regulatory approvals in other countries, we must comply with numerous and varying regulatory requirements of such countries regarding safety and efficacy. Other countries also have their own regulations governing, among other things, clinical trials and commercial sales, as well as pricing and distribution of our product candidates, and we may be required to expend significant resources to obtain regulatory approval and to comply with ongoing regulations in these jurisdictions.

The success of STRO-001 and STRO-002 and our other future product candidates will depend on many factors, including the following:

- successful enrollment of patients in, and the completion of, our clinical trials;
- receiving required regulatory approvals for the development and commercialization of our product candidates;
- establishing our commercial manufacturing capabilities or making arrangements with third-party manufacturers;
- establishing successful technology transfers and collaborations to develop our product candidates with licensees, including our licensee with rights in STRO-001 and STRO-002 in Greater China;
- obtaining and maintaining patent, trademark and trade secret protection and non-patent exclusivity for our product candidates and their components;
- enforcing and defending our intellectual property rights and claims and avoiding or defending against intellectual property rights and claims from third parties;
- achieving desirable therapeutic properties for our product candidates' intended indications;
- launching commercial sales of our product candidates, if and when approved, whether alone or in collaboration with third parties;
- acceptance of our product candidates, if and when approved, by patients, the medical community and third-party payors;
- effectively competing with other therapies; and
- maintaining an acceptable safety profile of our product candidates through clinical trials and following regulatory approval.

If we do not achieve one or more of these factors in a timely manner or at all, we could experience significant delays or an inability to successfully commercialize our product candidates, which would materially harm our business, financial condition, results of operations and prospects.

Additionally, we have in the past and may in the future create benchmark molecules for comparative purposes. For example, we have created a benchmark folate receptor-alpha, or FolR $\alpha$ , targeting antibody-drug conjugate, or ADC, using conventional technology that results in a heterogeneous ADC mixture. We have compared STRO-002 to this benchmark molecule in multiple preclinical models. We believe the results of these tests help us understand how the therapeutic index of STRO-002 compares to competitors' product candidates. However, we cannot be certain that any benchmark molecule that we create is the same as the molecule we are attempting to recreate, and the results of the tests comparing any such benchmark molecule to any other potential or current product candidate may be different than the actual results of a head-to-head test of any such other potential or current product candidate against a competitor molecule. Additional preclinical and clinical testing will be needed to evaluate the therapeutic index of our potential or current product candidates, and to understand their therapeutic potential relative to other product candidates in development. While we believe our ADCs may be superior to other investigative agents in development, without head-to-head comparative data, we will not be able to make claims of superiority to other products in our promotional materials, if our product candidates are approved.

***If we do not achieve our projected development goals in the time frames we announce and expect, the commercialization of our products may be delayed and our stock price may decline.***

From time to time, we estimate the timing of the anticipated accomplishment of various scientific, clinical, regulatory, commercial and other product development goals, which we sometimes refer to as milestones. These milestones may include the commencement or completion of scientific studies and clinical trials and the submission of regulatory filings. From time to time, we may publicly announce the expected timing of some of these milestones. All of these milestones are and will be based on numerous assumptions. The actual timing of these milestones can vary dramatically compared to our estimates, in some cases for reasons beyond our control. If we do not meet these milestones as publicly announced, or at all, the commercialization of our products may be delayed or never achieved and, as a result, our stock price may decline.

***Our approach to the discovery and development of our therapeutic treatments is based on novel technologies that are unproven and may not result in marketable products.***

We are developing a pipeline of product candidates using our proprietary XpressCF $^{\circledR}$  and XpressCF+ $^{\circledR}$  platforms. We believe that product candidates identified with our product discovery platform may offer an improved therapeutic approach by taking advantage of precision design and rapid empirical optimization, thereby reducing the dose-limiting toxic effects associated with existing products. However, the scientific research that forms the basis of our efforts to develop product candidates based on our XpressCF $^{\circledR}$  and XpressCF+ $^{\circledR}$  platforms is ongoing. Further, the scientific evidence to support the feasibility of developing therapeutic treatments based on our XpressCF $^{\circledR}$  and XpressCF+ $^{\circledR}$  platforms is both preliminary and limited.

To date, we have tested our first clinical stage product candidates, STRO-001 and STRO-002, our partner BMS has tested CC-99712, and our partner EMD Serono has tested M1231 in a limited number of clinical trial patients. In addition, Vaxcyte's IND for its lead product candidate, VAX-24, a 24-valent pneumococcal conjugate vaccine, was cleared by the FDA in January 2022. We may ultimately discover that our XpressCF $^{\circledR}$  and XpressCF+ $^{\circledR}$  platforms and any product candidates resulting therefrom do not possess certain properties required for therapeutic effectiveness. XpressCF $^{\circledR}$  product candidates may also be unable to remain stable in the human body for the period of time required for the drug to reach the target tissue or they may trigger immune responses that inhibit the ability of the product candidate to reach the target tissue or that cause adverse side effects in humans. We currently have only limited data, and no conclusive evidence, to suggest that we can introduce these necessary properties into these product candidates derived from our XpressCF $^{\circledR}$  and XpressCF+ $^{\circledR}$  platforms. We may spend substantial funds attempting to introduce these properties and may never succeed in doing so. In addition, product candidates based on our XpressCF $^{\circledR}$  and XpressCF+ $^{\circledR}$  platforms may demonstrate different chemical and pharmacological properties in patients than they do in laboratory studies. Although our XpressCF $^{\circledR}$  and XpressCF+ $^{\circledR}$  platforms and certain product candidates have produced successful results in animal studies, they may not demonstrate the same chemical and pharmacological properties in humans and may interact with human biological systems in unforeseen, ineffective or harmful ways. Further, in our oncology clinical trials to date, we have used achievement of stable disease as evidence for disease control (stable disease, partial response or complete response) by our product candidates; however, the FDA does not view stable disease as an objective response for the purposes of FDA approval.

We presented updated data from the dose escalation portion of our STRO-001 Phase 1 trial in December 2020. As of October 30, 2020, most treatment emergent adverse events were grade 1 or 2, with the most common grade 1-2 treatment emergent adverse events, or TEAEs, of nausea, fatigue, chills, anemia, headache, dyspnea, abdominal pain, vomiting, decreased appetite and pyrexia, and no ocular or neuropathy toxicity signals have been observed. Two grade 3 and no grade 4 treatment emergent adverse events were observed, one instance each of anemia and dyspnea. Subsequent to a previously announced protocol amendment in 2019 requiring pre-treatment screening imaging for patients at risk for thromboses, no thromboembolic events have been observed.

We presented updated data from the dose escalation portion of our STRO-002 Phase 1 trial in May 2021. Based on data from the trial through April 23, 2021, STRO-002 was generally well tolerated and was mostly associated with mild adverse events. Eighty-six percent (86%) of observed adverse events were grade 1 or grade 2. The most common Grade 3 and 4 TEAEs were reversible neutropenia (64%). Grade 3 arthralgia (13%), fatigue (10%), and neuropathy (8%) were observed and managed with standard medical treatment, including dose reductions or delays.

We released initial results of the dose-expansion portion of our STRO-002 Phase 1 trial in January 2022. Based on data from the trial through November 8, 2021, safety signals were generally consistent with data from the dose-escalation cohort. No new safety signals were observed in the dose-expansion cohort, including the absence of keratopathy, and 85.5% of TEAEs were Grade 1-2. Neutropenia was the leading TEAE, resulting in treatment delay or dose reduction. The majority of the cases of neutropenia were generally asymptomatic and resolved with a one-week dose delay or, in other cases, with standard medical treatment, including the use of granulocyte colony stimulating factor, or G-CSF, a type of growth factor. There were limited observed cases of febrile neutropenia, including one Grade 5 event at the 5.2 mg/kg starting dose level and one Grade 3 event at the 4.3 mg/kg starting dose level. The trial protocol was subsequently updated to require dose reduction for Grade 4 neutropenia.

If product candidates based on our XpressCF® and XpressCF+®™ platforms are unable to demonstrate sufficient safety and efficacy data to obtain marketing approval, we may never succeed in developing a marketable product, we may not become profitable and the value of our common stock will decline. The regulatory approval process for novel product candidates such as ours can be more expensive and take longer than for other, better known or extensively studied product candidates. We are not aware of any company currently developing a therapeutic using our approach to ADC development and no regulatory authority has granted approval for such a therapeutic. We believe the FDA has limited experience with therapeutics in oncology or other disease areas developed in cell-free-based synthesis systems, which may increase the complexity, uncertainty and length of the regulatory approval process for our product candidates. For example, our XpressCF® ADC product candidates contain cleavable or non-cleavable linker-warhead combinations or novel warheads that may result in unforeseen events when administered in a human. We and our existing or future collaborators may never receive approval to market and commercialize any product candidate. Even if we or an existing or future collaborator obtains regulatory approval, the approval may be for targets, disease indications or patient populations that are not as broad as we intended or desired or may require labeling that includes significant use or distribution restrictions or safety warnings. We or an existing or future collaborator may be required to perform additional or unanticipated clinical trials to obtain approval or be subject to post-marketing testing requirements to maintain regulatory approval. If the products resulting from our XpressCF® platform prove to be ineffective, unsafe or commercially unviable, our entire platform and pipeline would have little, if any, value, which would have a material and adverse effect on our business, financial condition, results of operations and prospects.

***Results of preclinical studies and early clinical trials may not be predictive of results of future clinical trials.***

The outcome of preclinical studies and early clinical trials may not be predictive of the success of later clinical trials, and preliminary results of clinical trials do not necessarily predict success in future clinical trials. Many companies in the pharmaceutical and biotechnology industries have suffered significant setbacks in late-stage clinical trials after achieving positive results in earlier development, and we could face similar setbacks. The design of a clinical trial can determine whether its results will support approval of a product, and flaws in the design of a clinical trial may not become apparent until the clinical trial is well advanced. While certain relevant members of our company have significant clinical experience, we in general have limited experience in designing clinical trials and may be unable to design and execute a clinical trial to support marketing approval. In addition, preclinical and clinical data are often susceptible to varying interpretations and analyses. Many companies that believed their product candidates performed satisfactorily in preclinical studies and clinical trials have nonetheless failed to obtain marketing approval for the product candidates. Even if we, or future collaborators, believe that the results of clinical trials for our product candidates warrant marketing approval, the FDA or comparable foreign regulatory authorities may disagree and may not grant marketing approval of our product candidates.

In some instances, there can be significant variability in safety or efficacy results between different clinical trials of the same product candidate due to numerous factors, including changes in trial procedures set forth in protocols, differences in the size and type of the patient populations, changes in and adherence to the dosing regimen and other clinical trial protocols and the rate of dropout among clinical trial patients. If we fail to receive positive results in clinical trials of our product candidates, the development timeline and regulatory approval and commercialization prospects for our most advanced product candidates, and, correspondingly, our business and financial prospects would be negatively impacted.

***The market may not be receptive to our product candidates based on a novel therapeutic modality, and we may not generate any future revenue from the sale or licensing of product candidates.***

Even if regulatory approval is obtained for a product candidate, we may not generate or sustain revenue from sales of the product due to factors such as whether the product can be sold at a competitive cost, competition in the therapeutic area(s) we have received or may receive approval for, and whether it will otherwise be accepted in the market. Historically, there have been concerns regarding the safety and efficacy of ADCs, and an ADC drug was voluntarily withdrawn from the market for an extended period of time. These historical concerns may negatively impact the perception market participants have on ADCs, including our product candidates. Additionally, the product candidates that we are developing are based on our proprietary XpressCF<sup>®</sup> and XpressCF+<sup>®</sup>™ platforms, which are new technologies. Market participants with significant influence over acceptance of new treatments, such as physicians and third-party payors, may not adopt an ADC product, or a product or treatment based on our novel cell-free production technologies, and we may not be able to convince the medical community and third-party payors to accept and use, or to provide favorable reimbursement for, any product candidates developed by us or our existing or future collaborators. Market acceptance of our product candidates will depend on, among other factors:

- the timing of our receipt of any marketing and commercialization approvals;
- the terms of any approvals and the countries in which approvals are obtained;
- the safety and efficacy of our product candidates;
- the prevalence and severity of any adverse side effects associated with our product candidates;
- limitations or warnings contained in any labeling approved by the FDA or other regulatory authority;
- relative convenience and ease of administration of our product candidates;
- the willingness of patients to accept any new methods of administration;
- the success of our physician education programs;

- the availability of coverage and adequate reimbursement from government and third-party payors;
- the pricing of our products, particularly as compared to alternative treatments; and
- the availability of alternative effective treatments for the disease indications our product candidates are intended to treat and the relative risks, benefits and costs of those treatments.

Because our product candidates are based on new technology, we expect that they will require extensive research and development and have substantial manufacturing and processing costs. In addition, our estimates regarding potential market size for any indication may be materially different from what we discover to exist at the time we commence commercialization, if any, for a product, which could result in significant changes in our business plan and have a material adverse effect on our business, financial condition, results of operations and prospects. Moreover, if any product candidate we commercialize fails to achieve market acceptance, it could have a material and adverse effect on our business, financial condition, results of operations and prospects.

***We have entered, and may in the future seek to enter, into collaborations with third parties for the development and commercialization of our product candidates using our XpressCF® platform. If we fail to enter into such collaborations, or such collaborations are not successful, we may not be able to capitalize on the market potential of our XpressCF® platform and resulting product candidates.***

Since 2014, we have entered into collaborations with Merck Sharp & Dohme Corp., a subsidiary of Merck & Co., Inc., or Merck, Celgene Corporation, or Celgene, a wholly owned subsidiary of Bristol Myers Squibb Company, or BMS, Merck KGaA, Darmstadt Germany (operating in the United States under the name "EMD Serono", the biopharmaceutical business of Merck KGaA, Darmstadt, Germany in the US), BioNova Pharmaceuticals Limited, or BioNova, and Tasly Biopharmaceuticals Co., Ltd, or Tasly, to develop and commercialize certain cancer and other therapeutics. Our XpressCF® and XpressCF+®™ platforms have also supported a spin-out company, Vaxcyte Inc., focused on discovery and development of vaccines for the treatment and prophylaxis of infectious disease. In addition, we may in the future seek third-party collaborators for research, development and commercialization of other therapeutic technologies or product candidates. Biopharmaceutical companies are our prior and likely future collaborators for any marketing, distribution, development, licensing or broader collaboration arrangements. With respect to our existing collaboration agreements, and what we expect will be the case with any future collaboration agreements, we have and would expect to have limited control over the amount and timing of resources that our collaborators dedicate to the development or commercialization of our product candidates. Moreover, our ability to generate revenues from these arrangements will depend on our collaborators' abilities to successfully perform the functions assigned to them in these arrangements.

Collaborations involving our product candidates currently pose, and will continue to pose, the following risks to us:

- collaborators have significant discretion in determining the efforts and resources that they will apply to these collaborations;
- collaborators may not pursue development and commercialization of our product candidates or may elect not to continue or renew development or commercialization programs based on preclinical studies or clinical trial results, changes in the collaborators' strategic focus or available funding, or external factors such as an acquisition that diverts resources or creates competing priorities;
- collaborators may delay clinical trials, provide insufficient funding for a clinical trial program, stop a clinical trial or abandon a product candidate, repeat or conduct new clinical trials or require a new formulation of a product candidate for clinical testing;
- collaborators could independently develop, or develop with third parties, products that compete directly or indirectly with our product candidates if the collaborators believe that competitive products are more likely to be successfully developed or can be commercialized under terms that are more economically attractive than ours;
- collaborators with marketing and distribution rights to one or more products may not commit sufficient resources to the marketing and distribution of such product or products;

- collaborators may not properly maintain or defend our intellectual property rights or may use our proprietary information in such a way as to invite litigation that could jeopardize or invalidate our intellectual property or proprietary information or expose us to litigation or potential liability;
- collaborators may infringe the intellectual property rights of third parties, which may expose us to litigation and potential liability;
- disputes may arise between the collaborators and us that result in the delay or termination of the research, development or commercialization of our product candidates or that result in costly litigation or arbitration that diverts management attention and resources; and
- collaborations may be terminated and, if terminated, may result in a need for additional capital to pursue further development or commercialization of the applicable product candidates.

As a result of the foregoing, our current and any future collaboration agreements may not lead to development or commercialization of our product candidates in the most efficient manner or at all. Moreover, if a collaborator of ours were to be involved in a business combination, the continued pursuit and emphasis on our product development or commercialization program could be delayed, diminished or terminated. Any failure to successfully develop or commercialize our product candidates pursuant to our current or any future collaboration agreements could have a material and adverse effect on our business, financial condition, results of operations and prospects.

***To date, no product developed on a cell-free manufacturing platform has received approval from the FDA, so the requirements for the manufacturing of products using our XpressCF® platform are uncertain.***

We have invested in our own current Good Manufacturing Practices, or cGMP, compliant manufacturing facility in San Carlos, California. In this facility, we are developing and implementing novel cell-free production technologies to supply our planned preclinical and clinical trials. However, before we may initiate a clinical trial or commercialize any of our product candidates, we must demonstrate to the FDA that the chemistry, manufacturing and controls for our product candidates meet applicable requirements, and in the European Union, or EU, a manufacturing authorization must be obtained from the appropriate EU regulatory authorities. The FDA has allowed Phase 1 clinical trial use of our product candidates STRO-001 and STRO-002 and our partner BMS's CC-99712 product candidate, and our partner EMD Serono's M1231 product candidate, portions of which are manufactured in our San Carlos manufacturing facility; however, because no product manufactured on a cell-free manufacturing platform has yet been approved in the United States, there is no manufacturing facility that has demonstrated the ability to comply with FDA requirements for later stage clinical development or commercialization, and, therefore, the time frame for demonstrating compliance to the FDA's satisfaction is uncertain. Delays in establishing that our manufacturing process and facility comply with cGMPs or disruptions in our manufacturing processes, implementation of novel in-house technologies or scale-up activities, may delay or disrupt our development efforts.

We expect that development of our own manufacturing facility will provide us with enhanced control of material supply for preclinical studies, clinical trials and the commercial market, enable the more rapid implementation of process changes and allow for better long-term margins. However, we have limited experience as a company in establishing and operating a manufacturing facility and there exist only a small number of contract manufacturing organizations, or CMOs, with the experience necessary to manufacture our product candidates. We may have difficulty hiring experts for internal manufacturing or finding and maintaining relationships with external CMOs and, accordingly, our production capacity could be limited.

We have initiated technology transfers to enable large scale manufacture of extract and the reagents necessary to manufacture our products using our XpressCF® platform. These large scale technology transfers may fail or be delayed, resulting in impacts to our development timelines and the costs associated with manufacturing our development products.

***Our existing collaborations with Merck, BMS, EMD Serono, Vaxcyte, BioNova and Tasly are important to our business. If our collaborators cease development efforts under our existing or future collaboration agreements, fail to fulfill their contract obligations, or if any of those agreements are terminated, these collaborations may fail to lead to commercial products and we may never receive milestone payments or future royalties under these agreements.***

We have entered into collaborations with other biotechnology companies to develop or commercialize several of our product candidates, and such collaborations currently represent a significant portion of our product pipeline and discovery and preclinical programs. Substantially all of our revenue to date has been derived from our existing collaboration agreements with Merck, BMS and EMD Serono, and a significant portion of our future revenue and cash resources is expected to be derived from these agreements or other similar agreements into which we may enter in the future. Revenue from research and development collaborations depends upon continuation of the collaborations, payments for research and development and other services and product supply, and the achievement of milestones, contingent payments and royalties, if any, derived from future products developed from our research. If we are unable to successfully advance the development of our product candidates, achieve milestones or earn contingent payments under our collaboration agreements, future revenue and cash resources will be substantially less than expected.

We are unable to predict the success of our collaborations and we may not realize the anticipated benefits of our strategic collaborations. Our collaborators have discretion in determining and directing the efforts and resources, including the ability to discontinue all efforts and resources, they apply to the development and, if approval is obtained, commercialization and marketing of the product candidates covered by such collaborations. As a result, our collaborators may elect to de-prioritize our programs, change their strategic focus or pursue alternative technologies in a manner that results in reduced, delayed or no revenue to us. For example, Celgene, now BMS, was advancing four preclinical collaboration programs, one of which is CC-99712, an ADC targeting B-cell maturation antigen, or BCMA, for the treatment of multiple myeloma. BMS has worldwide development and commercialization rights with respect to this BCMA ADC, for which the FDA cleared the IND application, and a Phase 1 clinical trial has commenced enrolling patients. However, in 2019, Celgene, now BMS, decided to not exercise the option to acquire U.S. clinical development and commercialization rights to a second collaboration program and subsequently allowed the ex-U.S. rights to three additional collaboration programs (BCMA-CD3, PD1-LAG3, and PD1-TIM3) to revert to us at no cost to us. EMD Serono has advanced a collaboration program, M1231, a MUC1-EGFR bispecific ADC, into a Phase 1 clinical trial in the first quarter of 2021. EMD Serono has worldwide rights to M1231 and sole discretion in the clinical development and commercialization of this product. Additionally, in September 2021, Merck extended the research term for an additional two years for one target program covering two distinct cytokine derivative molecules for the treatment of cancer, to facilitate completion of preclinical research and development activities for a second candidate molecule with a novel design and approach. In December 2021, Merck did not extend the research term for another target program of the collaboration and that program reverted to us. Our collaborators may have other marketed products and product candidates under collaboration with other companies, including some of our competitors, and their corporate objectives may not be consistent with our best interests. Our collaborators may also be unsuccessful in developing or commercializing our products. If our collaborations are unsuccessful, our business, financial condition, results of operations and prospects could be adversely affected.

In addition, any dispute or litigation proceedings we may have with our collaborators in the future could delay development programs, create uncertainty as to ownership of intellectual property rights, distract management from other business activities and generate substantial expense. For example, in February 2022, Tasly indicated to us that it would like to discuss and renegotiate the terms of the Tasly License Agreement. We are uncertain whether Tasly intends to fulfill its obligations under the terms of the Tasly License Agreement, including timely delivery of the \$40.0 million upfront payment. If Tasly does not fulfill its obligations under the Tasly License Agreement, or terminates the Tasly License Agreement, we may fail to recognize the expected future revenue and may be unable to collaborate to develop STRO-002 in Greater China on similar terms, or at all.

Moreover, to the extent that any of our existing or future collaborators were to terminate a collaboration agreement, we may be forced to independently develop these product candidates, including funding preclinical studies or clinical trials, assuming marketing and distribution costs and defending intellectual property rights, or, in certain instances, abandon product candidates altogether, any of which could result in a change to our business plan and have a material adverse effect on our business, financial condition, results of operations and prospects.

***We may not successfully engage in strategic transactions, including any additional collaborations we seek, which could adversely affect our ability to develop and commercialize product candidates, impact our cash position, increase our expenses and present significant distractions to our management.***

From time to time, we may consider strategic transactions, such as additional collaborations, acquisitions of companies, asset purchases and out- or in-licensing of product candidates or technologies that we believe will complement or augment our existing business. In particular, we will evaluate and, if strategically attractive, seek to enter into additional collaborations, including with major biotechnology or biopharmaceutical companies. The competition for collaborators is intense, and the negotiation process is time-consuming and complex. Any new collaboration may be on terms that are not optimal for us, and we may not be able to maintain any new collaboration if, for example, development or approval of a product candidate is delayed, sales of an approved product candidate do not meet expectations, or the collaborator terminates the collaboration. In addition, there have been a significant number of recent business combinations among large pharmaceutical companies that have resulted in a reduced number of potential future strategic partners. Our ability to reach a definitive agreement for a collaboration will depend, among other things, upon our assessment of the strategic partner's resources and expertise, the terms and conditions of the proposed collaboration and the proposed strategic partner's evaluation of a number of factors. These factors may include the design or results of clinical trials, the likelihood of approval by the FDA or similar regulatory authorities outside the United States, the potential market for the subject product candidate, the costs and complexities of manufacturing and delivering such product candidate to patients, the potential of competing products, the existence of uncertainty with respect to our ownership of technology, which can exist if there is a challenge to such ownership, without regard to the merits of the challenge, and industry and market conditions generally. Moreover, if we acquire assets with promising markets or technologies, we may not be able to realize the benefit of acquiring such assets due to an inability to successfully integrate them with our existing technologies and may encounter numerous difficulties in developing, manufacturing and marketing any new products resulting from a strategic acquisition that delay or prevent us from realizing their expected benefits or enhancing our business.

We cannot assure you that following any such collaboration, or other strategic transaction, we will achieve the expected synergies to justify the transaction. For example, such transactions may require us to incur non-recurring or other charges, increase our near- and long-term expenditures and pose significant integration or implementation challenges or disrupt our management or business. These transactions would entail numerous operational and financial risks, including exposure to unknown liabilities, disruption of our business and diversion of our management's time and attention in order to manage a collaboration or develop acquired products, product candidates or technologies, incurrence of substantial debt or dilutive issuances of equity securities to pay transaction consideration or costs, higher than expected collaboration, acquisition or integration costs, write-downs of assets or goodwill or impairment charges, increased amortization expenses, difficulty and cost in facilitating the collaboration or combining the operations and personnel of any acquired business, impairment of relationships with key suppliers, manufacturers or customers of any acquired business due to changes in management and ownership and the inability to retain key employees of any acquired business. Also, such strategic alliance, joint venture or acquisition may be prohibited. For example, our Loan and Security Agreement, in the absence of the related lenders' prior written consent, restricts our ability to pursue certain mergers, acquisitions, amalgamations or consolidations that we may believe to be in our best interest.

Accordingly, although there can be no assurance that we will undertake or successfully complete any transactions of the nature described above, any transactions that we do complete may be subject to the foregoing or other risks and would have a material and adverse effect on our business, financial condition, results of operations and prospects. Conversely, any failure to enter any additional collaboration or other strategic transaction that would be beneficial to us could delay the development and potential commercialization of our product candidates and have a negative impact on the competitiveness of any product candidate that reaches market.



***We expect to rely on third parties to conduct certain of our preclinical studies or clinical trials. If those third parties do not perform as contractually required, fail to satisfy regulatory or legal requirements or miss expected deadlines, our development program could be delayed with potentially material and adverse effects on our business, financial condition, results of operations and prospects.***

We have relied in some cases and intend to rely in the future on third-party clinical investigators, clinical research organizations, or CROs, clinical data management organizations and consultants to assist or provide the design, conduct, supervision and monitoring of preclinical studies and clinical trials of our product candidates. Because we intend to rely on these third parties and will not have the ability to conduct all preclinical studies or clinical trials independently, we will have less control over the timing, quality and other aspects of preclinical studies and clinical trials than we would have had we conducted them on our own. These investigators, CROs and consultants will not be our employees and we will have limited control over the amount of time and resources that they dedicate to our programs. These third parties may have contractual relationships with other entities, some of which may be our competitors, which may draw time and resources from our programs. The third parties with which we may contract might not be diligent, careful or timely in conducting our preclinical studies or clinical trials, resulting in the preclinical studies or clinical trials being delayed or unsuccessful.

If we cannot contract with acceptable third parties on commercially reasonable terms, or at all, or if these third parties do not carry out their contractual duties, satisfy legal and regulatory requirements for the conduct of preclinical studies or clinical trials or meet expected deadlines, our clinical development programs could be delayed and otherwise adversely affected. In all events, we will be responsible for ensuring that each of our preclinical studies and clinical trials are conducted in accordance with the general investigational plan and protocols for the trial. The FDA requires preclinical studies to be conducted in accordance with good laboratory practices and clinical trials to be conducted in accordance with good clinical practices, including for designing, conducting, recording and reporting the results of preclinical studies and clinical trials to assure that data and reported results are credible and accurate and that the rights, integrity and confidentiality of clinical trial participants are protected. Our reliance on third parties that we do not control will not relieve us of these responsibilities and requirements. Any adverse development or delay in our preclinical studies or clinical trials as a result of our reliance on third parties could have a material and adverse effect on our business, financial condition, results of operations and prospects.

***If we are unable to obtain sufficient raw and intermediate materials on a timely basis or if we experience other manufacturing or supply difficulties, our business may be adversely affected.***

The manufacture of certain of our product candidates requires the timely delivery of sufficient amounts of raw and intermediate materials. We work closely with our suppliers to ensure the continuity of supply, but cannot guarantee these efforts will always be successful. Further, while efforts are made to diversify our sources of raw and intermediate materials, in certain instances we acquire raw and intermediate materials from a sole supplier. While we believe that alternative sources of supply exist where we rely on sole supplier relationships, there can be no assurance that we will be able to quickly establish additional or replacement sources for some materials. A reduction or interruption in supply, and an inability to develop alternative sources for such supply, could adversely affect our ability to manufacture our product candidates in a timely or cost-effective manner.

***We currently manufacture a portion of our product candidates internally and also rely on third-party manufacturing and supply partners to supply components of our product candidates. Our inability to manufacture sufficient quantities of our product candidates, or the loss of our third-party suppliers, or our or their failure to comply with applicable regulatory requirements or to supply sufficient quantities at acceptable quality levels or prices, or at all, would materially and adversely affect our business.***

Manufacturing is a vital component of our business strategy. To ensure timely and consistent product supply we currently use a hybrid product supply approach wherein certain elements of our product candidates are manufactured internally at our manufacturing facilities in San Carlos, California, and other elements are manufactured at qualified third-party CMOs. Since our own manufacturing facilities may be limited or unable to manufacture certain of our preclinical and clinical trial product materials and supplies, we rely on third-party contract manufacturers to manufacture such clinical trial product materials and supplies for our or our collaborator's needs. For example, we have entered into a manufacturing agreement with EMD Millipore Corporation to provide manufacturing services for certain linker-warhead materials used in our STRO-001 product candidate and to perform conjugation of the linker-warhead with the antibody component of our STRO-001 and

STRO-002 product candidates. There can be no assurance that our preclinical and clinical development product supplies will not be limited, interrupted, or of satisfactory quality or continue to be available at acceptable prices. In particular, any replacement of our manufacturer could require significant effort and expertise because there may be a limited number of qualified replacements. In addition, replacement of a manufacturer may require a technology transfer to the new manufacturer, which involves technical risk that the transfer may not succeed or may be delayed, and which can incur significant costs.

The manufacturing process for a product candidate is subject to FDA and foreign regulatory authority review. We, and our suppliers and manufacturers, must meet applicable manufacturing requirements and undergo rigorous facility and process validation tests required by regulatory authorities in order to comply with regulatory standards, such as cGMPs. If we or our contract manufacturers cannot successfully manufacture material that conforms to our specifications and the strict regulatory requirements of the FDA or comparable foreign regulatory authorities, we may not be able to rely on our or their manufacturing facilities for the manufacture of elements of our product candidates. Moreover, we do not control the manufacturing process at our contract manufacturers and are completely dependent on them for compliance with current regulatory requirements. In the event that any of our manufacturers fails to comply with such requirements or to perform its obligations in relation to quality, timing or otherwise, or if our supply of components or other materials becomes limited or interrupted for other reasons, we may be forced to manufacture the materials ourselves or enter into an agreement with another third party, which we may not be able to do on reasonable terms, if at all. In some cases, the technical skills or technology required to manufacture our product candidates may be unique or proprietary to the original manufacturer and we may have difficulty applying such skills or technology ourselves, or in transferring such to another third party. These factors would increase our reliance on such manufacturer or require us to obtain a license from such manufacturer in order to enable us, or to have another third party, manufacture our product candidates. If we are required to change manufacturers for any reason, we will be required to verify that the new manufacturer maintains facilities and procedures that comply with quality standards and with all applicable regulations and guidelines; and we may be required to repeat some of the development program. The delays associated with the verification of a new manufacturer could negatively affect our ability to develop product candidates in a timely manner or within budget.

We expect to continue to rely on third-party manufacturers if we receive regulatory approval for any product candidate. To the extent that we have existing, or enter into future, manufacturing arrangements with third parties, we will depend on these third parties to perform their obligations in a timely manner consistent with contractual and regulatory requirements, including those related to quality control and assurance. If we are unable to obtain or maintain third-party manufacturing for product candidates, or to do so on commercially reasonable terms, we may not be able to develop and commercialize our product candidates successfully. Our or a third party's failure to execute on our manufacturing requirements and comply with cGMPs could adversely affect our business in a number of ways, including:

- an inability to initiate or continue clinical trials of product candidates under development;
- delay in submitting regulatory applications, or receiving regulatory approvals, for product candidates;
- loss of the cooperation of an existing or future collaborator;
- subjecting third-party manufacturing facilities or our manufacturing facilities to additional inspections by regulatory authorities;
- requirements to cease distribution or to recall batches of our product candidates; and
- in the event of approval to market and commercialize a product candidate, an inability to meet commercial demands for our products.

Additionally, we and our contract manufacturers may experience manufacturing difficulties due to resource constraints or as a result of labor disputes, unstable political environments, or epidemics, pandemics, or contagious diseases, such as the COVID-19 pandemic, or failures or delays in our manufacturing supply chain. If we or our contract manufacturers were to encounter interruptions from any of these events or other unforeseen events, our ability to provide our product candidates to patients in clinical trials, or to provide product for treatment of patients once approved, would be jeopardized.

***We, or third-party manufacturers, may be unable to successfully scale-up manufacturing of our product candidates in sufficient quality and quantity, which would delay or prevent us from developing our product candidates and commercializing approved products, if any.***

In order to conduct clinical trials of our product candidates, we will need to manufacture them in large quantities. We, or any manufacturing partners, may be unable to successfully increase the manufacturing capacity for any of our product candidates in a timely or cost-effective manner, or at all. In addition, quality issues may arise during scale-up activities. If we, or any manufacturing partners, are unable to successfully scale up the manufacture of our product candidates in sufficient quality and quantity, the development, testing, and clinical trials of that product candidate may be delayed or infeasible, and regulatory approval or commercial launch of any resulting product may be delayed or not obtained, which could significantly harm our business.

Scaling up a biologic manufacturing process is a difficult and uncertain task, and we may not be successful in transferring our production system or our third-party manufacturers may not have the necessary capabilities to complete the implementation and development process. If we are unable to adequately validate or scale-up the manufacturing process at our own manufacturing facilities or those of our current manufacturers, we will need to transfer to another manufacturer and complete the manufacturing validation process, which can be lengthy. If we are able to adequately validate and scale-up the manufacturing process for our product candidates at our manufacturing facility or with a contract manufacturer, we will still need to negotiate with such contract manufacturer an agreement for commercial supply and it is not certain we will be able to come to agreement on terms acceptable to us.

***The manufacture of biologics is complex and we or our third-party manufacturers may encounter difficulties in production. If we or any of our third-party manufacturers encounter such difficulties, our ability to provide supply of our product candidates for clinical trials, our ability to obtain marketing approval, or our ability to provide supply of our products for patients, if approved, could be delayed or stopped.***

Our product candidates are considered to be biologics and the process of manufacturing biologics is complex, time-consuming, highly regulated and subject to multiple risks. We and our contract manufacturers must comply with cGMPs, regulations and guidelines for the manufacturing of biologics used in clinical trials and, if approved, marketed products. To date, we and our contract manufacturers have limited experience in the manufacturing of cGMP batches of our product candidates.

Manufacturing biologics is highly susceptible to product loss due to contamination, equipment failure, improper installation or operation of equipment, vendor or operator error, inconsistency in yields, variability in product characteristics and difficulties in scaling the production process. Even minor deviations from normal manufacturing processes could result in reduced production yields, product defects and other supply disruptions. If microbial, viral or other contaminations are discovered at our manufacturing facilities or those of our third-party manufacturers, such facilities may need to be closed for an extended period of time to investigate and remedy the contamination, which could delay clinical trials and adversely harm our business. Moreover, if the FDA determines that our manufacturing facilities or those of our third-party manufacturers are not in compliance with FDA laws and regulations, including those governing cGMPs, the FDA may deny BLA approval until the deficiencies are corrected or we replace the manufacturer in our BLA with a manufacturer that is in compliance.

In addition, there are risks associated with large scale manufacturing for clinical trials or commercial scale including, among others, cost overruns, potential problems with process scale-up, process reproducibility, stability issues, compliance with cGMPs, lot consistency, timely availability of raw materials and other technical challenges. Even if we or our collaborators obtain regulatory approval for any of our product candidates, there is no assurance that manufacturers will be able to manufacture the approved product to specifications acceptable to the FDA or other regulatory authorities, to produce it in sufficient quantities to meet the requirements for the potential launch of the product or to meet potential future demand. If our manufacturers are unable to produce sufficient quantities for clinical trials or for commercialization, commercialization efforts would be impaired, which would have an adverse effect on our business, financial condition, results of operations and prospects.

We cannot assure you that any stability or other issues relating to the manufacture of any of our product candidates or products will not occur in the future. If we or our third-party manufacturers were to encounter any of these difficulties, our ability to provide any product candidates to patients in planned clinical trials and products to patients, once approved, would be jeopardized. Any delay or interruption in the supply of clinical trial supplies could delay the completion of planned clinical trials, increase the costs associated with maintaining clinical trial programs and, depending upon the period of delay, require us to commence new clinical trials at additional expense or terminate clinical trials completely. Any adverse developments affecting clinical or commercial manufacturing of our product candidates or products, such as epidemics, pandemics or contagious diseases, may result in shipment delays, inventory shortages, lot failures, product withdrawals or recalls, or other interruptions in the supply of our product candidates or products. We may also have to take inventory write-offs and incur other charges and expenses for product candidates or products that fail to meet specifications, undertake costly remediation efforts or seek more costly manufacturing alternatives. Accordingly, failures or difficulties faced at any level of our supply chain could adversely affect our business and delay or impede the development and commercialization of any of our product candidates or products, if approved, and could have an adverse effect on our business, financial condition, results of operations and prospects.

As part of our process development efforts, we also may make changes to our manufacturing processes at various points during development, for various reasons, such as controlling costs, achieving scale, decreasing processing time, increasing manufacturing success rate or other reasons. Such changes carry the risk that they will not achieve their intended objectives, and any of these changes could cause our product candidates to perform differently and affect the results of our ongoing clinical trials or future clinical trials. In some circumstances, changes in the manufacturing process may require us to perform *ex vivo* comparability studies and to collect additional data from patients prior to undertaking more advanced clinical trials. For instance, changes in our process during the course of clinical development may require us to show the comparability of the product used in earlier clinical phases or at earlier portions of a trial to the product used in later clinical phases or later portions of the trial.

***We may not be successful in our efforts to use our XpressCF® and XpressCF+®™ platforms to expand our pipeline of product candidates and develop marketable products.***

The success of our business depends in large part upon our ability to identify, develop and commercialize products based on our XpressCF® and XpressCF+®™ platforms. STRO-001 and STRO-002 are our most advanced clinical stage programs and our preclinical and research programs may fail to identify other potential product candidates for clinical development for a number of reasons. Our research methodology may be unsuccessful in identifying potential product candidates or our potential product candidates may be shown to have harmful side effects or may have other characteristics that may make the products unmarketable or unlikely to receive marketing approval. If any of these events occur, we may be forced to abandon our development efforts for a program or for multiple programs, which would materially harm our business and could potentially cause us to cease operations. Research programs to identify new product candidates require substantial technical, financial and human resources. We may focus our efforts and resources on potential programs or product candidates that ultimately prove to be unsuccessful.

***We may expend our limited resources to pursue a particular product candidate and fail to capitalize on product candidates that may be more profitable or for which there is a greater likelihood of success.***

Because we have limited financial and managerial resources, we focus our research and development efforts on certain selected product candidates. As a result, we may forgo or delay pursuit of opportunities with other product candidates that later prove to have greater commercial potential. Our resource allocation decisions may cause us to fail to capitalize on viable commercial products or profitable market opportunities. Our spending on current and future research and development programs and product candidates for specific indications may not yield any commercially viable product candidates. If we do not accurately evaluate the commercial potential or target market for a particular product candidate, we may relinquish valuable rights to that product candidate through collaboration, licensing or other royalty arrangements in cases in which it would have been more advantageous for us to retain sole development and commercialization rights to such product candidate.

**Failure to successfully validate, develop and obtain regulatory approval for companion diagnostics for our product candidates could harm our drug development strategy and operational results.**

If companion diagnostics are developed in conjunction with clinical programs, the FDA may require regulatory approval of a companion diagnostic as a condition to approval of the product candidate. For example, if we use a diagnostic test to determine which patients are most likely to benefit from STRO-001 for the treatment of multiple myeloma and NHL by designing our pivotal trial or trials of STRO-001 in that indication to require that clinical trial patients have elevated CD74 expression as a criterion for enrollment, then we will likely be required to obtain FDA approval or clearance of a companion diagnostic, concurrent with approval of STRO-001, to test for elevated CD74 expression; we may also be required to demonstrate to the FDA the predictive utility of the companion diagnostic—namely, that the diagnostic selects for patients in whom the biologic therapy will be effective or more effective compared to patients not selected for by the diagnostic. Similarly, as we are developing STRO-002 for a potential indication in patients with elevated FolR $\alpha$  expression levels, we are likely to be required to obtain FDA approval or clearance of a companion diagnostic, concurrent with approval of STRO-002, to test for elevated FolR $\alpha$  expression. We do not have experience or capabilities in developing or commercializing diagnostics and plan to rely in large part on third parties to perform these functions. We have entered into an agreement to develop diagnostic assays suitable for use as a companion diagnostic for STRO-002. Companion diagnostics are subject to regulation by the FDA and foreign regulatory authorities as medical devices and require separate regulatory approval or clearance prior to commercialization. In addition, our partner BMS may be required to develop and obtain regulatory clearance for a companion diagnostic to assess BCMA expression in patients in connection with their development of CC-99712. Similarly, our partner EMD Serono may be required to develop and obtain regulatory clearance for companion diagnostics to assess MUC1 and EGFR expression in patients in connection with their development of M1231.

If we or our collaborators, or any third party, are unable to successfully develop companion diagnostics for our product candidates, or experience delays in doing so:

- the development of our product candidates may be adversely affected if we are unable to appropriately select patients for enrollment in our planned clinical trials;
- our product candidates may not receive marketing approval if their safe and effective use depends on a companion diagnostic; and
- we may not realize the full commercial potential of any product candidates that receive marketing approval if, among other reasons, we are unable to appropriately identify patients with the specific genetic alterations targeted by our product candidates.

In addition, although we believe genetic testing is becoming more prevalent in the diagnosis and treatment of various diseases and conditions, our product candidates may be perceived negatively compared to alternative treatments that do not require the use of companion diagnostics, either due to the additional cost of the companion diagnostic or the need to complete additional procedures to identify genetic markers prior to administering our product candidates. If any of these events were to occur, our business would be harmed, possibly materially.

***We face competition from entities that have developed or may develop product candidates for cancer, including companies developing novel treatments and technology platforms. If these companies develop technologies or product candidates more rapidly than we do or their technologies are more effective, our ability to develop and successfully commercialize product candidates may be adversely affected.***

The development and commercialization of drugs and therapeutic biologics is highly competitive. Our product candidates, if approved, will face significant competition and our failure to effectively compete may prevent us from achieving significant market penetration. Most of our competitors have significantly greater resources than we do and we may not be able to successfully compete. We compete with a variety of multinational biopharmaceutical companies, specialized biotechnology companies and emerging biotechnology companies, as well as with technologies and product candidates being developed at universities and other research institutions. Our competitors have developed, are developing or will develop product candidates and processes competitive with our product candidates and processes. Competitive therapeutic treatments include those that have already been approved and accepted by the medical community and any new treatments, including those based on novel

technology platforms, that enter the market. We believe that a significant number of products are currently under development, and may become commercially available in the future, for the treatment of conditions for which we are trying, or may try, to develop product candidates. There is intense and rapidly evolving competition in the biotechnology, biopharmaceutical and antibody and immunoregulatory therapeutics fields. While we believe that our XpressCF® platform, associated intellectual property and our scientific and technical know-how give us a competitive advantage in this space, competition from many sources exists or may arise in the future. Our competitors include larger and better funded biopharmaceutical, biotechnological and therapeutics companies, including companies focused on cancer immunotherapies, such as AstraZeneca PLC, BMS, GlaxoSmithKline PLC, Merck, Novartis AG, Pfizer Inc., or Pfizer, Roche Holding Ltd, Sanofi S.A., and companies focused on ADCs, such as Pfizer, GlaxoSmithKline PLC, Daiichi Sankyo Company, Limited, ImmunoGen, Inc., Seagen, Inc., Genentech, Inc., or Genentech, Gilead Sciences Inc., Mersana Therapeutics, Inc., and ADC Therapeutics SA, as well as numerous small companies. Moreover, we also compete with current and future therapeutics developed at universities and other research institutions.

We are aware of several companies that are developing ADCs, cytokine derivatives, bispecific antibodies and cancer immunotherapies. Many of these companies are well-capitalized and, in contrast to us, have significant clinical experience, and may include our existing or future collaborators. In addition, these companies compete with us in recruiting scientific and managerial talent.

Our success will depend partially on our ability to develop and protect therapeutics that are safer and more effective than competing products. Our commercial opportunity and success will be reduced or eliminated if competing products are safer, more effective, or less expensive than the therapeutics we develop.

If our most advanced product candidates are approved, they will compete with a range of therapeutic treatments that are either in development or currently marketed. Currently marketed oncology drugs and therapeutics range from monoclonal antibodies, such as Genentech's Herceptin; to ADCs, such as Genentech's Kadcyla; to immune checkpoint inhibitors, such as BMS's Opdivo; to T cell-engager immunotherapies, such as Amgen, Inc.'s Blincyto; and to CAR-T cell therapies, such as Gilead's Yescarta. In addition, numerous compounds are in clinical development for cancer treatment. With respect to B cell-based malignancies, such as multiple myeloma, the most common treatments are chemotherapeutic compounds, radiation therapy, stem cell transplantation, corticosteroids, immunomodulating agents, and targeted therapy. The clinical development pipeline for cancer includes small molecules, antibodies, vaccines, cell therapies and immunotherapies from a variety of companies and institutions.

Many of our competitors, either alone or with strategic partners, have significantly greater financial, technical, manufacturing, marketing, sales, supply, and human resources or experience than we have. If we successfully obtain approval for any product candidate, we will face competition based on many different factors, including the safety and effectiveness of our products, the ease with which our products can be administered and the extent to which patients accept relatively new routes of administration, the timing and scope of regulatory approvals for these products, the availability and cost of manufacturing, marketing and sales capabilities, price, reimbursement coverage and patent position. Competing products could present superior treatment alternatives, including by being more effective, safer, less expensive, or marketed and sold more effectively than any products we may develop. Competitive products may make any products we develop obsolete or noncompetitive before we recover the expense of developing and commercializing our product candidates. Such competitors could also recruit our employees, which could negatively impact our level of expertise and our ability to execute our business plan.

***Any inability to attract and retain qualified key management and technical personnel would impair our ability to implement our business plan.***

We are highly dependent on the research and development, clinical development, manufacturing, and business development expertise of our management team, advisors and other specialized personnel. The loss of one or more members of our management team or other key employees or advisors could delay our research and development programs and have a material and adverse effect on our business, financial condition, results of operations and prospects. The relationships that our key managers have cultivated within our industry make us particularly dependent upon their continued employment with us. We are dependent on the continued service of our technical personnel because of the highly technical nature of our product candidates and XpressCF® platform technologies and the specialized nature of the regulatory approval process. Because our management team and key employees are not obligated to provide us with continued service, they could terminate their employment with us at any time without penalty. Our future success will depend in large part on our continued ability to attract and retain other highly qualified scientific, technical and management personnel, as well as personnel with expertise in clinical testing, manufacturing, governmental regulation and commercialization. We face competition for personnel from other companies, universities, public and private research institutions, government entities and other organizations. If we are unable to continue to attract and retain high-quality personnel, the rate and success at which we can discover and develop product candidates will be limited, which could have a material and adverse effect on our business, financial condition, results of operations and prospects.

***We will need to grow our organization, and we may experience difficulties in managing our growth and expanding our operations.***

As of December 31, 2021, we had 224 full-time employees. As our development and commercialization plans and strategies develop, we expect to expand our employee base for managerial, operational, financial and other resources. In addition, we have limited experience in product development and began our first clinical trials for our first two product candidates in 2018 and 2019. As our product candidates enter and advance through preclinical studies and clinical trials, we will need to expand our development, regulatory and manufacturing capabilities or contract with other organizations to provide these capabilities for us. In the future, we expect to have to manage additional relationships with collaborators or partners, suppliers and other organizations. Our ability to manage our operations and future growth will require us to continue to improve our operational, financial and management controls, reporting systems and procedures. We may not be able to implement improvements to our management information and control systems in an efficient or timely manner and may discover deficiencies in existing systems and controls. Our inability to successfully manage our growth and expand our operations could have a material and adverse effect on our business, financial condition, results of operations and prospects.

***If any of our product candidates are approved for marketing and commercialization and we are unable to develop sales, marketing and distribution capabilities on our own or enter into agreements with third parties to perform these functions on acceptable terms, we will be unable to commercialize successfully any such future products.***

We currently have limited sales, marketing and distribution capabilities or experience. If any of our product candidates are approved, we will need to develop internal sales, marketing and distribution capabilities to commercialize such products, which would be expensive and time consuming, or enter into collaborations with third parties to perform these services. If we decide to market our products directly, we will need to commit significant financial and managerial resources to develop a marketing and sales force with technical expertise and supporting distribution, administration and compliance capabilities. If we rely on third parties with such capabilities to market our products or decide to co-promote products with collaborators, we will need to establish and maintain marketing and distribution arrangements with third parties, and there can be no assurance that we will be able to enter into such arrangements on acceptable terms or at all. In entering into third-party marketing or distribution arrangements, any revenue we receive will depend upon the efforts of the third parties and there can be no assurance that such third parties will establish adequate sales and distribution capabilities or be successful in gaining market acceptance of any approved product. If we are not successful in commercializing any product approved in the future, either on our own or through third parties, our business, financial condition, results of operations and prospects could be materially and adversely affected.

***Our future growth may depend, in part, on our ability to operate in foreign markets, where we would be subject to additional regulatory burdens and other risks and uncertainties.***

Our future growth may depend, in part, on our ability to develop and commercialize our product candidates in foreign markets, for which we may rely on collaboration with third parties. We are not permitted to market or promote any of our product candidates before we receive regulatory approval from the applicable regulatory authority in that foreign market, and may never receive such regulatory approval for any of our product candidates. To obtain separate regulatory approval in many other countries, we must comply with numerous and varying regulatory requirements of such countries regarding safety and efficacy and governing, among other things, clinical trials and commercial sales, pricing and distribution of our product candidates, and we cannot predict success in these jurisdictions. If we fail to comply with the regulatory requirements in international markets and do not receive applicable marketing approvals, our target market will be reduced and our ability to realize the full market potential of our product candidates will be harmed and our business will be adversely affected. We may not obtain foreign regulatory approvals on a timely basis, if at all. Our failure to obtain approval of any of our product candidates by regulatory authorities in another country may significantly diminish the commercial prospects of that product candidate and our business, financial condition, results of operations and prospects could be materially and adversely affected. Moreover, even if we obtain approval of our product candidates and ultimately commercialize our product candidates in foreign markets, we would be subject to the risks and uncertainties, including the burden of complying with complex and changing foreign regulatory, tax, accounting and legal requirements and reduced protection of intellectual property rights in some foreign countries.

***Price controls imposed in foreign markets may adversely affect our future profitability.***

In some countries, particularly member states of the EU, the pricing of prescription drugs is subject to governmental control. In these countries, pricing negotiations with governmental authorities can take considerable time after receipt of marketing approval for a product. In addition, there can be considerable pressure by governments and other stakeholders on prices and reimbursement levels, including as part of cost containment measures. Political, economic and regulatory developments may further complicate pricing negotiations, and pricing negotiations may continue after reimbursement has been obtained. Reference pricing used by various EU member states and parallel distribution, or arbitrage between low-priced and high-priced member states, can further reduce prices. In some countries, we or current or future collaborators may be required to conduct a clinical trial or other studies that compare the cost-effectiveness of our therapeutic candidates to other available therapies in order to obtain or maintain reimbursement or pricing approval. Publication of discounts by third-party payors or authorities may lead to further pressure on the prices or reimbursement levels within the country of publication and other countries. If reimbursement of any product candidate approved for marketing is unavailable or limited in scope or amount, or if pricing is set at unsatisfactory levels, our business, financial condition, results of operations and prospects could be materially and adversely affected.

***Price controls imposed in the U.S. may affect our future profitability.***

Recently there has been heightened governmental scrutiny over the manner in which manufacturers set prices for their marketed products, which has resulted in recent Executive Orders, several Congressional inquiries and proposed and enacted federal and state legislation designed to, among other things, bring more transparency to product pricing, review the relationship between pricing and manufacturer patient programs, and reform government program reimbursement methodologies for drug products. Current and future presidential budget proposals and future legislation may contain further drug price control measures that could be enacted. Congress and current and future U.S. presidential administrations may continue to seek new legislative and/or administrative measures to control drug costs. At the state level, legislatures are increasingly passing legislation and implementing regulations designed to control pharmaceutical and biological product pricing, including price or patient reimbursement constraints, discounts, restrictions on certain product access and marketing cost disclosure and transparency measures, and, in some cases, designed to encourage importation from other countries and bulk purchasing. If such pricing controls are enacted and are set at unsatisfactory levels, our business, financial condition, results of operations and prospects could be materially and adversely affected.



***Our business entails a significant risk of product liability and our ability to obtain sufficient insurance coverage could have a material and adverse effect on our business, financial condition, results of operations and prospects.***

As we are conducting clinical trials of our product candidates, we may be exposed to significant product liability risks inherent in the development, testing, manufacturing and marketing of therapeutic treatments. Product liability claims could delay or prevent completion of our development programs. If we succeed in marketing products, such claims could result in an FDA investigation of the safety and effectiveness of our products, our manufacturing processes and facilities or our marketing programs and potentially a recall of our products or more serious enforcement action, limitations on the approved indications for which they may be used or suspension or withdrawal of approvals. Regardless of the merits or eventual outcome, liability claims may also result in decreased demand for our products, injury to our reputation, costs to defend the related litigation, a diversion of management's time and our resources, substantial monetary awards to trial participants or patients and a decline in our stock price. While we currently have product liability insurance that we believe is appropriate for our stage of development, we may need to obtain higher levels prior to later stages of clinical development or marketing any of our product candidates. Any insurance we have or may obtain may not provide sufficient coverage against potential liabilities. Furthermore, clinical trial and product liability insurance is becoming increasingly expensive. As a result, we may be unable to obtain sufficient insurance at a reasonable cost to protect us against losses caused by product liability claims that could have a material and adverse effect on our business, financial condition, results of operations and prospects.

***Our employees may engage in misconduct or other improper activities, including noncompliance with regulatory standards and requirements.***

As with all companies, we are exposed to the risk of employee fraud or other misconduct. Misconduct by employees could include intentional failures to comply with FDA regulations, provide accurate information to the FDA, comply with manufacturing standards we may establish, comply with federal and state healthcare fraud and abuse laws and regulations, inappropriately share confidential and proprietary information externally, report financial information or data accurately or disclose unauthorized activities to us. In particular, sales, marketing and business arrangements in the healthcare industry are subject to extensive laws and regulations intended to prevent fraud, kickbacks, self-dealing and other abusive practices. These laws and regulations may restrict or prohibit a wide range of pricing, discounting, marketing and promotion, sales commission, customer incentive programs and other business arrangements. Employee misconduct could also involve the improper use of information obtained in the course of clinical trials, which could result in regulatory sanctions and serious harm to our reputation. It is not always possible to identify and deter employee misconduct, and the precautions we take to detect and prevent this activity may not be effective in controlling unknown or unmanaged risks or losses or in protecting us from governmental investigations or other actions or lawsuits stemming from a failure to be in compliance with such laws or regulations. If any such actions are instituted against us, and we are not successful in defending ourselves or asserting our rights, those actions could have a material and adverse effect on our business, financial condition, results of operations and prospects, including the imposition of significant civil, criminal and administrative penalties, damages, fines, disgorgement, imprisonment, the curtailment or restructuring of our operations, loss of eligibility to obtain approvals from the FDA, exclusion from participation in government contracting, healthcare reimbursement or other government programs, including Medicare and Medicaid, integrity oversight and reporting obligations, or reputational harm.

Moreover, our employees are increasingly utilizing social media tools and our website as a means of communication. Despite our efforts to monitor social media communications, there is risk that the unauthorized use of social media by our employees to communicate about our products or business, or any inadvertent disclosure of material, nonpublic information through these means, may result in violations of applicable laws and regulations, which may give rise to liability and result in harm to our business. In addition, there is also risk of inappropriate disclosure of sensitive information, which could result in significant legal and financial exposure and reputational damages that could potentially have a material adverse impact on our business, financial condition, results of operations and prospects.

***We depend on our information technology systems, and any failure of these systems, or those of our CROs, third-party vendors, or other contractors or consultants we may utilize, could harm our business. Security breaches, cyber-attacks, loss of data, and other disruptions could compromise sensitive information related to our business or other personal information or prevent us from accessing critical information and expose us to liability, which could adversely affect our business, reputation, results of operations, financial condition and prospects.***

We collect and maintain information in digital form that is necessary to conduct our business, and we are increasingly dependent on information technology systems and infrastructure to operate our business. In the ordinary course of our business, we collect, store and transmit large amounts of confidential information, including intellectual property, proprietary business information health information, and personal information. It is critical that we do so in a secure manner to maintain the confidentiality and integrity of such confidential information. We have established physical, electronic and organizational measures designed to safeguard and secure our systems to prevent a data security incident (for example: data breaches, viruses or other malicious code, coordinated attacks, data loss, phishing attacks, ransomware, denial of service attacks, or other security or information technology incidents caused by threat actors, technological vulnerabilities or human error), and rely on commercially available systems, software, tools, and monitoring to provide security for our information technology systems and the processing, transmission and storage of digital information. We have also outsourced elements of our information technology infrastructure, and as a result a number of third-party vendors may or could have access to our confidential information. Our internal information technology systems and infrastructure, and those of our current and any future collaborators, CROs, third-party vendors, contractors and consultants and other third parties on which we rely, are vulnerable to damage from computer viruses, malware, natural disasters, terrorism, war, telecommunication and electrical failures, cyber-attacks or cyber-intrusions over the Internet, attachments to emails, persons inside our organization, or persons with access to systems inside our organization.

The risk of a security breach or disruption or data loss, particularly through cyber-attacks or cyber intrusion, including by computer hackers, foreign governments and cyber terrorists, has generally increased as the number, intensity and sophistication of attempted attacks and intrusions from around the world have increased. In addition, the prevalent use of mobile devices that access confidential information increases the risk of data security breaches, which could lead to the loss of confidential information or other intellectual property. The costs to us or our CROs or other contractors or consultants we may utilize to mitigate network security problems, bugs, viruses, worms, phishing attempts, malicious software programs and security vulnerabilities could be significant, and while we have implemented security measures designed to protect our data security and information technology systems, our efforts to address these problems may not be successful, and these problems could result in unexpected interruptions, delays, cessation of service and other harm to our business and our competitive position. We have incurred successful phishing attempts in the past, and although believe that these attempts were detected and neutralized without any compromise to our data and prior to any significant impact to our business and we have implemented additional measures to prevent such attacks, we may still be subject to similar attacks in the future. We are also aware of publicly disclosed security breaches at certain third-parties on which we rely, although we have not been informed of any resulting breach to our data. If such an event were to occur, whether to us or a third-party on which we rely, and cause interruptions in our operations, it could result in a material disruption of our product development programs. For example, the loss of clinical trial data from completed or ongoing or planned clinical trials could result in delays in our regulatory approval efforts and significantly increase our costs to recover or reproduce the data. Moreover, if a computer security breach affects our systems or results in the unauthorized release of personally identifiable information, our reputation could be materially damaged. In addition, such a breach may require notification to governmental agencies, the media or individuals pursuant to various federal and state privacy and security laws, if applicable, including the Health Insurance Portability and Accountability Act of 1996, or HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act of 2009, or HITECH, and its implementing rules and regulations, as well as regulations promulgated by the Federal Trade Commission and state breach notification laws. We would also be exposed to a risk of loss or litigation and potential liability under laws, regulations and contracts that protect the privacy and security of personal information. For example, the California Consumer Privacy Act of 2018, or the CCPA, imposes a private right of action for security breaches that could lead to some form of remedy including regulatory scrutiny, fines, private right of action settlements, and other consequences. Compliance with these and any other applicable privacy and data security laws and regulations is a rigorous and time-intensive process, and we may be required to put in place additional mechanisms ensuring compliance with the new data protection rules and possible government oversight. Our failure to comply with such laws or to adequately secure

the information we hold could result in significant liability or reputational harm and, in turn, a material adverse effect on our client base, member base and revenue. Further, if we are unable to generate or maintain access to essential patient samples or data for our research and development and manufacturing activities for our programs, our business could be materially adversely affected.

***Our information technology systems could face serious disruptions that could adversely affect our business.***

Our information technology and other internal infrastructure systems, including corporate firewalls, servers, leased lines and connection to the Internet, face the risk of systemic failure that could disrupt our operations. A significant disruption in the availability of our information technology and other internal infrastructure systems could cause interruptions and delays in our research and development and manufacturing work.

***The terms of our Loan and Security Agreement require us to meet certain covenants and place restrictions on our operating and financial flexibility. If we raise additional capital through debt financing, the terms of any new debt could further restrict our ability to operate our business.***

The Loan and Security Agreement is secured by a lien covering all of our assets, excluding our intellectual property. Subject to the terms of the Loan and Security Agreement, we have the option to prepay all, but not less than all, of the amounts borrowed under the Loan and Security Agreement, subject to certain penalty payments, prior to the March 1, 2024 maturity date, at which time all amounts borrowed will be due and payable.

The Loan and Security Agreement contains customary affirmative and negative covenants, indemnification provisions and events of default. The affirmative covenants include, among others, covenants requiring us to maintain our legal existence and governmental approvals, deliver certain financial reports and maintain certain intellectual property rights. The negative covenants include, among others, restrictions on transferring or licensing our assets, changing our business, incurring additional indebtedness, engaging in mergers or acquisitions, paying dividends or making other distributions, and creating other liens on our assets, in each case subject to customary exceptions. If we default under the Loan and Security Agreement, the lenders will be able to declare all obligations immediately due and payable and take control of our collateral, potentially requiring us to renegotiate our agreement on terms less favorable to us or to immediately cease operations. Further, if we are liquidated, the rights of Oxford and SVB to repayment would be senior to the rights of the holders of our common stock to receive any proceeds from the liquidation. Oxford, acting as collateral agent for the lenders, could declare a default under the Loan and Security Agreement upon the occurrence of any event that Oxford and SVB interpret as a material adverse change as defined under the Loan and Security Agreement, thereby requiring us to repay the loan immediately or to attempt to reverse the declaration of default through negotiation or litigation. Any declaration by the collateral agent of an event of default could significantly harm our business, financial condition, results of operations and prospects and could cause the price of our common stock to decline. If we raise any additional debt financing, the terms of such additional debt could further restrict our operating and financial flexibility.

***If we do not comply with laws regulating the protection of the environment and health and human safety, our business could be affected adversely.***

Our research, development and manufacturing involve the use of hazardous chemicals and materials, including radioactive materials. We maintain quantities of various flammable and toxic chemicals in our facilities in South San Francisco and San Carlos, California that are required for our research, development and manufacturing activities. We are subject to federal, state and local laws and regulations governing the use, manufacture, storage, handling and disposal of these hazardous chemicals and materials. We believe our procedures for storing, handling and disposing these materials in our South San Francisco and San Carlos facilities comply with the relevant guidelines of the two municipalities, the county of San Mateo, the state of California and the Occupational Safety and Health Administration of the U.S. Department of Labor. Although we believe that our safety procedures for handling and disposing of these materials comply with the standards mandated by applicable regulations, the risk of accidental contamination or injury from these materials cannot be eliminated. If an accident occurs, we could be held liable for resulting damages, which could be substantial. We are also subject to numerous environmental, health and workplace safety laws and regulations, including those governing laboratory procedures, exposure to blood-borne pathogens and the handling of animals and biohazardous materials. Although we maintain workers' compensation insurance to cover us for costs and

expenses we may incur due to injuries to our employees resulting from the use of these materials, this insurance may not provide adequate coverage against potential liabilities. While we maintain pollution legal liability insurance for our manufacturing facility in San Carlos, California, we do not maintain insurance for environmental liability or toxic tort claims that may be asserted against us in connection with our storage or disposal of biological or hazardous materials in our other locations. Additional federal, state and local laws and regulations affecting our operations may be adopted in the future. We may incur substantial costs to comply with, and substantial fines or penalties if we violate, any of these laws or regulations.

***Our current operations are in two cities in the San Francisco Bay Area, and we, or the third parties upon whom we depend, may be adversely affected by earthquakes or other natural disasters and our business continuity and disaster recovery plans may not adequately protect us from a serious disaster.***

Our current operations are located in our facilities in South San Francisco and San Carlos, California. Any unplanned event, such as earthquake, flood, fire, explosion, extreme weather condition, epidemic, pandemic or contagious disease, power shortage, telecommunication failure or other natural or man-made accidents or incidents that result in us being unable to fully utilize our facilities, or the manufacturing facilities of our third-party contract manufacturers, may have a material and adverse effect on our ability to operate our business, particularly on a daily basis, and have significant negative consequences on our financial and operating conditions. Loss of access to these facilities may result in increased costs, delays in the development of our product candidates or interruption of our business operations. Earthquakes, epidemics, pandemics or contagious diseases, or other natural disasters could further disrupt our operations, and have a material and adverse effect on our business, financial condition, results of operations and prospects. If a natural disaster, power outage, epidemics, pandemics or contagious disease, or other events occurred that prevented us from using all or a significant portion of our headquarters, that damaged critical infrastructure, such as our research or manufacturing facilities or the manufacturing facilities of our third-party contract manufacturers, or that otherwise disrupted operations, it may be difficult or, in certain cases, impossible, for us to continue our business for a substantial period of time. The disaster recovery and business continuity plans we have in place may prove inadequate in the event of a serious disaster or similar event. We may incur substantial expenses as a result of the limited nature of our disaster recovery and business continuity plans, which could have a material adverse effect on our business. As part of our risk management policy, we maintain insurance coverage at levels that we believe are appropriate for our business. However, in the event of an accident or incident at these facilities, we cannot assure you that the amounts of insurance will be sufficient to satisfy any damages and losses. In addition, the long-term effects of climate change on general economic conditions and the pharmaceutical industry in particular are unclear, and may heighten or intensify existing risk of natural disasters. If our facilities, or the manufacturing facilities of our third-party contract manufacturers, are unable to operate because of an accident or incident or for any other reason, even for a short period of time, any or all of our research and development programs may be harmed. Any business interruption could have a material and adverse effect on our business, financial condition, results of operations and prospects.

***Changes in tax laws or regulations that are applied adversely to us or our customers may have a material adverse effect on our business, cash flows, financial condition or results of operations.***

New income, sales, use or other tax laws, statutes, rules, regulations or ordinances could be enacted at any time, which could adversely affect our business and financial condition. Further, existing tax laws, statutes, rules, regulations or ordinances could be interpreted, changed, modified or applied adversely to us. For example, legislation enacted in 2017, informally titled the Tax Cuts and Jobs Act, or the 2017 Tax Act, enacted many significant changes to the U.S. tax laws. Future guidance from the Internal Revenue Service and other tax authorities with respect to the 2017 Tax Act may affect us, and certain aspects of the 2017 Tax Act may be repealed or modified in future legislation. For example, the Coronavirus Aid, Relief, and Economic Security Act, or the CARES Act, modified certain provisions of the 2017 Tax Act. Changes in corporate tax rates, the realization of net deferred tax assets relating to our operations, and the deductibility of expenses under the 2017 Tax Act or future reform legislation could have a material impact on the value of our deferred tax assets, could result in significant one-time charges, and could increase our future U.S. tax expense.

***Our ability to use net operating loss carryforwards to offset taxable income could be limited.***

We plan to use our current year operating losses to offset taxable income from any revenue generated from operations, including revenue from licensing and collaboration agreements and other similar transactions. To the extent that our taxable income exceeds any current year operating losses, we plan to use our net operating loss carryforwards from prior taxable years to offset income that would otherwise be taxable. Our net operating loss carryforwards generated in tax years ending on or prior to December 31, 2017, are only permitted to be carried forward for 20 years under applicable U.S. tax law. Under the 2017 Tax Act, as modified by the CARES Act, our federal net operating losses generated in tax years beginning after December 31, 2017, may be carried forward indefinitely, but the deductibility of such federal net operating losses in tax years beginning after December 31, 2020, is limited to 80% of taxable income. It is uncertain if and to what extent various states will conform to the 2017 Tax Act or the CARES Act.

In addition, under Section 382 of the U.S. Internal Revenue Code of 1986, as amended, and corresponding provisions of state law, if we experience an "ownership change" which is generally defined as a greater than 50% change, by value, in its equity ownership over a three-year period, our ability to use our pre-change net operating loss carryforwards to offset our post-change income may be limited. Based on Section 382 studies performed for certain prior periods, it is more likely than not that we experienced an ownership change on November 20, 2019, which imposed limitations on the use of our net operating losses arising before that date. In addition, we may have experienced other ownership changes in the past and may also experience ownership changes in the future as a result of equity offerings or other shifts in our stock ownership, some of which are outside our control. As a result, our use of federal NOL carryforwards could be limited. State net operating loss carryforwards may be similarly limited. In addition, at the state level, there may be periods during which the use of net operating losses is suspended or otherwise limited, which could accelerate or permanently increase state taxes owed. Any such limitations may result in greater tax liabilities than we would incur in the absence of such limitations and any increased liabilities could adversely affect our business, results of operations, financial position and cash flows.

***Our investment in Vaxcyte is subject to risk***

As of December 31, 2021, we held Vaxcyte common stock with a fair value of \$37.2 million. Vaxcyte common stock is publicly traded and therefore subject to the various risk factors associated with any publicly traded company, including risks associated with Vaxcyte's business, its business outlook, cash flow requirements and financial performance, the state of the market and the general economic climate, including the impact of the COVID-19 pandemic. Vaxcyte common stock has been subject to substantial volatility, and the change in fair value of our interests in Vaxcyte will materially impact our reported net income or net loss in our financial statements.

***Our financial results may be adversely affected by changes in accounting principles generally accepted in the United States.***

Generally accepted accounting principles in the United States, or U.S. GAAP, are subject to interpretation by the Financial Accounting Standards Board, or the FASB, the American Institute of Certified Public Accountants, the SEC and various bodies formed to promulgate and interpret appropriate accounting principles. For example, in May 2014, the FASB issued accounting standards update No. 2014-09 (Topic 606), Revenue from Contracts with Customers, which supersedes nearly all existing revenue recognition guidance under U.S. GAAP. We adopted this new accounting standard as of January 1, 2019. Any difficulties in implementing this guidance could cause us to fail to meet our financial reporting obligations, which could result in regulatory discipline and harm investors' confidence in us. Additionally, the implementation of this guidance or a change in other principles or interpretations could have a significant effect on our financial results, and could affect the reporting of transactions completed before the announcement of a change. Furthermore, we have adopted Topic 606 through the modified retrospective method. This will impact the comparability of our financial results, which might lead investors to draw incorrect conclusions that could harm investor interest in holding or purchasing our equity.

## Risks Related to Intellectual Property

***If we are not able to obtain, maintain and enforce sufficient patent and other intellectual property protection for our technologies or product candidates, development and commercialization of our product candidates may be adversely affected.***

Our success depends in part on our, our licensors's and our collaborators' ability to obtain and maintain patents and other forms of intellectual property rights, including in-licenses of intellectual property rights of others, for our product candidates, methods used to manufacture our product candidates and methods for treating patients using our product candidates, as well as our ability to preserve our trade secrets, to prevent third parties from infringing upon our proprietary rights and to operate without infringing upon the proprietary rights of others. We, our licensors and collaborators may not be able to apply for patents on certain aspects of our product candidates in a timely fashion or at all. Further, we, our licensors and collaborators may not be able to prosecute all necessary or desirable patent applications, or maintain, enforce and license any patents that may issue from such patent applications, at a reasonable cost or in a timely manner. It is also possible that we, our licensors and collaborators will fail to identify patentable aspects of our research and development output before it is too late to obtain patent protection. It is also possible that we, our licensors, and our collaborators will fail to file patent applications covering inventions made in the course of development and commercialization activities before a competitor or another third party files a patent application covering, or publishes information disclosing, a similar, independently-developed invention. Such competitor's patent application may pose obstacles to our ability to obtain or limit the scope of patent protection we may obtain. We may not have the right to control the preparation, filing and prosecution of all patent applications that we license from third parties, or to maintain the rights to patents licensed to third parties. Therefore, these patents and applications may not be prosecuted and enforced in a manner consistent with the best interests of our business. If our licensors or collaborators fail to establish, maintain or protect such patents and other intellectual property rights, such rights may be reduced or eliminated. If our licensors, licensees or collaborators are not fully cooperative or disagree with us as to the prosecution, maintenance or enforcement of any patent rights, such patent rights could be compromised. Also, although we enter into non-disclosure and confidentiality agreements with parties who have access to confidential or patentable aspects of our research and development output, such as our employees, collaborators, CROs, contract manufacturers, consultants, advisors and other third parties, any of these parties may breach the agreements and disclose such output before a patent application is filed, thereby jeopardizing our ability to seek patent protection. In addition, publications of discoveries in the scientific literature often lag behind the actual discoveries, and patent applications in the United States and other jurisdictions are typically not published until 18 months after filing, or in some cases not at all. Therefore, we cannot be certain that we, our licensors or collaborators were the first to make the inventions claimed in our patents or pending patent applications, or were the first to file for patent protection of such inventions, or if such patents rights may otherwise become invalid. Our existing issued and granted patents and any future patents we obtain may not be sufficiently broad to prevent others from using our technology or from developing competing products and technology. There is no guarantee that any of our pending patent applications will result in issued or granted patents, that any of our issued or granted patents will not later be found to be invalid or unenforceable or that any issued or granted patents will include claims that are sufficiently broad to cover our product candidates or to provide meaningful protection from our competitors. Moreover, the patent position of biotechnology and biopharmaceutical companies can be highly uncertain because it involves complex legal and factual questions. We will be able to protect our proprietary rights from unauthorized use by third parties only to the extent that our current and future proprietary technology and product candidates are covered by valid and enforceable patents or are effectively maintained as trade secrets. If third parties disclose or misappropriate our proprietary rights, it may materially and adversely affect our position in the market.

The U.S. Patent and Trademark Office, or USPTO, and various foreign governmental patent agencies require compliance with a number of procedural, documentary, fee payment and other provisions during the patent process. There are situations in which noncompliance can result in abandonment or lapse of a patent or patent application, resulting in partial or complete loss of patent rights in the relevant jurisdiction. In such an event, competitors might be able to enter the market earlier than would otherwise have been the case. The standards applied by the USPTO and foreign patent offices in granting patents are not always applied uniformly or predictably. For example, there is no uniform worldwide policy regarding patentable subject matter or the scope of claims allowable in biotechnology and biopharmaceutical patents. As such, we do not know the degree of future protection that we will have on our proprietary products and technology. While we will endeavor to try to protect our product candidates with intellectual property rights such as patents, as appropriate, the process of obtaining patents is time consuming, expensive and sometimes unpredictable.

Once granted, patents may remain open to opposition, interference, re-examination, post-grant review, *inter partes* review, nullification or derivation action in court or before patent offices or similar proceedings for a given period after allowance or grant, during which time third parties can raise objections against such initial grant. In the course of such proceedings, which may continue for a protracted period of time, the patent owner may be compelled to limit the scope of the allowed or granted claims thus attacked, or may lose the allowed or granted claims altogether. In addition, there can be no assurance that:

- others will not or may not be able to make, use or sell compounds that are the same as or similar to our product candidates but that are not covered by the claims of the patents that we own or license;
- we or our licensors, or our existing or future collaborators are the first to make the inventions covered by each of our issued patents and pending patent applications that we own or license;
- we or our licensors, or our existing or future collaborators are the first to file patent applications covering certain aspects of our inventions;
- others will not independently develop similar or alternative technologies or duplicate any of our technologies without infringing our intellectual property rights;
- a third party may not challenge our patents and, if challenged, a court would hold that our patents are valid, enforceable and infringed;
- any issued patents that we own or have licensed will provide us with any competitive advantages, or will not be challenged by third parties;
- we may develop additional proprietary technologies that are patentable;
- the patents of others will not have a material or adverse effect on our business, financial condition, results of operations and prospects; and
- our competitors do not conduct research and development activities in countries where we do not have enforceable patent rights and then use the information learned from such activities to develop competitive products for sale in our major commercial markets.

If we or our licensors or collaborators fail to maintain the patents and patent applications covering our product candidates, our competitors might be able to enter the market, which could have a material and adverse effect on our business, financial condition, results of operations and prospects.

In addition, our in-licensed patents may be subject to a reservation of rights by the licensor, its affiliates and one or more third parties. When new technologies are developed with government funding, the government generally obtains certain rights in any resulting patents, including a non-exclusive license authorizing the government to use the invention for noncommercial purposes. These rights may permit the government to disclose our confidential information to third parties or allow third parties to use our licensed technology. The government can also exercise its march-in rights if it determines that action is necessary because we fail to achieve practical application of the government-funded technology, because action is necessary to alleviate health or safety needs, to meet requirements of federal regulations, or to give preference to U.S. industry. In addition, our rights in such inventions may be subject to certain requirements to manufacture products embodying such inventions in the United States. Any of the foregoing could harm our competitive position, business, financial condition, results of operations and prospects.

***If we are unable to protect the confidentiality of our trade secrets, our business and competitive position would be harmed.***

In addition to seeking patent protection for certain aspects of our product candidates, we also consider trade secrets, including confidential and unpatented know-how important to the maintenance of our competitive position. We protect trade secrets and confidential and unpatented know-how, in part, by entering into non-disclosure and confidentiality agreements with parties who have access to such knowledge, such as our employees, corporate collaborators, outside scientific collaborators, CROs, contract manufacturers, consultants, advisors and other third parties. We also enter into confidentiality and invention or patent assignment agreements with our employees and consultants that obligate them to maintain confidentiality and assign their inventions to us. Despite these efforts, any of these parties may breach the agreements and disclose our proprietary information, including our trade secrets, and we may not be able to obtain adequate remedies for such breaches. Enforcing a claim that a party illegally disclosed or misappropriated a trade secret is difficult, expensive and time-consuming, and the outcome is unpredictable. In addition, some courts in the United States and certain foreign jurisdictions are less willing or unwilling to protect trade secrets. If any of our trade secrets were to be lawfully obtained or independently developed by a competitor, we would have no right to prevent them from using that technology or information to compete with us. If any of our trade secrets were to be disclosed to or independently developed by a competitor, our competitive position would be harmed which could have a material and adverse effect on our business, financial condition, results of operations and prospects.

***Other companies or organizations may challenge our or our licensors' patent rights or may assert patent rights that prevent us from developing and commercializing our products.***

Therapeutics in oncology or other disease areas developed in cell-free-based synthesis systems are a relatively new scientific field. We have obtained grants and issuances of, and have obtained a license from a third party on an exclusive basis to, patents related to our proprietary XpressCF® platform. The issued patents and pending patent applications in the United States and in key markets around the world that we own or license claim many different methods, compositions and processes relating to the discovery, development, manufacture and commercialization of antibody-based and other therapeutics.

As the field of antibody-based therapeutics continues to mature, patent applications are being processed by national patent offices around the world. There is uncertainty about which patents will issue and, if they do, as to when, to whom, and with what claims. In addition, third parties may attempt to invalidate our intellectual property rights. Even if our rights are not directly challenged, disputes could lead to the weakening of our intellectual property rights. Our defense against any attempt by third parties to circumvent or invalidate our intellectual property rights could be costly to us, could require significant time and attention of our management and could have a material and adverse effect on our business, financial condition, results of operations and prospects or our ability to successfully compete.



***We may not be able to protect our intellectual property rights throughout the world.***

Obtaining a valid and enforceable issued or granted patent covering our technology in the United States and worldwide can be extremely costly, and our or our licensors' or collaborators' intellectual property rights may not exist in some countries outside the United States or may be less extensive in some countries than in the United States. In jurisdictions where we or our licensors or collaborators have not obtained patent protection, competitors may seek to use our or their technology to develop their own products and further, may export otherwise infringing products to territories where we or they have patent protection, but where it is more difficult to enforce a patent as compared to the United States. Competitor products may compete with our future products in jurisdictions where we do not have issued or granted patents or where our or our licensors' or collaborators' issued or granted patent claims or other intellectual property rights are not sufficient to prevent competitor activities in these jurisdictions. The legal systems of certain countries, particularly certain developing countries, make it difficult to enforce patents and such countries may not recognize other types of intellectual property protection, particularly relating to biopharmaceuticals. This could make it difficult for us or our licensors or collaborators to prevent the infringement of our or their patents or marketing of competing products in violation of our or their proprietary rights generally in certain jurisdictions. Proceedings to enforce our patent rights in foreign jurisdictions could result in substantial cost and divert our and our licensors' or collaborators' efforts and attention from other aspects of our business, could put our and our licensors' or collaborators' patents at risk of being invalidated or interpreted narrowly and our and our licensors' or collaborators' patent applications at risk of not issuing and could provoke third parties to assert claims against us or our licensors or collaborators. We or our licensors or collaborators may not prevail in any lawsuits that we or our licensors or collaborators initiate, and the damages or other remedies awarded, if any, may not be commercially meaningful.

We generally file a provisional patent application first (a priority filing) at the USPTO. An international application under the Patent Cooperation Treaty, PCT, is usually filed within twelve months after the priority filing. Based on the PCT filing, national and regional patent applications may be filed in the United States, EU, Japan, Australia and Canada and, depending on the individual case, also in any or all of, inter alia, Brazil, China, Hong Kong, India, Israel, Mexico, New Zealand, Russia, South Africa, South Korea and other jurisdictions. We have so far not filed for patent protection in all national and regional jurisdictions where such protection may be available. In addition, we may decide to abandon national and regional patent applications before grant. Finally, the grant proceeding of each national or regional patent is an independent proceeding which may lead to situations in which applications might in some jurisdictions be refused by the relevant registration authorities, while granted by others. It is also quite common that depending on the country, various scopes of patent protection may be granted on the same product candidate or technology.

The laws of some jurisdictions do not protect intellectual property rights to the same extent as the laws in the United States, and many companies have encountered significant difficulties in protecting and defending such rights in such jurisdictions. If we or our licensors or collaborators encounter difficulties in protecting, or are otherwise precluded from effectively protecting, the intellectual property rights important for our business in such jurisdictions, the value of these rights may be diminished and we may face additional competition from others in those jurisdictions. Many countries have compulsory licensing laws under which a patent owner may be compelled to grant licenses to third parties. In addition, many countries limit the enforceability of patents against government agencies or government contractors. In these countries, the patent owner may have limited remedies, which could materially diminish the value of such patent. If we or any of our licensors or collaborators are forced to grant a license to third parties with respect to any patents relevant to our business, our competitive position in the relevant jurisdiction may be impaired and our business, financial condition, results of operations and prospects may be adversely affected.

***We, our licensors or collaborators, or any future strategic partners may need to resort to litigation to protect or enforce our patents or other proprietary rights, all of which could be costly, time consuming, delay or prevent the development and commercialization of our product candidates, or put our patents and other proprietary rights at risk.***

Competitors may infringe our patents or other intellectual property. If we were to initiate legal proceedings against a third party to enforce a patent covering one of our products or our technology, the defendant could counterclaim that our patent is invalid or unenforceable. In patent litigation in the United States, defendant counterclaims alleging invalidity or unenforceability are commonplace. Grounds for a validity challenge could be an alleged failure to meet any of several statutory requirements, for example, lack of novelty, obviousness or

non-enablement. Grounds for an unenforceability assertion could be an allegation that an individual connected with prosecution of the patent withheld relevant information from the USPTO, or made a misleading statement, during prosecution. The outcome following legal assertions of invalidity and unenforceability during patent litigation is unpredictable. With respect to the validity question, for example, we cannot be certain that there is no invalidating prior art, of which we and the patent examiner were unaware during prosecution. If a defendant were to prevail on a legal assertion of invalidity or unenforceability, we would lose at least part, and perhaps all, of the patent protection on one or more of our products or certain aspects of our platform technology. Such a loss of patent protection could have a material and adverse effect on our business, financial condition, results of operations and prospects. Interference or derivation proceedings provoked by third parties or brought by us or declared by the USPTO may be necessary to determine the priority of inventions with respect to our patents or patent applications. An unfavorable outcome could require us to cease using the related technology or to attempt to license rights to it from the prevailing party. Our business could be harmed if the prevailing party does not offer us a license on commercially reasonable terms or at all, or if a non-exclusive license is offered and our competitors gain access to the same technology. Furthermore, because of the substantial amount of discovery required in connection with intellectual property litigation, there is a risk that some of our confidential information could be compromised by disclosure during this type of litigation. There could also be public announcements of the results of hearings, motions, or other interim proceedings or developments. If securities analysts or investors perceive these results to be negative, it could have a material adverse effect on the price of our common stock. Patents and other intellectual property rights also will not protect our technology if competitors design around our protected technology without legally infringing our patents or other intellectual property rights.

***Intellectual property rights of third parties could adversely affect our ability to commercialize our product candidates, and we, our licensors or collaborators, or any future strategic partners may become subject to third party claims or litigation alleging infringement of patents or other proprietary rights or seeking to invalidate patents or other proprietary rights. We might be required to litigate or obtain licenses from third parties in order to develop or market our product candidates. Such litigation or licenses could be costly or not available on commercially reasonable terms.***

We, our licensors or collaborators, or any future strategic partners may be subject to third-party claims for infringement or misappropriation of patent or other proprietary rights. There is a substantial amount of litigation, both within and outside the United States, involving patent and other intellectual property rights in the biotechnology and pharmaceutical industries, including patent infringement lawsuits, interferences, oppositions and *inter partes* review proceedings before the USPTO, and corresponding foreign patent offices. For example, one of our European patents related to technology auxiliary to our XpressCF® platform was involved in an opposition proceeding at the European Patent Office, or EPO, and was revoked by the EPO in 2021. This will prevent us from asserting this patent against our competitors practicing otherwise infringing methods in relevant European countries where this patent has been granted. There are many issued and pending patents that might claim aspects of our product candidates and modifications that we may need to apply to our product candidates. There are also many issued patents that claim antibodies, portions of antibodies, cytokines, half-life extending polymers, linkers, cytotoxins, or other warheads that may be relevant for the products we wish to develop. Thus, it is possible that one or more organizations will hold patent rights to which we will need a license. If those organizations refuse to grant us a license to such patent rights on reasonable terms, we may be delayed or may not be able to market products or perform research and development or other activities covered by these patents which could have a material and adverse effect on our business, financial condition, results of operations and prospects. We are obligated under certain of our license and collaboration agreements to indemnify and hold harmless our licensors or collaborators for damages arising from intellectual property infringement by use. For example, we are obligated under the Stanford Agreement to indemnify and hold harmless Stanford for damages arising from intellectual property infringement by us resulting from exercise of the license from Stanford. If we, our licensors or collaborators, or any future strategic partners are found to infringe a third-party patent or other intellectual property rights, we could be required to pay damages, potentially including treble damages, if we are found to have infringed willfully. In addition, we, our licensors or collaborators, or any future strategic partners may choose to seek, or be required to seek, a license from a third party, which may not be available on acceptable terms, if at all. Even if a license can be obtained on acceptable terms, the rights may be non-exclusive, which could give our competitors access to the same technology or intellectual property rights licensed to us. If we fail to obtain a required license, we or our existing or future collaborators may be unable to effectively market product candidates based on our technology, which could limit our ability to generate revenue or achieve profitability and possibly prevent us from generating revenue sufficient to sustain our operations. In addition, we may find it necessary to pursue claims or initiate lawsuits to protect or enforce our patent or other intellectual property rights.

The cost to us in defending or initiating any litigation or other proceeding relating to patent or other proprietary rights, even if resolved in our favor, could be substantial, and litigation could divert our management's attention. Some of our competitors may be able to sustain the costs of complex patent litigation more effectively than we can because they have substantially greater resources. Uncertainties resulting from the initiation and continuation of patent litigation or other proceedings could delay our research and development efforts and limit our ability to continue our operations.

Because the antibody-based therapeutics landscape is still evolving, it is difficult to conclusively assess our freedom to operate without infringing on third-party rights. There are numerous companies that have pending patent applications and issued patents broadly covering antibodies generally, covering antibodies directed against the same targets as, or targets similar to, those we are pursuing, or covering linkers and cytotoxic warheads similar to those that we are using in our product candidates. For example, we are aware of an issued patent, expected to expire in 2023, which has claims relating to methods of treating CD74-positive multiple myeloma with an ADC targeting CD74. As another example, we are aware of another issued patent, expected to expire in 2031, that relates to strained alkyne reagents that can be used as synthetic precursors for certain of our linker-warheads. We are also aware of an issued patent expected to expire in 2028, relating to methods for targeting maytansinoids to a selected population of cells with a cell-binding agent conjugated to a maytansinoid with a non-cleavable linker. If any of these patents are valid and not yet expired when, and if, we receive marketing approval for STRO-001, we may need to seek a license to one or more of these patents, each of which may not be available on commercially reasonable terms or at all. Failure to receive a license to any of these patents, or other potentially relevant patents currently unknown to us, could delay commercialization of STRO-001. Our competitive position may suffer if patents issued to third parties or other third-party intellectual property rights cover our products or product candidates or elements thereof, or our manufacture or uses relevant to our development plans. In such cases, we may not be in a position to develop or commercialize products or product candidates until such patents expire or unless we successfully pursue litigation to nullify or invalidate the third-party intellectual property right concerned, or enter into a license agreement with the intellectual property right holder, if available on commercially reasonable terms. There may be issued patents of which we are not aware, held by third parties that, if found to be valid and enforceable, could be alleged to be infringed by our XpressCF® platform and related technologies and product candidates. There also may be pending patent applications of which we are not aware that may result in issued patents, which could be alleged to be infringed by our XpressCF® platform and related technologies and product candidates. If such an infringement claim should be brought and be successful, we may be required to pay substantial damages, including potentially treble damages and attorneys' fees for willful infringement, and we may be forced to abandon our product candidates or seek a license from any patent holders. No assurances can be given that a license will be available on commercially reasonable terms, if at all.

It is also possible that we have failed to identify relevant third-party patents or applications. For example, U.S. applications filed before November 29, 2000 and certain U.S. applications filed after that date that will not be filed outside the United States remain confidential until patents issue. Patent applications in the United States and elsewhere are published approximately 18 months after the earliest filing for which priority is claimed, with such earliest filing date being commonly referred to as the priority date. Therefore, patent applications covering our products or platform technology could have been filed by others without our knowledge. Additionally, pending patent applications that have been published can, subject to certain limitations, be later amended in a manner that could cover our platform technology, our products or the use of our products. Third-party intellectual property right holders may also actively bring infringement claims against us. We cannot guarantee that we will be able to successfully settle or otherwise resolve such infringement claims. If we are unable to successfully settle future claims on terms acceptable to us, we may be required to engage in or continue costly, unpredictable and time-consuming litigation and may be prevented from or experience substantial delays in marketing our products. Parties making claims against us may be able to sustain the costs of complex patent litigation more effectively than we can because they have substantially greater resources. Furthermore, because of the substantial amount of discovery required in connection with intellectual property litigation or administrative proceedings, there is a risk that some of our confidential information could be compromised by disclosure. In addition, any uncertainties resulting from the initiation and continuation of any litigation could have material adverse effect on our ability to raise additional funds or otherwise have a material adverse effect on our business, results of operations, financial condition and prospects. If we fail in any such dispute, in addition to being forced to pay damages, we may be temporarily or permanently prohibited from commercializing any of our product candidates that are held to be infringing. We might, if possible, also be forced to redesign product candidates so that we no longer infringe the third-party intellectual property rights. Any of these events, even if we were ultimately to prevail, could require us to divert substantial financial and management resources that we would otherwise be able to devote to our

business and could have a material and adverse effect on our business, financial condition, results of operations and prospects.

***Intellectual property litigation could cause us to spend substantial resources and distract our personnel from their normal responsibilities.***

Litigation or other legal proceedings relating to intellectual property claims, with or without merit, is unpredictable and generally expensive and time consuming and is likely to divert significant resources from our core business, including distracting our technical and management personnel from their normal responsibilities. Furthermore, because of the substantial amount of discovery required in connection with intellectual property litigation, there is a risk that some of our confidential information could be compromised by disclosure during this type of litigation. In addition, there could be public announcements of the results of hearings, motions or other interim proceedings or developments and if securities analysts or investors perceive these results to be negative, it could have a substantial adverse effect on the price of our common stock. Moreover, such litigation or proceedings could substantially increase our operating losses and reduce the resources available for development activities or any future sales, marketing or distribution activities.

We may not have sufficient financial or other resources to adequately conduct such litigation or proceedings. Some of our competitors may be able to sustain the costs of such litigation or proceedings more effectively than we can because of their greater financial resources and more mature and developed intellectual property portfolios. Accordingly, despite our efforts, we may not be able to prevent third parties from infringing upon or misappropriating or from successfully challenging our intellectual property rights. Uncertainties resulting from the initiation and continuation of patent litigation or other proceedings could have a material adverse effect on our ability to compete in the marketplace.

***If we fail to comply with our obligations under any license, collaboration or other agreements, we may be required to pay damages and could lose intellectual property rights that are necessary for developing and protecting our product candidates or we could lose certain rights to grant sublicenses.***

Our current licenses impose, and any future licenses we enter into are likely to impose, various development, commercialization, funding, milestone, royalty, diligence, sublicensing, insurance, patent prosecution and enforcement and/or other obligations on us. If we breach any of these obligations, or use the intellectual property licensed to us in an unauthorized manner, we may be required to pay damages and the licensor may have the right to terminate the license, which could result in us being unable to develop, manufacture and sell any future products that are covered by the licensed technology or enable a competitor to gain access to the licensed technology. Moreover, our licensors may own or control intellectual property that has not been licensed to us and, as a result, we may be subject to claims, regardless of their merit, that we are infringing or otherwise violating the licensor's rights. In addition, while we cannot determine currently the amount of the royalty obligations we would be required to pay on sales of future products, if any, the amounts may be significant. The amount of our future royalty obligations will depend on the technology and intellectual property we use in products that we successfully develop and commercialize, if any. Therefore, even if we successfully develop and commercialize products, we may be unable to achieve or maintain profitability.

Moreover, disputes may arise regarding intellectual property subject to a licensing agreement, including:

- the scope of rights granted under the license agreement and other interpretation-related issues;
- the extent to which our product candidates, technologies and processes infringe on intellectual property of the licensor that is not subject to the licensing agreement;
- the sublicensing of patent and other rights under our collaborative development relationships;
- our diligence obligations under the license agreement and what activities satisfy those diligence obligations;
- the inventorship and ownership of inventions and know-how resulting from the joint creation or use of intellectual property by our licensors and us and our partners; and

- the priority of invention of patented technology.

In addition, the agreements under which we currently license intellectual property or technology from third parties are complex, and certain provisions in such agreements may be susceptible to multiple interpretations. The resolution of any contract interpretation disagreement that may arise could narrow what we believe to be the scope of our rights to the relevant intellectual property or technology, or increase what we believe to be our financial or other obligations under the relevant agreement, either of which could have a material adverse effect on our business, financial condition, results of operations, and prospects. Moreover, if disputes over intellectual property that we have licensed prevent or impair our ability to maintain our current licensing arrangements on commercially acceptable terms, we may be unable to successfully develop and commercialize the affected product candidates, which could have a material adverse effect on our business, financial conditions, results of operations, and prospects.

***We may be subject to claims that we or our employees or consultants have wrongfully used or disclosed alleged trade secrets of our employees' or consultants' former employers or their clients. These claims may be costly to defend and if we do not successfully do so, we may be required to pay monetary damages and may lose valuable intellectual property rights or personnel.***

Many of our employees were previously employed at universities or biotechnology or biopharmaceutical companies, including our competitors or potential competitors. Although no claims against us are currently pending, we may be subject to claims that these employees or we have inadvertently or otherwise used or disclosed trade secrets or other proprietary information of their former employers. Litigation may be necessary to defend against these claims. If we fail in defending such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights or personnel. A loss of key research personnel or their work product could hamper our ability to commercialize, or prevent us from commercializing, our product candidates, which could severely harm our business. Even if we are successful in defending against these claims, litigation could result in substantial costs and be a distraction to management.

***Patent terms may be inadequate to protect our competitive position on our product candidates for an adequate amount of time.***

Patents have a limited lifespan. In the United States, if all maintenance fees are timely paid, the natural expiration of a patent is generally 20 years from its earliest U.S. non-provisional filing date. Various extensions may be available, but the life of a patent, and the protection it affords, is limited. Even if patents covering our product candidates are obtained, once the patent life has expired, we may be open to competition from competitive products, including generics or biosimilars. Given the amount of time required for the development, testing and regulatory review of new product candidates, patents protecting such candidates might expire before or shortly after such candidates are commercialized. As a result, our owned and licensed patent portfolio may not provide us with sufficient rights to exclude others from commercializing products similar or identical to ours.

Depending upon the timing, duration and conditions of any FDA marketing approval of our product candidates, one or more of our U.S. patents may be eligible for limited patent term extension under the Drug Price Competition and Patent Term Restoration Act of 1984, referred to as the Hatch-Waxman Amendments, and similar legislation in the European Union. The Hatch-Waxman Amendments permit a patent term extension of up to five years for a patent covering an approved product as compensation for effective patent term lost during product development and the FDA regulatory review process. However, we may not receive an extension if we fail to exercise due diligence during the testing phase or regulatory review process, fail to apply within applicable deadlines, fail to apply prior to expiration of relevant patents or otherwise fail to satisfy applicable requirements. Moreover, the length of the extension could be less than we request. Only one patent per approved product can be extended, the extension cannot extend the total patent term beyond 14 years from approval and only those claims covering the approved drug, a method for using it or a method for manufacturing it may be extended. If we are unable to obtain patent term extension or the term of any such extension is less than we request, the period during which we can enforce our patent rights for the applicable product candidate will be shortened and our competitors may obtain approval to market competing products sooner. As a result, our revenue from applicable products could be reduced. Further, if this occurs, our competitors may take advantage of our investment in development and trials by referencing our clinical and preclinical data and launch their product earlier than might otherwise be the case, and our competitive position, business, financial condition, results of operations and prospects could be materially harmed.

***Obtaining and maintaining our patent protection depends on compliance with various procedural, document submission, fee payment and other requirements imposed by governmental patent agencies, and our patent protection could be reduced or eliminated for non-compliance with these requirements.***

Periodic maintenance fees, renewal fees, annuity fees and various other governmental fees on patents and/or applications will be due to be paid to the USPTO and various governmental patent agencies outside of the United States in several stages over the lifetime of the patents and/or applications. We have systems in place to remind us to pay these fees, and we employ an outside firm and/or rely on our outside counsel to pay these fees due to non-U.S. patent agencies. The USPTO and various non-U.S. governmental patent agencies require compliance with a number of procedural, documentary, fee payment and other similar provisions during the patent application process. We employ reputable law firms and other professionals to help us comply, and in many cases, an inadvertent lapse can be cured by payment of a late fee or by other means in accordance with the applicable rules. However, there are situations in which non-compliance can result in abandonment or lapse of the patent or patent application, resulting in partial or complete loss of patent rights in the relevant jurisdiction. In such an event, our competitors might be able to enter the market and this circumstance would have a material adverse effect on our business.

***Changes in U.S. patent and ex-U.S. patent laws could diminish the value of patents in general, thereby impairing our ability to protect our products.***

Changes in either the patent laws or interpretation of the patent laws in the United States or in other ex-U.S. jurisdictions could increase the uncertainties and costs surrounding the prosecution of patent applications and the enforcement or defense of issued patents. In the United States, numerous recent changes to the patent laws and proposed changes to the rules of the USPTO that may have a significant impact on our ability to protect our technology and enforce our intellectual property rights. For example, the America Invents Act, enacted within the last several years involves significant changes in patent legislation. The U.S. Supreme Court has ruled on several patent cases in recent years, some of which cases either narrow the scope of patent protection available in certain circumstances or weaken the rights of patent owners in certain situations. For example, the decision by the U.S. Supreme Court in *Association for Molecular Pathology v. Myriad Genetics, Inc.* precludes a claim to a nucleic acid having a stated nucleotide sequence that is identical to a sequence found in nature and unmodified. We currently are not aware of an immediate impact of this decision on our patents or patent applications because we are developing product candidates that contain modifications that we believe are not found in nature. However, this decision has yet to be clearly interpreted by courts and by the USPTO. We cannot assure you that the interpretations of this decision or subsequent rulings will not adversely impact our patents or patent applications. In addition to increasing uncertainty with regard to our ability to obtain patents in the future, this combination of events has created uncertainty with respect to the value of patents, once obtained. Depending on decisions by the U.S. Congress, the federal courts and the USPTO, and similar legislative and regulatory bodies in other countries in which we may pursue patent protection, the laws and regulations governing patents could change in unpredictable ways that would weaken our ability to obtain new patents or to enforce our existing patents and patents that we might obtain in the future.

***If our trademarks and trade names are not adequately protected, then we may not be able to build name recognition in our markets of interest and our business may be adversely affected.***

Our trademarks or trade names may be challenged, infringed, circumvented or declared generic or determined to be infringing on other marks. We may not be able to protect our rights to these trademarks and trade names or may be forced to stop using these names, which we need for name recognition by potential partners or customers in our markets of interest. If we are unable to establish name recognition based on our trademarks and trade names, we may not be able to compete effectively, which could have a material and adverse effect on our business, financial condition, results of operations and prospects.

## Risks Related to Government Regulation

***Clinical development involves a lengthy and expensive process with an uncertain outcome, and results of earlier studies and trials may not be predictive of future trial results. If we are unable to develop, obtain regulatory approval for and commercialize our product candidates, or experience significant delays in doing so, our business will be materially harmed.***

All of our product candidates are in preclinical or early clinical development and their risk of failure is high. It is impossible to predict when or if any of our product candidates will receive regulatory approval. Before obtaining marketing approval from regulatory authorities for the sale of any product candidate, we must complete preclinical studies and then conduct extensive clinical trials to demonstrate the safety and efficacy of our product candidates in humans. Clinical testing is expensive and can take many years to complete, and its outcome is inherently uncertain. Failure can occur at any time during the development process. The results of preclinical studies and early clinical trials of our product candidates may not be predictive of the results of later-stage clinical trials. Product candidates in later stages of clinical trials may fail to show the desired safety and efficacy traits, despite having progressed through preclinical studies and initial clinical trials. A number of companies in the biopharmaceutical industry have suffered significant setbacks in advanced clinical trials due to lack of efficacy or safety profiles, notwithstanding promising results in earlier trials.

We commenced a Phase 1 clinical trial of STRO-001, an ADC directed against CD74, for certain cancers in April 2018 and commenced a STRO-002 Phase 1 trial focused on ovarian and endometrial cancers in March 2019. Additionally, in the fourth quarter of 2021, we initiated a new cohort of the Phase 1 dose-expansion study of STRO-002 for endometrial cancer and a STRO-002 study in combination with bevacizumab. Commencing our future clinical trials is subject to finalizing the trial design and submitting an IND or similar submission with the FDA or similar foreign regulatory authority. Even after we submit our IND or comparable submissions in other jurisdictions, the FDA or other regulatory authorities could disagree that we have satisfied their requirements to commence our clinical trials or disagree with our study design, which may require us to complete additional preclinical studies or amend our protocols or impose stricter conditions on the commencement of clinical trials.

We or our collaborators may experience delays in completing our preclinical studies and initiating or completing clinical trials of our product candidates. We do not know whether planned preclinical studies and clinical trials will be completed on schedule or at all, or whether planned clinical trials will begin on time, need to be redesigned, have patients enrolled on time or be completed on schedule, if at all. We or our collaborators may experience numerous unforeseen events during, or as a result of, clinical trials that could delay or prevent our ability to receive marketing approval to commercialize our product candidates. Our development programs may be delayed for a variety of reasons, including delays related to:

- the FDA or other regulatory authorities requiring us or our collaborators to submit additional data or imposing other requirements before permitting us to initiate a clinical trial;
- obtaining regulatory approval to commence a clinical trial;
- the FDA or other regulatory authorities placing a clinical trial on clinical hold;
- a temporary U.S. federal government shutdown;
- reaching agreement on acceptable terms with prospective CROs and clinical trial sites, the terms of which can be subject to extensive negotiation and may vary significantly among different CROs and clinical trial sites;
- clinical trials of our product candidates producing negative or inconclusive results, and we or our collaborators deciding, or regulators requiring us, to conduct additional clinical trials, including testing in more subjects, or abandoning product development programs;
- third-party contractors used by us or our collaborators failing to comply with regulatory requirements or meeting their contractual obligations in a timely manner, or at all;
- obtaining institutional review board, or IRB, approval at each clinical trial site;

- recruiting suitable patients to participate in a clinical trial;
- developing and validating any companion diagnostic that would be used in a clinical trial;
- developing and validating an appropriate scoring algorithm to support a biomarker enrichment strategy for certain of our product candidates;
- cost of clinical trials being greater than anticipated;
- the supply or quality of our product candidates or other materials necessary to conduct clinical trials of our product candidates being insufficient or inadequate;
- having patients complete a clinical trial or return for post-treatment follow-up;
- clinical trial sites deviating from trial protocol or dropping out of a trial;
- adding new clinical trial sites;
- epidemics, pandemics or contagious diseases, such as COVID-19; or
- manufacturing sufficient quantities of our product candidates for use in clinical trials.

Patient enrollment, a significant factor in the timing of clinical trials, is affected by many factors including the size and nature of the patient population, the proximity of patients to clinical sites, the eligibility criteria for the trial, the design of the clinical trial, competing clinical trials and clinicians' and patients' perceptions as to the potential advantages of the product candidate being studied in relation to other available therapies, including any new drugs or therapeutic biologics that may be approved for the indications being investigated by us. Furthermore, we expect to rely on our collaborators, CROs and clinical trial sites to ensure the proper and timely conduct of our clinical trials and, while we expect to enter into agreements governing their committed activities, we have limited influence over their actual performance.

We could encounter delays if prescribing physicians encounter unresolved ethical issues associated with enrolling patients in clinical trials of our product candidates in lieu of prescribing existing treatments that have established safety and efficacy profiles.

Further, a clinical trial may be suspended or terminated by us, our collaborators, the IRBs of the institutions in which such trials are being conducted, the Data Safety Monitoring Board for such trial, or placed on clinical hold by the FDA or other regulatory authorities due to a number of factors, including failure to conduct the clinical trial in accordance with regulatory requirements or our clinical protocols, inspection of the clinical trial operations or trial site by the FDA or other regulatory authorities resulting in the imposition of a clinical hold, unforeseen safety issues or adverse side effects, failure to demonstrate a benefit from using a drug or therapeutic biologic, changes in governmental regulations or administrative actions or lack of adequate funding to continue the clinical trial. If we experience delays in the completion of, or termination of, any clinical trial of our product candidates, the commercial prospects of our product candidates will be harmed, and our ability to generate product revenues from any of these product candidates will be delayed. In addition, any delays in completing our clinical trials will increase our costs, slow down our product development and approval process and jeopardize our ability to commence product sales and generate revenues. Any of these occurrences could materially and adversely affect our business, financial condition, results of operations and prospects. In addition, many of the factors that cause, or lead to, a delay in the commencement or completion of clinical trials may also ultimately lead to the denial of regulatory approval of our product candidates.

***We and/or our collaborators may be unable to obtain, or may be delayed in obtaining, U.S. or foreign regulatory approval and, as a result, unable to commercialize our product candidates.***

Our product candidates are subject to extensive governmental regulations relating to, among other things, research, testing, development, manufacturing, safety, efficacy, approval, recordkeeping, reporting, labeling, storage, packaging, advertising and promotion, pricing, marketing and distribution of drugs and therapeutic biologics. Rigorous preclinical testing and clinical trials and an extensive regulatory approval process are required



to be completed successfully in the United States and in many foreign jurisdictions before a new drug or therapeutic biologic can be marketed. Satisfaction of these and other regulatory requirements is costly, time consuming, uncertain and subject to unanticipated delays. It is possible that none of the product candidates we may develop, either alone or with our collaborators, will obtain the regulatory approvals necessary for us or our existing or future collaborators to begin selling them.

Although our employees have experience in conducting and managing clinical trials from prior employment at other companies, we, as a company, have no prior experience in conducting and managing the clinical trials necessary to obtain regulatory approvals, including approval by the FDA. The time required to obtain FDA and other approvals is unpredictable but typically takes many years following the commencement of clinical trials, depending upon the type, complexity and novelty of the product candidate, and may be further delayed due to one or more temporary federal government shutdowns. The standards that the FDA and its foreign counterparts use when regulating us require judgment and can change, which makes it difficult to predict with certainty their application. Any analysis we perform of data from preclinical and clinical activities is subject to confirmation and interpretation by regulatory authorities, which could delay, limit or prevent regulatory approval. We or our collaborators may also encounter unexpected delays or increased costs due to new government regulations, for example, from future legislation or administrative action, or from changes in FDA policy during the period of product development, clinical trials and FDA regulatory review. It is impossible to predict whether legislative changes will be enacted, or whether FDA or foreign regulations, guidance or interpretations will be changed, or the impact of such changes, if any. Given that the product candidates we are developing, either alone or with our collaborators, represent a new approach to the manufacturing and type of therapeutic biologics, the FDA and its foreign counterparts have not yet established any definitive policies, practices or guidelines in relation to these product candidates. Moreover, the FDA may respond to any BLA that we may submit by defining requirements that we do not anticipate. Such responses could delay clinical development of our product candidates. In addition, because there may be approved treatments for some of the diseases for which we may seek approval, in order to receive regulatory approval, we may need to demonstrate through clinical trials that the product candidates we develop to treat these diseases, if any, are not only safe and effective, but safer or more effective than existing products. Furthermore, in recent years, there has been increased public and political pressure on the FDA with respect to the approval process for new drugs and therapeutic biologics, and FDA standards, especially regarding product safety, appear to have become more stringent.

Any delay or failure in obtaining required approvals could have a material and adverse effect on our ability to generate revenues from the particular product candidate for which we are seeking approval. Furthermore, any regulatory approval to market a product may be subject to limitations on the approved uses for which we may market the product or on the labeling or other restrictions. In addition, the FDA has the authority to require a risk evaluation and mitigation strategy, or REMS, as part of a BLA or after approval, which may impose further requirements or restrictions on the distribution or use of an approved biologic, such as limiting prescribing to certain physicians or medical centers that have undergone specialized training, limiting treatment to patients who meet certain safe-use criteria and requiring treated patients to enroll in a registry. These limitations and restrictions may limit the size of the market for the product and affect reimbursement by third-party payors.

We are also subject to numerous foreign regulatory requirements governing, among other things, the conduct of clinical trials, manufacturing and marketing authorization, pricing and third-party reimbursement. The foreign regulatory approval process varies among countries and may include all of the risks associated with FDA approval process described above, as well as risks attributable to the satisfaction of local regulations in foreign jurisdictions. Moreover, the time required to obtain approval may differ from that required to obtain FDA approval. FDA approval does not ensure approval by regulatory authorities outside the United States and vice versa. Any delay or failure to obtain U.S. or foreign regulatory approval for a product candidate could have a material and adverse effect on our business, financial condition, results of operations and prospects.

***Delays in obtaining regulatory approval of our manufacturing process may delay or disrupt our commercialization efforts. To date, no product using a cell-free manufacturing process in the United States has received approval from the FDA.***

Before we can begin to commercially manufacture our product candidates in third-party or our own facilities, we must obtain regulatory approval from the FDA for a BLA that describes in detail the chemistry, manufacturing, and controls for the product. A manufacturing authorization must also be obtained from the appropriate EU regulatory authorities. The timeframe required to obtain such approval or authorization is uncertain. In addition, we must pass a pre-approval inspection of our manufacturing facility by the FDA before any of our product candidates can obtain marketing approval, if ever. In order to obtain approval, we will need to ensure that all of our processes, methods and equipment are compliant with cGMP, and perform extensive audits of vendors, contract laboratories and suppliers. If any of our vendors, contract laboratories or suppliers is found to be out of compliance with cGMP, we may experience delays or disruptions in manufacturing while we work with these third parties to remedy the violation or while we work to identify suitable replacement vendors. The cGMP requirements govern quality control of the manufacturing process and documentation policies and procedures. In complying with cGMP, we will be obligated to expend time, money and effort in production, record keeping and quality control to assure that the product meets applicable specifications and other requirements. If we fail to comply with these requirements, we would be subject to possible regulatory action and may not be permitted to sell any products that we may develop.

***Even if we receive regulatory approval for any of our product candidates, we will be subject to ongoing regulatory obligations and continued regulatory review, which may result in significant additional expense. Additionally, our product candidates, if approved, could be subject to labeling and other restrictions and market withdrawal. We may also be subject to penalties if we fail to comply with regulatory requirements or experience unanticipated problems with our products.***

Any regulatory approvals that we or our existing or future collaborators obtain for our product candidates may also be subject to limitations on the approved indicated uses for which a product may be marketed or to the conditions of approval, or contain requirements for potentially costly post-marketing testing, including Phase 4 clinical trials, and surveillance to monitor the safety and efficacy of the product candidate.

In addition, if the FDA or a comparable foreign regulatory authority approves any of our product candidates, the manufacturing processes, labeling, packaging, distribution, adverse event reporting, storage, import, export, advertising, promotion and recordkeeping for the product will be subject to extensive and ongoing regulatory requirements. The FDA has significant post-market authority, including the authority to require labeling changes based on new safety information and to require post-market studies or clinical trials to evaluate safety risks related to the use of a product or to require withdrawal of the product from the market. The FDA also has the authority to require a REMS plan after approval, which may impose further requirements or restrictions on the distribution or use of an approved drug or therapeutic biologic. The manufacturing facilities we use to make a future product, if any, will also be subject to periodic review and inspection by the FDA and other regulatory agencies, including for continued compliance with cGMP requirements. The discovery of any new or previously unknown problems with our third-party manufacturers, manufacturing processes or facilities may result in restrictions on the product, manufacturer or facility, including withdrawal of the product from the market. If we rely on third-party manufacturers, we will not have control over compliance with applicable rules and regulations by such manufacturers. Any product promotion and advertising will also be subject to regulatory requirements and continuing regulatory review. If we or our existing or future collaborators, manufacturers or service providers fail to comply with applicable continuing regulatory requirements in the United States or foreign jurisdictions in which we seek to market our products, we or they may be subject to, among other things, fines, warning letters, holds on clinical trials, delay of approval or refusal by the FDA or similar foreign regulatory bodies to approve pending applications or supplements to approved applications, suspension or withdrawal of regulatory approval, product recalls and seizures, administrative detention of products, refusal to permit the import or export of products, operating restrictions, injunction, civil penalties and criminal prosecution.

Subsequent discovery of previously unknown problems with a product, including adverse events of unanticipated severity or frequency, or with our third-party manufacturers or manufacturing processes, or failure to comply with regulatory requirements, may result in, among other things:

- restrictions on the marketing or manufacturing of the product, withdrawal of the product from the market or voluntary or mandatory product recalls;
- fines, warning or untitled letters or holds on clinical trials;
- refusal by the FDA to approve pending applications or supplements to approved applications filed by us or our strategic partners;
- suspension or revocation of product license approvals;
- product seizure or detention or refusal to permit the import or export of products; and
- injunctions or the imposition of civil or criminal penalties.

The FDA policies may change and additional government regulations may be enacted that could prevent, limit or delay regulatory approval of our product candidates. If we are slow or unable to adapt to changes in existing requirements or the adoption of new requirements or policies, or if we are not able to maintain regulatory compliance, we may lose any marketing approval that we may have obtained and we may not achieve or sustain profitability, which would adversely affect our business.

We also cannot predict the likelihood, nature or extent of government regulation that may arise from future legislation or administrative or executive action, either in the United States or abroad.

The ability of the FDA to review and approve new products can be affected by a variety of factors, including government budget and funding levels, statutory, regulatory and policy changes, the FDA's ability to hire and retain key personnel and accept the payment of user fees, and other events that may otherwise affect the FDA's ability to perform routine functions. In addition, government funding of other government agencies that fund research and development activities is subject to the political process, which is inherently fluid and unpredictable. Disruptions at the FDA and other agencies may also slow the time necessary for new drugs to be reviewed and/or approved by necessary government agencies, which would adversely affect our business. For example, over the last several years, including for 35 days beginning on December 22, 2018, the U.S. government has shut down several times and certain regulatory agencies, such as the FDA, have had to furlough critical employees and stop critical activities.

The ability of the FDA and other government agencies to properly administer their functions is highly dependent on the levels of government funding and the ability to fill key leadership appointments, among various factors. Delays in filling or replacing key positions could significantly impact the ability of the FDA and other agencies to fulfill their functions, and could greatly impact healthcare and the pharmaceutical industry.

Separately, in response to the COVID-19 pandemic, on March 10, 2020, the FDA announced its intention to postpone most foreign inspections of manufacturing facilities and, subsequently, on March 18, 2020, the FDA temporarily postponed routine surveillance inspections of domestic manufacturing facilities. Regulatory authorities outside the United States may adopt similar restrictions or other policy measures in response to the COVID-19 pandemic. Subsequently, on July 10, 2020, the FDA announced its intention to resume certain on-site inspections of domestic manufacturing facilities subject to a risk-based prioritization system. The FDA intends to use this risk-based assessment system to identify the categories of regulatory activity that can occur within a given geographic area, ranging from mission critical inspections to resumption of all regulatory activities. Regulatory authorities outside the United States may adopt similar restrictions or other policy measures in response to the COVID-19 pandemic. If a prolonged government shutdown occurs, or if global health concerns continue to prevent the FDA or other regulatory authorities from conducting their regular inspections, reviews, or other regulatory activities, it could significantly impact the ability of the FDA or other regulatory authorities to timely review and process our regulatory submissions, which could have a material adverse effect on our business.

***We may face difficulties from healthcare legislative reform measures.***

Existing regulatory policies may change and additional government regulations may be enacted that could prevent, limit or delay regulatory approval of our product candidates. We cannot predict the likelihood, nature or extent of government regulation that may arise from future legislation or administrative action, either in the United States or abroad. If we are slow or unable to adapt to changes in existing requirements or the adoption of new requirements or policies, or if we are not able to maintain regulatory compliance, we may lose any marketing approval that we may have obtained and we may not achieve or sustain profitability.

In the United States, there have been and continue to be a number of legislative initiatives to contain healthcare costs. For example, in March 2010, the Patient Protection and Affordable Care Act, as amended by the Healthcare and Education Reconciliation Act, or together, the ACA, was enacted, which substantially changed the way healthcare is financed by both governmental and private insurers, and significantly impacts the U.S. pharmaceutical industry.

There have been legislative and judicial efforts to modify, repeal or otherwise invalidate all or certain aspects of the ACA, including measures taken during the former presidential administration. By way of example, the Tax Cuts and Jobs Act, or the TCJA, was enacted, effective January 1, 2019, and included, among other things, a provision repealing the tax-based shared responsibility payment imposed by the ACA on certain individuals who fail to maintain qualifying health coverage for all or part of a year that is commonly referred to as the "individual mandate." On June 17, 2021, the U.S. Supreme Court dismissed a challenge on procedural grounds that argued the ACA is unconstitutional in its entirety because the "individual mandate" was repealed by Congress. Thus, the ACA will remain in effect in its current form. It is possible that the ACA will be subject to judicial or Congressional challenges in the future.

The 2020 federal spending package permanently eliminated, effective January 1, 2020, the ACA-mandated "Cadillac" tax on certain high cost employer-sponsored insurance plans and the medical device excise tax on non-exempt medical devices, and effective January 1, 2021, also eliminates the health insurer tax. Further, the Bipartisan Budget Act of 2018, or the BBA, among other things, amended the ACA, effective January 1, 2019, to increase from 50% to 70% the point-of-sale discount that is owed by pharmaceutical manufacturers who participate in Medicare Part D and to close the coverage gap in most Medicare drug plans, commonly referred to as the "donut hole." In addition, CMS published a final rule that would give states greater marketplaces, which may have the effect of relaxing essential health benefits required under the ACA for plans sold through such marketplaces.

In addition, other legislative changes have been proposed and adopted in the United States since the ACA was enacted to reduce healthcare expenditures. U.S. federal government agencies also currently face potentially significant spending reductions, which may further impact healthcare expenditures. On August 2, 2011, the Budget Control Act of 2011 among other things, created measures for spending reductions by Congress. A joint select committee on deficit reduction, tasked with recommending a targeted deficit reduction of at least \$1.2 trillion for the years 2013 through 2021, was unable to reach required goals, thereby triggering the legislation's automatic reduction to several government programs. This includes aggregate reductions of Medicare payments to providers of 2% per fiscal year. These reductions went into effect on April 1, 2013 and, due to subsequent legislative amendments to the statute, including the BBA, will remain in effect through 2030 with the exception of a temporary suspension from May 1, 2020 through March 31, 2022 due to the COVID-19 pandemic. The Medicare reductions phase back in starting with a 1% reduction in effect from April 1, 2022 to June 30, 2022, before increasing to the full 2% reduction. Moreover, on January 2, 2013, the American Taxpayer Relief Act of 2012 was signed into law, which, among other things, further reduced Medicare payments to several types of providers, including hospitals, imaging centers and cancer treatment centers, and increased the statute of limitations period for the government to recover overpayments to providers from three to five years. If federal spending is further reduced, anticipated budgetary shortfalls may also impact the ability of relevant agencies, such as the FDA or the National Institutes of Health to continue to function at current levels. Amounts allocated to federal grants and contracts may be reduced or eliminated. These reductions may also impact the ability of relevant agencies to timely review and approve research and development, manufacturing, and marketing activities, which may delay our ability to develop, market and sell any products we may develop.

Moreover, payment methodologies, including payment for companion diagnostics, may be subject to changes in healthcare legislation and regulatory initiatives. For example, the Medicare Prescription Drug, Improvement, and Modernization Act of 2003, or MMA, changed the way Medicare covers and pays for pharmaceutical products. The legislation expanded Medicare coverage for drug purchases by the elderly and introduced a new reimbursement methodology based on average sales prices for physician-administered drugs. In addition, this legislation provided authority for limiting the number of drugs that will be covered in any therapeutic class. While the MMA only applies to drug benefits for Medicare beneficiaries, private payors often follow Medicare coverage policy and payment limitations in setting their own reimbursement rates. Therefore, any reduction in reimbursement that results from the MMA may result in a similar reduction in payments from private payors. In addition, CMS has begun bundling the Medicare payments for certain laboratory tests ordered while a patient received services in a hospital outpatient setting and, beginning in 2018, CMS will pay for clinical laboratory services based on a weighted average of reported prices that private payors, Medicare Advantage plans, and Medicaid Managed Care plans pay for laboratory services. Further, on March 16, 2018, CMS finalized its National Coverage Determination, or NCD, for certain diagnostic laboratory tests using next generation sequencing that are approved by the FDA as a companion *in vitro* diagnostic and used in a cancer with an FDA-approved companion diagnostic indication. Under the NCD, diagnostic tests that gain FDA approval or clearance as an *in vitro* companion diagnostic will automatically receive full coverage and be available for patients with recurrent, metastatic relapsed, refractory or stages III and IV cancer. Additionally, the NCD extended coverage to repeat testing when the patient has a new primary diagnosis of cancer.

Recently there has been heightened governmental scrutiny over the manner in which manufacturers set prices for their marketed products, which has resulted in several Congressional inquiries and proposed and enacted federal and state legislation designed to, among other things, bring more transparency to product pricing, review the relationship between pricing and manufacturer patient programs, and reform government program reimbursement methodologies for drug products. The FDA released a final rule in September 2020 providing guidance for states to build and submit importation plans for drugs from Canada. Litigation was initiated with regard to this final rule, and the Biden Administration has defended the final rule. The litigation is ongoing.

Further, in November 2020, HHS finalized a regulation removing safe harbor protection for price reductions from pharmaceutical manufacturers to plan sponsors under Part D, either directly or through pharmacy benefit managers, unless the price reduction is required by law. The rule also creates a new safe harbor for price reductions reflected at the point-of-sale, as well as a safe harbor for certain fixed fee arrangements between pharmacy benefit managers and manufacturers. The implementation of the rule has been delayed by the Biden Administration from January 1, 2022 to January 1, 2023 in response to ongoing litigation. The rule also creates a new safe harbor for price reductions reflected at the point-of-sale, as well as a safe harbor for certain fixed fee arrangements between pharmacy benefit managers and manufacturers, the implementation of which have also been delayed by the Biden administration until January 1, 2023. In December 2020, CMS issued a final rule implementing significant manufacturer price reporting changes under the Medicaid Drug Rebate Program, including regulations that affect manufacturer-sponsored patient assistance programs subject to pharmacy benefit manager accumulator programs and Best Price reporting related to certain value-based purchasing arrangements. It is unclear to what extent these new regulations will be implemented and to what extent these regulations or any future legislation or regulations by the Biden administration will have on our business, including our ability to generate revenue and achieve profitability.

On September 9, 2021, the Biden Administration published a wide-ranging list of policy proposals, most of which would need to be carried out by Congress, to reduce drug prices and drug payment. The HHS plan includes, among other reform measures, proposals to (1) give Medicare authority to directly negotiate drug prices with manufacturers, (2) authorize HHS to negotiate Medicaid supplemental rebates on behalf of states, (3) allow employer-based, ACA marketplace and commercial health insurance plans to access Medicare negotiated drug prices, (4) place a cap on out-of-pocket costs for Medicare Part D beneficiaries and redistribute a higher proportion of drug costs to Part D and manufacturers, (5) mandate purchase of the least costly-alternative and to institute value-based or outcomes-based pricing arrangements, (6) disincentivize drug price increases, (8) facilitate approval and prescription of biosimilar and generic drugs, (9) increase drug pricing transparency, (10) prohibit certain types of rebates to pharmacy benefit managers, and (11) develop drug pricing models by tying price to outcomes. Similar proposals, including the plans to give Medicare authority to negotiate drug prices and cap out-of-pocket costs, have been included in legislation currently being debated by Congress.

At the state level, legislatures are increasingly passing legislation and implementing regulations designed to control pharmaceutical and biological product pricing, including price or patient reimbursement constraints, discounts, restrictions on certain product access and marketing cost disclosure and transparency measures, and, in some cases, designed to encourage importation from other countries and bulk purchasing.

Additionally, on May 30, 2018, the Trickett Wendler, Frank Mongiello, Jordan McLinn, and Matthew Bellina Right to Try Act of 2017 was signed into law. The law, among other things, provides a federal framework for certain patients to access certain investigational new drug products that have completed a Phase 1 clinical trial and that are undergoing investigation for FDA approval. Under certain circumstances, eligible patients can seek treatment without enrolling in clinical trials and without obtaining FDA authorization under an FDA expanded access program; however, manufacturers are not obligated to provide investigational new drug products under the current federal right to try law. We may choose to seek an expanded access program for our product candidates, or to utilize comparable rules in other countries that allow the use of a drug, on a named patient basis or under a compassionate use program.

We expect that the ACA, as well as other healthcare reform measures that may be adopted in the future, may result in more rigorous coverage criteria and in additional downward pressure on the price that we receive for any approved product. The implementation of cost containment measures or other healthcare reforms may prevent us from being able to generate revenue, attain profitability, or commercialize our products.

***Our operations and relationships with healthcare providers, healthcare organizations, customers and third-party payors will be subject to applicable anti-bribery, anti-kickback, fraud and abuse, transparency and other healthcare laws and regulations, which could expose us to, among other things, enforcement actions, criminal sanctions, civil penalties, contractual damages, reputational harm, administrative burdens and diminished profits and future earnings.***

Our current and future arrangements with healthcare providers, healthcare organizations, third-party payors and customers expose us to broadly applicable anti-bribery, fraud and abuse and other healthcare laws and regulations that may constrain the business or financial arrangements and relationships through which we research, market, sell and distribute our product candidates. In addition, we may be subject to patient data privacy and security regulation by the U.S. federal government and the states and the foreign governments in which we conduct our business. Restrictions under applicable federal and state anti-bribery and healthcare laws and regulations, include the following:

- the federal Anti-Kickback Statute, which prohibits, among other things, individuals and entities from knowingly and willfully soliciting, offering, receiving or providing remuneration, directly or indirectly, in cash or in kind, to induce or reward, or in return for, either the referral of an individual for, or the purchase, order or recommendation of, any good or service, for which payment may be made under a federal and state healthcare program such as Medicare and Medicaid. A person or entity does not need to have actual knowledge of the statute or specific intent to violate it in order to have committed a violation;
- the federal criminal and civil false claims and civil monetary penalties laws, including the federal False Claims Act, which can be imposed through civil whistleblower or qui tam actions against individuals or entities, prohibits, among other things, knowingly presenting, or causing to be presented, to the federal government, claims for payment that are false or fraudulent, knowingly making, using or causing to be made or used, a false record or statement material to a false or fraudulent claim, or from knowingly making a false statement to avoid, decrease or conceal an obligation to pay money to the federal government. In addition, certain marketing practices, including off-label promotion, may also violate false claims laws. Moreover, the government may assert that a claim including items and services resulting from a violation of the federal Anti-Kickback Statute constitutes a false or fraudulent claim for purposes of the federal False Claims Act;
- HIPAA, which imposes criminal and civil liability, prohibits, among other things, knowingly and willfully executing, or attempting to execute a scheme to defraud any healthcare benefit program, or knowingly and willfully falsifying, concealing or covering up a material fact or making any materially false statement in connection with the delivery of or payment for healthcare benefits, items or services; similar to the federal Anti-Kickback Statute, a person or entity does not need to have actual knowledge of the statute or specific intent to violate it in order to have committed a violation;

- HIPAA, as amended by HITECH, which impose obligations on certain healthcare providers, health plans, and healthcare clearinghouses, known as covered entities, as well as their business associates that perform certain services involving the storage, use or disclosure of individually identifiable health information, including mandatory contractual terms, with respect to safeguarding the privacy, security, and transmission of individually identifiable health information, and require notification to affected individuals and regulatory authorities of certain breaches of security of individually identifiable health information;

- the federal legislation commonly referred to as Physician Payments Sunshine Act, enacted as part of the ACA, and its implementing regulations, which requires certain manufacturers of covered drugs, devices, biologics and medical supplies that are reimbursable under Medicare, Medicaid, or the Children's Health Insurance Program, with certain exceptions, to report annually to CMS information related to certain payments and other transfers of value to physicians (defined to include doctors, dentists, optometrists, podiatrists and chiropractors), physician assistants, certain types of advanced practice nurses, and teaching hospitals, as well as ownership and investment interests held by the physicians described above and their immediate family members, with the information made publicly available on a searchable website;

- the U.S. Foreign Corrupt Practices Act of 1977, as amended, which prohibits, among other things, U.S. companies and their employees and agents from authorizing, promising, offering, or providing, directly or indirectly, corrupt or improper payments or anything else of value to foreign government officials, employees of public international organizations and foreign government owned or affiliated entities, candidates for foreign political office, and foreign political parties or officials thereof;

- analogous state and foreign laws and regulations, such as state anti-kickback and false claims laws, that may apply to sales or marketing arrangements and claims involving healthcare items or services reimbursed by non-governmental third-party payors, including private insurers; and

- certain state laws that require pharmaceutical companies to comply with the pharmaceutical industry's voluntary compliance guidelines and the relevant compliance guidance promulgated by the federal government in addition to requiring drug and therapeutic biologics manufacturers to report information related to payments to physicians and other healthcare providers or marketing expenditures and pricing information, state and local laws that require the registration of pharmaceutical sales representatives, and state laws governing the privacy and security of health information in certain circumstances, many of which differ from each other in significant ways and often are not preempted by HIPAA, thus complicating compliance efforts.

If we or our collaborators, manufacturers or service providers fail to comply with applicable federal, state or foreign laws or regulations, we could be subject to enforcement actions, which could affect our ability to develop, market and sell our products successfully and could harm our reputation and lead to reduced acceptance of our products by the market. These enforcement actions include, among others:

- exclusion from participation in government-funded healthcare programs;
- exclusion of company products from coverage under federal health care programs; and
- exclusion from eligibility for the award of government contracts for our products.

Efforts to ensure that our current and future business arrangements with third parties comply with applicable healthcare laws and regulations could involve substantial costs. It is possible that governmental authorities will conclude that our business practices do not comply with current or future statutes, regulations, agency guidance or case law involving applicable fraud and abuse or other healthcare laws and regulations. If our operations are found to be in violation of any such requirements, we may be subject to significant penalties, including civil, criminal and administrative penalties, damages, fines, disgorgement, imprisonment, the curtailment or restructuring of our operations, loss of eligibility to obtain approvals from the FDA, exclusion from participation in government contracting, healthcare reimbursement or other government programs, including Medicare and Medicaid, integrity oversight and reporting obligations, or reputational harm, any of which could adversely affect our financial results. Although effective compliance programs can mitigate the risk of investigation and prosecution for violations of these laws, these risks cannot be entirely eliminated. Any action against us for an alleged or suspected violation could cause us to incur significant legal expenses and could divert our management's attention from the operation of our business, even if our defense is successful. In addition, achieving and sustaining compliance with applicable laws and regulations may be costly to us in terms of money, time and resources.

***Our failure to comply with privacy and data security laws, regulations and standards may cause our business to be materially adversely affected.***

We are, and may increasingly become, subject to various laws and regulations, as well as contractual obligations, relating to data privacy and security in the jurisdictions in which we operate. Personal privacy and data security have become significant issues in the United States, Europe and in many other jurisdictions. The regulatory framework for privacy and security issues worldwide is rapidly evolving and is likely to remain uncertain for the foreseeable future. We maintain a large quantity of sensitive information, including confidential business and patient health information in connection with our clinical development regarding the patients enrolled in our clinical trials. Any violations of these rules by us could subject us to civil and criminal penalties and adverse publicity and could harm our ability to initiate and complete clinical trials. We cannot provide assurance that current or future legislation will not prevent us from generating or maintaining personal data or that patients will consent to the use of their personal data (as necessary); either of these circumstances may prevent us from undertaking or publishing essential research and development, manufacturing, and commercialization, which could have a material adverse effect on our business, results of operations, financial condition, and prospects.

In the United States, there are numerous federal and state consumer, privacy and data security laws and regulations governing the collection, use, disclosure, and protection of personal information, including health information privacy laws, security breach notification laws, and consumer protection laws. Each of these laws is subject to varying interpretations and constantly evolving.

Federal law obligations may include HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act of 2009, or HITECH, and their respective implementing regulations, imposes privacy, security, and breach notification obligations on certain health care providers, health plans, and health care clearinghouses, known as covered entities, as well as their business associates that perform certain services involving creating, receiving, maintaining or transmitting individually identifiable health information for or on behalf of such covered entities. Entities that are found to be in violation of HIPAA as the result of a breach of unsecured protected health information, a complaint about privacy practices or an audit by Health and Human Services Administration (HHS), may be subject to significant civil, criminal, and administrative fines and penalties and/or additional reporting and oversight obligations if required to enter into a resolution agreement and corrective action plan with HHS to settle allegations of HIPAA non-compliance. Further, entities that knowingly obtain, use, or disclose individually identifiable health information maintained by a HIPAA covered entity in a manner that is not authorized or permitted by HIPAA may be subject to criminal penalties. HITECH also created four new tiers of civil monetary penalties, amended HIPAA to make civil and criminal penalties directly applicable to business associates, and gave state attorneys general new authority to file civil actions for damages or injunctions in federal courts to enforce the federal HIPAA laws and seek attorneys' fees and costs associated with pursuing federal civil actions. In addition, state laws govern the privacy and security of health information in specified circumstances, many of which differ from each other in significant ways and may not have the same effect, thus complicating compliance efforts. Notably, we may obtain health information from third parties (including research institutions from which we obtain clinical trial data) that are subject to privacy and security requirements under HIPAA.



Even when HIPAA does not apply, violating consumers' privacy rights or failing to take appropriate steps to keep consumers' personal information secure may constitute unfair acts or practices in or affecting commerce in violation of Section 5(a) of the Federal Trade Commission Act, 15 U.S.C. § 45(a). The Federal Trade Commission (FTC) expects a company's data security measures to be reasonable and appropriate considering the sensitivity and volume of consumer information it holds, the size and complexity of its business, and the cost of available tools to improve security and reduce vulnerabilities. Individually identifiable health information is considered sensitive data that merits stronger safeguards. The FTC may also take action against companies for unfair acts or practices for failing to keep promises made in public statements, such as privacy policies. We make public statements about our use and disclosure of personal data through our privacy policy, information described on our website and in press statements. Although we endeavor to ensure that our public statements are complete and accurate, any failure (real or perceived) by us to comply with our privacy commitments could be considered an "unfair and deceptive" act by the FTC resulting in an FTC consent decree that may include fines and sustained government-mandated audits for a period of 20 years. A violation of an FTC privacy or data security consent decree can also subject the responding company to very high monetary penalties, as evidenced by the FTC obtaining \$5 billion in negotiated monetary relief against Facebook for violation of a consent decree. State attorneys general may enforce comparable state law statutes covering unfair and deceptive practices with similar resulting consequences.

Certain states have also adopted comparable privacy and security laws and regulations, some of which may be more stringent than HIPAA. California recently enacted legislation, the California Consumer Privacy Act, or CCPA, which went into effect January 1, 2020. The CCPA became enforceable by the California Attorney General on July 1, 2020, along with related regulations which came into force on August 14, 2020. Additionally, although not effective until January 1, 2023, the California Privacy Rights Act, or the CPRA, expands upon the CCPA and was passed in the recent election on November 3, 2020. The CCPA created individual privacy rights and places increased privacy and security obligations on entities handling personal information. The CPRA significantly modifies the CCPA, including by expanding consumers' rights with respect to certain personal information and creating a new state agency to oversee implementation and enforcement efforts; future actions by this new agency could significantly impact our business activities and require substantial compliance costs that adversely affect our business, operating results, prospects and financial condition.

Other states have followed California's lead. The Virginia Consumer Data Protection Act, or VCDPA, which will go into effect in 2023, gives new data protection rights to Virginia residents and imposes additional obligations on controllers and processors of personal data. Colorado has also adopted a new state data protection act titled the Colorado Privacy Act, which is set to take effect on July 1, 2023. As of January 2022, fourteen states have pending consumer privacy legislation under review, which if enacted would add additional costs and expense of resources to maintain compliance.

Internationally, many jurisdictions in which we operate have established their own data security and privacy legal framework with which we or our customers must comply. For example, the EU's General Data Protection Regulation, or GDPR, which became effective in May 2018, greatly increased the European Commission's jurisdictional reach of its laws and adds a broad array of requirements for handling personal information, including, for example, requirements to establish a legal basis for processing, higher standards for obtaining consent from individuals to process their personal information, more robust disclosures to individuals and a strengthened individual data rights regime, requirements to implement safeguards to protect the security and confidentiality of personal information that requires the adoption of administrative, physical and technical safeguards, shortened timelines for data breach notifications to appropriate data protection authorities or data subjects, limitations on retention and secondary use of information, increased requirements pertaining to health data and additional requirements that we impose certain contractual obligations on third-party processors in connection with the processing of the personal information. The GDPR, together with national legislation, regulations and guidelines of the EU member states governing the processing of personal information, impose strict obligations and restrictions on the ability to collect, use, retain, protect, disclose, transfer and otherwise process personal information. In particular, the GDPR includes obligations and restrictions concerning the consent and rights of individuals to whom the personal information relates, the transfer of personal information out of the European Economic Area, security breach notifications and the security and confidentiality of personal information. The GDPR authorizes fines for certain violations of up to 4% of global annual revenue or €20 million, whichever is greater, and other administrative penalties. Additionally, the United Kingdom, or UK, implemented the Data Protection Act effective in May 2018 and statutorily amended in 2019, that substantially implements the GDPR and contains provisions, including UK-specific derogations, for how GDPR is applied in the UK. From the

beginning of 2021 (when the transitional period following Brexit expired), we have continued to comply with the GDPR and also the Data Protection Act, with each regime having the ability to fine up to the greater of €20 million (£17 million) or 4% of global turnover. The costs of compliance with, and other burdens imposed by, such laws and regulations that are applicable to our business operations may limit the use and adoption of our services, reduce overall demand for them. Changes in these legislations may add additional complexity, variation in requirements, restrictions and potential legal risk, require additional investment in resources for compliance programs, could impact strategies and availability of previously useful data, and could result in increased compliance costs and/or changes in business practices and policies.

The GDPR, as well as law in the United Kingdom and Switzerland, also prohibits the international transfer of personal data from the EEA/UK/Switzerland to countries outside of those jurisdictions unless made to a country deemed to have adequate data privacy laws by the European Commission or where a data transfer mechanism has been put in place. We rely on a mixture of mechanisms to transfer personal data to countries outside of the EEA, Switzerland, and the United Kingdom, including to the United States and therefore are continuing to evaluate the guidance and mechanisms required to establish adequate safeguards for personal data. Until recently, one such data transfer mechanism was the EU-US Privacy Shield. However, in July 2020 the Court of Justice of the European Union (CJEU), declared the Privacy Shield to be invalid. The CJEU upheld the validity of the standard contractual clauses (SCCs) as a legal mechanism to transfer personal data but companies relying on SCCs will—continually subject to guidance from regulators in the EEA—need to evaluate and implement supplementary measures that provide privacy protections additional to those provided under SCCs. For example, German and Irish supervisory authorities have indicated that the Standard Contractual Clauses alone provide inadequate protection for EU-U.S. data transfers. Use of the data transfer mechanisms must now be assessed on a case-by-case basis taking into account the legal regime applicable in the destination country, in particular applicable surveillance laws and rights of individuals.

In turn, the findings of the CJEU will have significant implications for cross-border data flows. On June 4, 2021, the European Commission adopted new Standard Contractual Clauses (SCCs) to apply to international data transfers outside of the EEA. We will have until December 27, 2022 to update any existing agreements, or any new agreements executed before September 27, 2021, that rely on the former SCCs. If we are otherwise unable to transfer personal data between and among countries and regions in which we operate, it could affect the manner in which we conduct our operations, and we may find it necessary to establish systems in the EEA, Switzerland, and the United Kingdom to maintain personal data originating from the EEA and the United Kingdom, which may involve substantial expense and distraction from other aspects of our business. We may need to implement additional safeguards to further enhance the security of data transferred out of the EEA/Switzerland/United Kingdom, conduct data transfer impact assessments, and review existing agreements which could increase our compliance costs, expose us to further regulatory scrutiny and liability, and adversely affect our business. Further, the GDPR provides that countries in the EEA may establish their own laws and regulations further restricting the processing of certain personal data, including genetic data, biometric data, and health data.

Some countries (including some outside the EEA) also are considering or have passed legislation requiring local storage and processing of data, or similar requirements, which could increase the cost and complexity of delivering our products and services if we were to operate in those countries. If we are required to implement additional measures to transfer data from the European Economic Area, this could increase our compliance costs, and could adversely affect our business, financial condition and results of operations.

The myriad international and U.S. privacy and data breach laws are not consistent, and compliance in the event of a widespread data breach is difficult and may be costly. In many jurisdictions, enforcement actions and consequences for noncompliance are also rising. In addition to government regulation, privacy advocates and industry groups may propose new and different self-regulatory standards that either legally or contractually applies to us. Any inability to adequately address privacy and security concerns, even if unfounded, or comply with applicable privacy and data security laws, regulations and policies, could result in additional cost and liability to us, damage our reputation, and adversely affect our business. Additionally, all of these evolving compliance and operational requirements impose significant costs, such as costs related to organizational changes, implementing additional protection technologies, training employees and engaging consultants, which are likely to increase over time. In addition, such requirements may require us to modify our data processing practices and policies, distract management or divert resources from other initiatives and projects, all of which could have a material adverse effect on our business, financial condition, results of operations and prospects.

Enforcement actions and investigations by regulatory authorities related to data security incidents and privacy violations continue to increase. Any failure or perceived failure by us (or the third parties with whom we have contracted to process such information) to comply with applicable privacy and data security laws, policies or related contractual obligations, or any compromise of security that results in unauthorized access, use or transmission of, personal user information, could result in a variety of claims against us, including governmental enforcement actions and investigations, class action privacy litigation in certain jurisdictions and proceedings by data protection authorities, potentially amounting to significant compensation or damages liabilities, as well as associated costs, diversion of internal resources, and reputational harm. When such events occur, our reputation may be harmed, we may lose current and potential users and the competitive positions of our brand might be diminished, any or all of which could materially adversely affect our business, operating results, and financial condition. In addition, if our practices are not consistent or viewed as not consistent with legal and regulatory requirements, including changes in laws, regulations and standards or new interpretations or applications of existing laws, regulations and standards, we may become subject to audits, inquiries, whistleblower complaints, adverse media coverage, investigations, loss of export privileges, or severe criminal or civil sanctions, all of which may have a material adverse effect on our business, operating results, reputation, and financial condition.

***Even if we are able to commercialize any product candidate, such product candidate may become subject to unfavorable pricing regulations or third-party coverage and reimbursement policies, which would harm our business.***

The regulations that govern regulatory approvals, pricing and reimbursement for new drugs and therapeutic biologics vary widely from country to country. Some countries require approval of the sale price of a drug or therapeutic biologic before it can be marketed. In many countries, the pricing review period begins after marketing approval is granted. In some foreign markets, prescription biopharmaceutical pricing remains subject to continuing governmental control even after initial approval is granted. As a result, we might obtain regulatory approval for a product in a particular country, but then be subject to price regulations that delay our commercial launch of the product, possibly for lengthy time periods and negatively impact the revenues we are able to generate from the sale of the product in that country. Adverse pricing limitations may hinder our ability to recoup our investment in one or more product candidates, even if our product candidates obtain regulatory approval.

Our ability to commercialize any products successfully also will depend in part on the extent to which coverage and adequate reimbursement for these products and related treatments will be available from government authorities, private health insurers and other organizations. Even if we succeed in bringing one or more products to the market, these products may not be considered cost-effective, and the amount reimbursed for any products may be insufficient to allow us to sell our products on a competitive basis. Because our programs are in the early stages of development, we are unable at this time to determine their cost effectiveness or the likely level or method of coverage and reimbursement. Increasingly, the third-party payors who reimburse patients or healthcare providers, such as government and private insurance plans, are requiring that drug companies provide them with predetermined discounts from list prices, and are seeking to reduce the prices charged or the amounts reimbursed for biopharmaceutical products. If the price we are able to charge for any products we develop, or the coverage and reimbursement provided for such products, is inadequate in light of our development and other costs, our return on investment could be affected adversely.

There may be significant delays in obtaining reimbursement for newly approved drugs or therapeutic biologics, and coverage may be more limited than the purposes for which the drug or therapeutic biologic is approved by the FDA or similar foreign regulatory authorities. Moreover, eligibility for reimbursement does not imply that any drug or therapeutic biologic will be reimbursed in all cases or at a rate that covers our costs, including research, development, manufacture, sale and distribution.

Interim reimbursement levels for new drugs or therapeutic biologics, if applicable, may also be insufficient to cover our costs and may not be made permanent. Reimbursement rates may be based on payments allowed for lower cost drugs or therapeutic biologics that are already reimbursed, may be incorporated into existing payments for other services and may reflect budgetary constraints or imperfections in Medicare data. Net prices for drugs or therapeutic biologics may be reduced by mandatory discounts or rebates required by government healthcare programs or private payors and by any future relaxation of laws that presently restrict imports of drugs or therapeutic biologics from countries where they may be sold at lower prices than in the United States. Further, no uniform policy for coverage and reimbursement exists in the United States, and coverage and reimbursement can differ significantly from payor to payor. Third-party payors often rely upon Medicare coverage policy and payment limitations in setting their own reimbursement rates, but also have their own methods and approval processes apart from Medicare determinations. Our inability to promptly obtain coverage and adequate reimbursement rates from both government-funded and private payors for new drugs or therapeutic biologics that we develop and for which we obtain regulatory approval could have a material and adverse effect on our business, financial condition, results of operations and prospects.

***If in the future we are unable to establish U.S. or global sales and marketing capabilities or enter into agreements with third parties to sell and market our product candidates, we may not be successful in commercializing our product candidates if they are approved and we may not be able to generate any revenue.***

We currently have a limited team for the marketing, sales and distribution of any of our product candidates that are able to obtain regulatory approval. To commercialize any product candidates after approval, we must build, on a territory-by-territory basis, marketing, sales, distribution, managerial and other non-technical capabilities or make arrangements with third parties to perform these services, and we may not be successful in doing so. If our product candidates receive regulatory approval, we may decide to establish an internal sales or marketing team with technical expertise and supporting distribution capabilities to commercialize our product candidates, which will be expensive and time consuming and will require significant attention of our executive officers to manage. For example, some state and local jurisdictions have licensing and continuing education requirements for pharmaceutical sales representatives, which requires time and financial resources. Any failure or delay in the development of our internal sales, marketing and distribution capabilities would adversely impact the commercialization of any of our product candidates that we obtain approval to market.

With respect to the commercialization of all or certain of our product candidates, we may choose to collaborate, either globally or on a territory-by-territory basis, with third parties that have direct sales forces and established distribution systems, either to augment our own sales force and distribution systems or in lieu of our own sales force and distribution systems. If we are unable to enter into such arrangements when needed on acceptable terms, or at all, we may not be able to successfully commercialize any of our product candidates that receive regulatory approval or any such commercialization may experience delays or limitations. If we are not successful in commercializing our product candidates, either on our own or through collaborations with one or more third parties, our future product revenue will suffer and we may incur significant additional losses.

***Our product candidates for which we intend to seek approval as biologic products may face competition sooner than anticipated.***

With the enactment of the Biologics Price Competition and Innovation Act of 2009, or BPCIA, an abbreviated pathway for the approval of biosimilar biological products (both highly similar and interchangeable biological products) was created. The abbreviated regulatory pathway establishes legal authority for the FDA to review and approve biosimilar biologics, including the possible designation of a biosimilar as interchangeable based on its similarity to an existing reference product. The BPCIA provides a period of exclusivity for products granted "reference product exclusivity," under which an application for a biosimilar product referencing such products cannot be approved by the FDA until 12 years after the first licensure date of the reference product licensed under a BLA. On March 6, 2015, the FDA approved the first biosimilar product under the BPCIA. FDA has accelerated licensure of biosimilar products since the first biosimilar was approved in 2015. However, FDA has yet to deem a biosimilar product interchangeable with the reference product. While FDA has implemented certain procedures intended to implement the BPCIA, other processes remain in development and may be adopted by the FDA; any such processes could have a material adverse effect on the future commercial prospects for our biological products.

A biological product submitted for licensure under a BLA is eligible for a period of exclusivity that commences on the date of its licensure, unless its date of licensure is not considered a date of first licensure because it falls within an exclusion under the BPCIA. There is a risk that this exclusivity could be shortened due to congressional action or otherwise, potentially creating the opportunity for biosimilar competition sooner than anticipated. Additionally, this period of regulatory exclusivity does not apply to companies pursuing regulatory approval via their own traditional BLA, rather than via the abbreviated pathway. Most states have enacted substitution laws that permit substitution of only interchangeable biosimilars. The extent to which a highly similar biosimilar, once approved, will be substituted for any one of our reference products that may be approved in a way that is similar to traditional generic substitution for non-biological products is not yet clear, and will depend on a number of marketplace and regulatory factors that are still developing.

***If any of our product candidates receives marketing approval and we or others later identify undesirable side effects caused by the product candidates, our ability to market and derive revenue from the product candidates could be compromised.***

Undesirable side effects caused by our product candidates could cause regulatory authorities to interrupt, delay or halt clinical trials and could result in more restrictive labeling or the delay or denial of regulatory approval by the FDA or other regulatory authorities. We have only recently initiated our first clinical trials for our first two product candidates. Given the nature of ADCs, it is likely that there may be side effects associated with their use. Results of our clinical trials could reveal a high and unacceptable severity and prevalence of side effects. In such an event, our clinical trials could be suspended or terminated and the FDA or comparable foreign regulatory authorities could order us to cease further development of or deny approval of our product candidates for any or all targeted indications. Such side effects could also affect patient recruitment or the ability of enrolled patients to complete the clinical trials or result in potential product liability claims. Any of these occurrences may materially and adversely affect our business, financial condition, results of operations and prospects.

Further, clinical trials by their nature utilize a sample of the potential patient population. With a limited number of patients and limited duration of exposure, rare and severe side effects of our product candidates may only be uncovered with a significantly larger number of patients exposed to the product candidate.

In the event that any of our product candidates receive regulatory approval and we or others identify undesirable side effects caused by one of our products, any of the following adverse events could occur:

- regulatory authorities may withdraw their approval of the product or seize the product;
- we may be required to recall the product or change the way the product is administered to patients;
- additional restrictions may be imposed on the marketing of the particular product or the manufacturing processes for the product or any component thereof;
- we may be subject to fines, injunctions or the imposition of civil or criminal penalties;
- regulatory authorities may require the addition of labeling statements, such as a black box warning or a contraindication;
- we may be required to create a medication guide outlining the risks of such side effects for distribution to patients;
- we could be sued and held liable for harm caused to patients;
- the product may become less competitive; and
- our reputation may suffer.

Any of these occurrences could have a material and adverse effect on our business, financial condition, results of operations and prospects.

***While we have been granted a Fast Track Designation by the FDA for STRO-002, it may not lead to a faster development or regulatory review or approval process.***

We have been granted a Fast Track Designation for STRO-002 for the treatment of patients with platinum-resistant epithelial ovarian, fallopian tube, or primary peritoneal cancer who have received one to three prior lines of systemic therapy. As part of our business strategy, we may also seek Fast Track Designation for other of our product candidates. If a drug or biologic is intended for the treatment of a serious or life-threatening condition and the drug or biologic demonstrates the potential to address unmet medical needs for this condition, the product sponsor may apply for FDA Fast Track Designation. The FDA has broad discretion whether or not to grant this designation, so even if we believe a particular product candidate is eligible for this designation, we cannot assure you that the FDA would decide to grant it. Even if we do receive Fast Track Designation, as we have for STRO-002, we may not experience a faster development process, review or approval compared to conventional FDA procedures. The FDA may withdraw Fast Track Designation if it believes that the designation is no longer supported by data from our clinical development program, which may happen in connection with STRO-002 or other of our product candidates if granted Fast Track Designation.

***While we have been granted Orphan Drug Designation by the FDA for STRO-001 for the treatment of multiple myeloma, if we decide to seek Orphan Drug Designation for some of our other product candidates, we may be unsuccessful or may be unable to maintain the benefits associated with Orphan Drug Designation, including the potential for orphan drug exclusivity.***

We have been granted Orphan Drug Designation by the FDA for STRO-001 for the treatment of multiple myeloma and our collaborator BMS was granted Orphan Drug Designation by the FDA for CC-99712. As part of our business strategy, we may seek Orphan Drug Designation for our other product candidates, and we may be unsuccessful. Regulatory authorities in some jurisdictions, including the United States and Europe, may designate drugs and therapeutic biologics for relatively small patient populations as orphan drugs. Under the Orphan Drug Act, the FDA may designate a drug or therapeutic biologic as an orphan drug if it is a drug or therapeutic biologic intended to treat a rare disease or condition, which is generally defined as a patient population of fewer than 200,000 individuals in the United States, or a patient population greater than 200,000 in the United States where there is no reasonable expectation that the cost of developing the drug or therapeutic biologic will be recovered from sales in the United States. In the United States, Orphan Drug Designation entitles a party to financial incentives such as tax advantages and user fee waivers. In addition, if a product that has Orphan Drug Designation subsequently receives the first FDA approval for the disease for which it has such designation, the product is entitled to orphan drug exclusivity, which means that the FDA may not approve any other applications, including a full BLA, to market the same product for the same indication for seven years, except in limited circumstances, such as a showing of clinical superiority to the product with orphan drug exclusivity or where the manufacturer is unable to assure sufficient product quantity.

Even if we obtain Orphan Drug Designation for our product candidates in specific indications, we may not be the first to obtain marketing approval of these product candidates for the orphan-designated indication due to the uncertainties associated with developing pharmaceutical products. In addition, exclusive marketing rights in the United States may be limited if we seek approval for an indication broader than the orphan-designated indication or may be lost if the FDA later determines that the request for designation was materially defective or if the manufacturer is unable to assure sufficient quantities of the product to meet the needs of patients with the rare disease or condition. Further, even if we obtain orphan drug exclusivity for a product, that exclusivity may not effectively protect the product from competition because different drugs or therapeutic biologics with different principal molecular structural features can be approved for the same condition. Even after an orphan product is approved, the FDA can subsequently approve the same drug or therapeutic biologic with the same principal molecular structural features for the same condition if the FDA concludes that the later drug or therapeutic biologic is safer, more effective or makes a major contribution to patient care. Orphan Drug Designation neither shortens the development time or regulatory review time of a drug or therapeutic biologic nor gives the drug or therapeutic biologic any advantage in the regulatory review or approval process. In addition, while we may seek Orphan Drug Designation for our product candidates, we may never receive such designations.

The tax reform legislation signed into law on December 22, 2017 reduced the amount of the qualified clinical research costs for a designated orphan product that a sponsor may claim as a credit from 50% to 25%. This may further limit the advantage and may impact our future business strategy of seeking the Orphan Drug Designation.

***If we decide to pursue accelerated approval for any of our product candidates, it may not lead to a faster development or regulatory review or approval process and does not increase the likelihood that our product candidates will receive marketing approval.***

In the future, we may decide to pursue accelerated approval for one or more of our product candidates. Under the FDA's accelerated approval program, the FDA may approve a drug or biologic for a serious or life-threatening disease or condition that provides a meaningful advantage over available therapies based upon a surrogate endpoint that is reasonably likely to predict clinical benefit, or on a clinical endpoint that can be measured earlier than irreversible morbidity or mortality that is reasonably likely to predict an effect on irreversible morbidity or mortality or other clinical benefit. For drugs or biologics granted accelerated approval, post-marketing confirmatory trials are required to verify and describe the anticipated effect on irreversible morbidity or mortality or other clinical benefit. These confirmatory trials must be completed with due diligence, and the FDA may require that the trial be designed, initiated, and/or fully enrolled prior to approval. If we were to pursue accelerated approval for a product candidate for a disease or condition, we would do so on the basis that there is no available therapy for that disease or condition. If any of our competitors were to receive full approval on the basis of a confirmatory trial for a drug or biologic for a disease or condition for which we are seeking accelerated approval before we receive accelerated approval, the disease or condition would no longer qualify as one for which there is no available therapy, and accelerated approval of our product candidate would not occur. Many cancer therapies rely on accelerated approval, and the treatment landscape can change quickly as the FDA converts accelerated approvals to full approvals on the basis of successful confirmatory trials.

Moreover, the FDA may withdraw approval of any product candidate approved under the accelerated approval pathway if, for example:

- the trial or trials required to verify the predicted clinical benefit of our product candidate fail to verify such benefit or do not demonstrate sufficient clinical benefit to justify the risks associated with such product;
- other evidence demonstrates that our product candidate is not shown to be safe or effective under the conditions of use;
- we fail to conduct any required post-approval trial of our product candidate with due diligence; or
- we disseminate false or misleading promotional materials relating to the relevant product candidate.

In addition, the FDA may terminate the accelerated approval program or change the standards under which accelerated approvals are considered and granted in response to public pressure or other concerns regarding the accelerated approval program. Changes to or termination of the accelerated approval program could prevent or limit our ability to obtain accelerated approval of any of our clinical development programs.

## Risks Related to Our Common Stock

***Our quarterly and annual operating results may fluctuate significantly or may fall below the expectations of investors or securities analysts, each of which may cause our stock price to fluctuate or decline.***

We expect our operating results to be subject to quarterly and annual fluctuations. Our net income or loss and other operating results will be affected by numerous factors, including:

- variations in the level of expense related to the ongoing development of our XpressCF<sup>®</sup> platform, our product candidates or future development programs;
- the fair value of our holding of common stock of Vaxcyte;
- results of preclinical and clinical trials, or the addition or termination of clinical trials or funding support by us, or existing or future collaborators or licensing partners;
- our execution of any additional collaboration, licensing or similar arrangements, and the timing of payments we may make or receive under existing or future arrangements or the termination or modification of any such existing or future arrangements;
- any intellectual property infringement lawsuit or opposition, interference or cancellation proceeding in which we may become involved;
- additions and departures of key personnel;
- strategic decisions by us or our competitors, such as acquisitions, divestitures, spin-offs, joint ventures, strategic investments or changes in business strategy;
- if any of our product candidates receives regulatory approval, the terms of such approval and market acceptance and demand for such product candidates;
- regulatory developments affecting our product candidates or those of our competitors;
- epidemics, pandemics or contagious diseases, such as COVID-19; and
- changes in general market and economic conditions.

If our quarterly and annual operating results fall below the expectations of investors or securities analysts, the price of our common stock could decline substantially. Furthermore, any quarterly and annual fluctuations in our operating results may, in turn, cause the price of our common stock to fluctuate substantially. We believe that quarterly and annual comparisons of our financial results are not necessarily meaningful and should not be relied upon as an indication of our future performance.

***Anti-takeover provisions in our charter documents and under Delaware law could make an acquisition of us, which may be beneficial to our stockholders, more difficult and may prevent attempts by our stockholders to replace or remove our current management.***

Our restated certificate of incorporation and our restated bylaws contain provisions that could delay or prevent a change in control of our company. These provisions could also make it difficult for stockholders to elect directors who are not nominated by current members of our board of directors or take other corporate actions, including effecting changes in our management. These provisions:

- establish a classified board of directors so that not all members of our board are elected at one time;
- permit only the board of directors to establish the number of directors and fill vacancies on the board;



- provide that directors may only be removed “for cause” and only with the approval of two-thirds of our stockholders;
- require super-majority voting to amend some provisions in our restated certificate of incorporation and restated bylaws;
- authorize the issuance of “blank check” preferred stock that our board could use to implement a stockholder rights plan;
- eliminate the ability of our stockholders to call special meetings of stockholders;
- prohibit stockholder action by written consent, which requires all stockholder actions to be taken at a meeting of our stockholders;
- prohibit cumulative voting; and
- establish advance notice requirements for nominations for election to our board or for proposing matters that can be acted upon by stockholders at annual stockholder meetings.

In addition, our restated certificate of incorporation, to the fullest extent permitted by law, provides that the Court of Chancery of the State of Delaware is the exclusive forum for: any derivative action or proceeding brought on our behalf; any action asserting a breach of fiduciary duty; any action asserting a claim against us arising pursuant to the Delaware General Corporation Law, or the DGCL, our restated certificate of incorporation, or our restated bylaws; or any action asserting a claim against us that is governed by the internal affairs doctrine. Furthermore, our amended and restated bylaws also provide that unless we consent in writing to the selection of an alternative forum, the federal district courts of the United States shall be the exclusive forum for the resolution of any complaint asserting a cause of action arising under the Securities Act (a Federal Forum Provision). While the Supreme Court of the State of Delaware has held that such provisions are facially valid under Delaware law, there can be no assurance that federal or state courts will follow the holding of the Delaware Supreme Court or determine that the Federal Forum Provision should be enforced in a particular case; application of the Federal Forum Provision means that suits brought by our stockholders to enforce any duty or liability created by the Securities Act must be brought in federal court and cannot be brought in state court.

These choice of forum provisions may limit a stockholder’s ability to bring a claim in a judicial forum that it finds favorable for disputes with us or any of our directors, officers, or other employees, which may discourage lawsuits against us and our directors, officers, employees and agents even though an action, if successful, might benefit our stockholders. Stockholders who do bring a claim in the specified courts could face additional litigation costs in pursuing any such claim. The specified courts may also reach different judgments or results than would other courts, including courts where a stockholder considering an action may be located or would otherwise choose to bring the action, and such judgments or results may be more favorable to us than to our stockholders. Alternatively, if a court were to find these provisions of our governance documents inapplicable to, or unenforceable in respect of, one or more of the specified types of actions or proceedings, we may incur additional costs associated with resolving such matters in other jurisdictions, which could have a material adverse effect on our business, financial condition, results of operations and prospects.

In addition, Section 203 of the DGCL may discourage, delay or prevent a change in control of our company. Section 203 imposes certain restrictions on mergers, business combinations and other transactions between us and holders of 15% or more of our common stock.

***Because we do not anticipate paying any cash dividends on our capital stock in the foreseeable future, capital appreciation, if any, will be your sole source of gain.***

We have never declared or paid cash dividends on our capital stock. We currently intend to retain all of our future earnings, if any, to finance the growth and development of our business. As a result, capital appreciation, if any, of our common stock will be your sole source of gain for the foreseeable future.

## General Risk Factors

### *The market price of our stock may be volatile, and you could lose all or part of your investment.*

The trading price of our common stock may be highly volatile and subject to wide fluctuations in response to various factors, some of which we cannot control. As a result of this volatility, investors may not be able to sell their common stock at or above the purchase price. The market price for our common stock may be influenced by many factors, including the other risks described in this section and the following:

- results of preclinical studies and clinical trials of our product candidates, or those of our competitors or our existing or future collaborators;
- regulatory or legal developments in the United States and other countries, especially changes in laws or regulations applicable to our product candidates;
- the success of competitive products or technologies;
- introductions and announcements of new products by us, our future commercialization partners, or our competitors, and the timing of these introductions or announcements;
- actions taken by regulatory agencies with respect to our products, clinical studies, manufacturing process or sales and marketing terms;
- actual or anticipated variations in our financial results or those of companies that are perceived to be similar to us;
- the success of our efforts to acquire or in-license additional technologies, products or product candidates;
- developments concerning current or future collaborations, including but not limited to those with our sources of manufacturing supply and our commercialization partners;
- market conditions in the pharmaceutical and biotechnology sectors;
- announcements by us or our competitors of significant acquisitions, strategic collaborations, joint ventures or capital commitments;
- developments or disputes concerning patents or other proprietary rights, including patents, litigation matters and our ability to obtain patent protection for our product candidates and products;
- our ability or inability to raise additional capital and the terms on which we raise it;
- the recruitment or departure of key personnel;
- changes in the structure of healthcare payment systems;
- actual or anticipated changes in earnings estimates or changes in stock market analyst recommendations regarding our common stock, other comparable companies or our industry generally;
- our failure or the failure of our competitors to meet analysts' projections or guidance that we or our competitors may give to the market;
- fluctuations in the valuation of companies perceived by investors to be comparable to us;
- announcement and expectation of additional financing efforts;
- speculation in the press or investment community;

- trading volume of our common stock;
- sales of our common stock by us or our stockholders;
- the concentrated ownership of our common stock;
- changes in accounting principles;
- terrorist acts, acts of war or periods of widespread civil unrest;
- natural disasters, epidemics, pandemics or contagious diseases, and other calamities;
- a temporary federal government shutdown; and
- general economic, industry and market conditions.

In addition, the stock market in general, and the markets for pharmaceutical, biopharmaceutical and biotechnology stocks in particular, have experienced extreme price and volume fluctuations that have been often unrelated or disproportionate to the operating performance of the issuer. These broad market and industry factors may seriously harm the market price of our common stock, regardless of our actual operating performance. The realization of any of the above risks or any of a broad range of other risks, including those described in this “Risk Factors” section, could have a dramatic and adverse impact on the market price of our common stock.

***The future sale and issuance of equity or of debt securities that are convertible into equity will dilute our share capital.***

We may choose to raise additional capital in the future, depending on market conditions, strategic considerations and operational requirements. To the extent that additional capital is raised through the sale and issuance of shares or other securities convertible into shares, our stockholders will be diluted. Future issuances of our common stock or other equity securities, or the perception that such sales may occur, could adversely affect the trading price of our common stock and impair our ability to raise capital through future offerings of shares or equity securities. No prediction can be made as to the effect, if any, that future sales of common stock or the availability of common stock for future sales will have on the trading price of our common stock.

***A sale of a substantial number of shares of our common stock may cause the price of our common stock to decline.***

Sales of a substantial number of shares of our common stock in the public market could occur at any time. If our stockholders sell, or the market perceives that our stockholders intend to sell, substantial amounts of our common stock in the public market, the market price of our common stock could decline significantly.

We cannot predict what effect, if any, sales of our shares in the public market or the availability of shares for sale will have on the market price of our common stock. However, future sales of substantial amounts of our common stock in the public market, including shares issued upon exercise of outstanding options or warrants, or the perception that such sales may occur, could adversely affect the market price of our common stock.

We also expect that significant additional capital may be needed in the future to continue our planned operations. To raise capital, we may sell common stock, convertible securities or other equity securities in one or more transactions at prices and in a manner we determine from time to time. These sales, or the perception in the market that the holders of a large number of shares intend to sell shares, could reduce the market price of our common stock.

***If securities or industry analysts do not publish research or reports about our business, or if they issue an adverse or misleading opinion regarding our stock, our stock price and trading volume could decline.***

The trading market for our common stock will be influenced by the research and reports that industry or securities analysts publish about us or our business. We do not have any control over the analysts or the content and opinions included in their reports. If any of the analysts who cover us issue an adverse or misleading opinion regarding us, our business model, financial condition and results of operations, our intellectual property or our stock performance, or if our preclinical studies and clinical trials and operating results fail to meet the expectations of analysts, our stock price would likely decline. If one or more of such analysts cease coverage of us or fail to publish reports on us regularly, we could lose visibility in the financial markets, which in turn could cause a decline in our stock price or trading volume.

**The requirements of being a public company may strain our resources, divert management's attention and affect our ability to attract and retain additional executive management and qualified board members, particularly now that we are considered a large accelerated filer. The additional requirements we must comply with may strain our resources and divert management's attention from other business concerns.**

As a public company, we are subject to the reporting requirements of the Exchange Act, the Sarbanes-Oxley Act of 2002, or the Sarbanes-Oxley Act, the Dodd-Frank Wall Street Reform and Consumer Protection Act of 2010, the listing requirements of The Nasdaq Global Select Market, and other applicable securities rules and regulations. Compliance with these rules and regulations will increase our legal and financial compliance costs, make some activities more difficult, time-consuming, or costly, and increase demand on our systems and resources, particularly now that we are a large accelerated filer. The Exchange Act requires, among other things, that we file annual, quarterly, and current reports with respect to our business and operating results. The Sarbanes-Oxley Act requires, among other things, that we maintain effective disclosure controls and procedures and internal control over financial reporting. In order to maintain and, if required, improve our disclosure controls and procedures and internal control over financial reporting to meet this standard, significant resources and management oversight may be required. As a result, management's attention may be diverted from other business concerns, which could adversely affect our business and operating results. In order to comply with these requirements, we may need to hire more employees in the future or engage outside consultants, or may have difficulty attracting and retaining sufficient employees, which would increase our costs and expenses.

As a result of no longer being an emerging growth company, we will incur significant additional expenses that we did not previously incur in complying with the Sarbanes-Oxley Act and rules implemented by the SEC. The cost of compliance with Section 404 of the Sarbanes-Oxley Act has required, and will continue to require, us to incur substantial accounting expense and expend significant management time on compliance-related issues as we implement additional corporate governance practices and comply with reporting requirements.

We have also previously taken advantage of the reduced disclosure requirements of the Jumpstart Our Business Startups Act applicable to emerging growth companies regarding executive compensation disclosures and exemption from the requirements of holding advisory "say-on-pay" votes on executive compensation. We are no longer eligible for such reduced disclosure requirements and exemptions and, as such, we will be required to hold a "say-on-pay" vote and a "say-on-frequency" vote at our 2022 annual meeting of stockholders. We expect that the increased disclosure requirements will require additional attention from management and will result in increased costs to us, which could include higher legal fees, accounting fees, and fees associated with investor relations activities, among others.

In addition, changing laws, regulations, and standards relating to corporate governance, stockholder litigation, and public disclosure are creating uncertainty for public companies, increasing legal and financial compliance costs, making some activities more time consuming, and increasing the likelihood and expense of litigation. These laws, regulations, and standards are subject to varying interpretations, in many cases due to their lack of specificity, and, as a result, their application in practice may evolve or otherwise change over time as new guidance is provided by regulatory and governing bodies. This could result in continuing uncertainty regarding compliance matters, higher costs necessitated by ongoing revisions to disclosure and governance practices, and increased expenses and management attention due to actual or threatened litigation. We intend to invest resources to comply with evolving laws, regulations and standards (or changing interpretations of them), and this investment may result in increased general and administrative expenses and a diversion of management's time and attention from revenue-generating activities to compliance activities. If our efforts to comply with these laws, regulations, and standards differ from the activities intended by regulatory or governing bodies, regulatory authorities may initiate legal proceedings against us, and our business may be adversely affected. Being a public company and complying with the associated rules and regulations, and being subject to heightened likelihood of litigation, makes it more expensive for us to obtain director and officer liability insurance, the costs of which can fluctuate significantly from year-to-year due to general market conditions in obtaining such insurance, but in recent years have risen significantly, consistent with the increase in market rates. As a result, we may be required to accept reduced coverage, incur substantially higher costs to obtain coverage or may be unable to obtain coverage on economically reasonable terms, or at all. These factors could also make it more difficult for us to attract and retain qualified executives and qualified members of our board of directors, particularly to serve on our audit committee, our compensation committee, and our nominating and corporate governance committee.

As a result of disclosure of information in filings required of a public company, our business and financial condition has become more visible, which may result in threatened or actual litigation, including by competitors. If such claims are successful, our business and operating results could be adversely affected, and even if the claims do not result in litigation or are resolved in our favor, these claims, and the time and resources necessary to resolve them, could divert the resources of our management and adversely affect our business and operating results.

In addition, as a result of our disclosure obligations as a public company, we could face pressure to focus on short-term results, which may adversely affect our ability to achieve long-term profitability.

***We may be subject to securities litigation, which is expensive and could divert management attention.***

The market price of our common stock may be volatile and, in the past, companies that have experienced volatility in the market price of their stock have been subject to securities class action litigation. We may be the target of this type of litigation in the future. Securities litigation against us could result in substantial costs and divert our management's attention from other business concerns, which could seriously harm our business.

**Item 1B. Unresolved Staff Comments**

None

**Item 2. Properties and Facilities**

Our principal executive office is located in South San Francisco, California, where we lease approximately 115,466 square feet for our corporate headquarters and for our research and development and other activities. The lease expires in December 2027.

We also have a manufacturing facility and manufacturing-support facility in San Carlos, California, where we lease a total of approximately 29,600 square feet of space in two buildings. In June 2021, we extended the lease of the manufacturing facility and manufacturing-support facility for a period of five years. The lease on such facilities will expire in July 2026 and June 2026, respectively, and both lease terms include the option to renew the lease for an additional five years.

**Item 3. Legal Proceedings**

From time to time, we may be involved in legal proceedings arising in the ordinary course of our business. We are not presently a party to any legal proceedings that, in the opinion of management, would have a material adverse effect on our business. Regardless of outcome, litigation can have an adverse impact on us due to defense and settlement costs, diversion of management resources, negative publicity and reputational harm, and other factors.

**Item 4. Mine Safety Disclosures**

Not applicable.

## PART II

### **Item 5. Market for Registrant's Common Equity, Related Stockholder Matters, and Issuer Purchases of Equity Securities**

#### **Market Information for Common Stock**

Our common stock is listed on The Nasdaq Global Market under the symbol "STRO."

#### **Holders of Record**

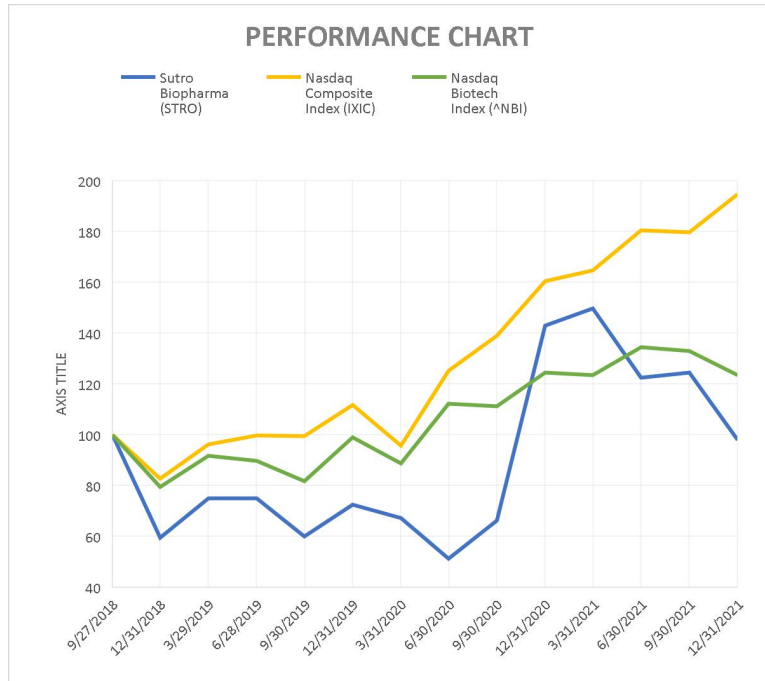
As of February 24, 2022, there were approximately 77 stockholders of record of our common stock. The actual number of stockholders is greater than this number of record holders, and includes stockholders who are beneficial owners, but whose shares are held in street name by brokers and other nominees. This number of holders of record also does not include stockholders whose shares may be held in trust by other entities.

#### **Dividend Policy**

We currently intend to retain future earnings, if any, for use in operation of our business and to fund future growth. We have never declared or paid any cash dividends on our capital stock and do not anticipate paying any cash dividends in the foreseeable future. Payment of cash dividends, if any, in the future will be at the discretion of our board of directors and will depend on then-existing conditions, including our financial condition, operating results, contractual restrictions, capital requirements, business prospects and other factors our board of directors may deem relevant.

## Stock Performance Graph

The following graph shows the total stockholder's return on an investment of \$100 in cash at market close on September 27, 2018 (the first day of trading of our common stock), through December 31, 2021 for (i) our common stock, (ii) the Nasdaq Composite Index and (iii) the Nasdaq Biotechnology Index. Pursuant to applicable Securities and Exchange Commission rules, all values assume reinvestment of pre-tax amount of all dividends; however, no dividends have been declared on our common stock to date. The stockholder return shown on the graph below is not necessarily indicative of future performance, and we do not make or endorse any predictions as to future stockholder return. This graph shall not be deemed "soliciting material" or be deemed "filed" for purposes of Section 18 of the Securities Exchange Act of 1934 as amended, or Exchange Act, or otherwise subject to the liabilities under that Section, and shall not be deemed to be incorporated by reference into any of our filings under the Securities Act of 1933, as amended, or Securities Act, whether made before or after the date hereof and irrespective of any general incorporation language in any such filing.



Trade Date	Sutro Biopharma (STRO)	Nasdaq Composite Index (IXIC)	Nasdaq Biotech Index (^NBI)
9/27/2018	100.00	100.00	100.00
12/31/2018	59.34	82.51	79.47
3/29/2019	74.93	96.11	91.71
6/28/2019	74.87	99.56	89.51
9/30/2019	59.80	99.47	81.67
12/31/2019	72.37	111.57	98.87
3/31/2020	67.11	95.75	88.57
6/30/2020	51.05	125.08	112.21
9/30/2020	66.12	138.87	111.15
12/31/2020	142.83	160.26	124.26
3/31/2021	149.74	164.72	123.37
6/30/2021	122.30	180.35	134.42
9/30/2021	124.28	179.66	132.78
12/31/2021	97.89	194.54	123.48



## **Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters**

The information required by this Item regarding equity compensation plans is incorporated by reference to the information set forth in Part III Item 12 of this Annual Report on Form 10-K.

### **Unregistered Sales of Equity Securities**

On November 18, 2021, we issued 9,308 shares of our common stock upon the cashless exercise of a warrant to purchase up to an aggregate of 25,453 shares of common stock. The warrant was exercised as to all 25,453 then-vested and exercisable shares. In lieu of a cash payment, the holder of the warrant surrendered 16,145 shares of common stock to cover the exercise price in accordance with the terms of the warrant. The offer, sale, and issuance of these securities was deemed to be exempt from registration under the Securities Act in reliance on Section 4(a)(2) of the Securities Act. The recipient of the securities was an accredited or sophisticated person and had adequate access, through business or other relationships, to information about us.

### **Purchases of Equity Securities by the Issuer and Affiliated Purchasers**

None.

### **Item 6. [Reserved]**

## Item 7. Management's Discussion and Analysis of Financial Condition and Results of Operations

*The following discussion should be read in conjunction with the attached financial statements and notes thereto. This Annual Report on Form 10-K, including the following sections, contains forward-looking statements within the meaning of the federal securities laws. These statements are subject to risks and uncertainties that could cause actual results and events to differ materially from those expressed or implied by such forward-looking statements. For a detailed discussion of these risks and uncertainties, see the "Risk Factors" section in Item 1A of this Annual Report on Form 10-K. We caution the reader not to place undue reliance on these forward-looking statements, which reflect management's analysis only as of the date of this Form 10-K. We undertake no obligation to update forward-looking statements, which reflect events or circumstances occurring after the date of this Form 10-K.*

### Overview

We are a clinical stage drug discovery, development and manufacturing company focused on deploying our proprietary integrated cell-free protein synthesis platform, XpressCF®, and our site specific conjugation platform, XpressCF+®™, to create a broad variety of optimally designed, next-generation protein therapeutics, initially for cancer. We aim to design therapeutics using the most relevant and potent modalities, including cytokine-based therapeutics, immunoncology, or I/O agents, antibody-drug conjugates, or ADCs, immunostimulatory ADCs, or iADCs, and bispecific antibodies that are directed primarily against clinically validated targets where the current standard of care is suboptimal. We believe our platform allows us to accelerate the discovery and development of potential first-in-class and best-in-class molecules by enabling the rapid and systematic evaluation of protein structure-activity relationships to create optimized homogeneous product candidates. Our mission is to transform the lives of patients by using our XpressCF® platform to create medicines with improved therapeutic profiles for areas of unmet need.

Once identified, production of protein drug candidates can be rapidly and predictably scaled in our current Good Manufacturing Practices compliant manufacturing facility. We have the ability to manufacture our cell-free extract that supports our production of proteins on a large scale using a semi-continuous fermentation process. Our two most advanced product candidates are wholly owned: STRO-002, an ADC directed against folate receptor-alpha, or FolRα, for patients with FolRα-expressing cancers, such as ovarian and endometrial cancers, and STRO-001, an ADC directed against CD74, for patients with B-cell malignancies, such as multiple myeloma and non-Hodgkin lymphoma, or NHL.

STRO-002 was designed and optimized for an improved therapeutic index by placing a precise number of linker-warheads at four specific locations within the antibody using our proprietary XpressCF+®™ platform. Our first Phase 1 trial for STRO-002 is an open-label study evaluating STRO-002 as a monotherapy for patients with ovarian and endometrial cancers. This trial is being conducted in two-parts, dose escalation and dose expansion. The primary objectives of the STRO-002 clinical trial are to determine the safety and tolerability profile, to define the recommended Phase 2 dose level and interval and to evaluate preliminary anti-tumor activity. Our secondary objectives are to characterize the human pharmacokinetics and additional safety, tolerability and efficacy measures.

We are developing STRO-001, an optimally designed ADC directed against the cancer target CD74, for multiple myeloma and NHL. STRO-001 was designed and optimized for maximal therapeutic index by placing linker-warheads at specific locations within the antibody using our proprietary XpressCF+®™ platform. The Phase 1 trial for STRO-001 is an open-label study that is evaluating STRO-001 as a monotherapy for patients with multiple myeloma and NHL. The trial is being conducted in two parts: dose escalation and dose expansion. The primary objectives of the trial are to determine the safety and tolerability profile of STRO-001, determine the recommended Phase 2 dose and interval and evaluate preliminary anti-tumor activity. The secondary objectives are to characterize the human pharmacokinetics of STRO-001 and additional safety, tolerability and efficacy measures.

In March 2019, STRO-002 began enrolling patients in a Phase 1 trial focused on ovarian and endometrial cancers. The dose escalation portion of the STRO-002 Phase 1 trial has been completed and the dose expansion portion of the trial is ongoing to assess the efficacy, safety and tolerability of STRO-002 at dose levels of 4.3 and 5.2 mg/kg. In May 2021, we reported data from the dose-escalation cohort. Based on such reported data, STRO-002 exhibited a manageable safety profile and promising preliminary efficacy data, as discussed in more detail in Item 1 of Part I "Business" of this document. In January 2022, we released initial results of the dose expansion

portion of the STRO-002 Phase 1 trial. These data suggested that STRO-002 exhibited a manageable safety profile together with promising preliminary efficacy data in the tested patient population, as discussed in more detail in Item 1 of Part I "Business" of this document. In August 2021, we were granted Fast Track designation for STRO-002 by the FDA for the treatment of patients with platinum-resistant epithelial ovarian, fallopian tube, or primary peritoneal cancer who have received one to three prior lines of systemic therapy. In December 2021, we entered into a licensing agreement with Tasly Biopharmaceuticals Co., Ltd, or Tasly, to grant Tasly an exclusive license to develop and commercialize STRO-002 in China, Hong Kong, Macau and Taiwan, referred to as Greater China, or the Tasly License Agreement.

Our second candidate, STRO-001, is currently enrolling patients in a Phase 1 trial, with updated data reported in December 2020, as discussed in more detail in Item 1 of Part I "Business" of this document. Based on such reported data, STRO-001 has been generally well-tolerated and, unlike certain other ADCs, no ocular toxicity signals have been observed, with no patients receiving prophylactic corticosteroid eye drops. Dose escalation in the STRO-001 Phase 1 trial is continuing, and the maximum tolerated dose has not yet been reached. In October 2018, we were granted Orphan Drug Designation by the FDA for STRO-001 for the treatment of multiple myeloma. In October 2021, we granted BioNova Pharmaceuticals Limited, or BioNova, an option to exclusively license the right to develop and commercialize STRO-001 in Greater China, or the BioNova Option Agreement.

Based on our proprietary XpressCF<sup>®</sup> and XpressCF+<sup>®</sup>™ platforms, we have also entered into multi-target, product-focused collaborations with leaders in the field of oncology, including a cytokine derivatives collaboration with Merck Sharp & Dohme Corp., a subsidiary of Merck & Co., Inc., Kenilworth, NJ, or Merck; a B Cell Maturation Antigen, or BCMA, ADC collaboration with Celgene Corporation, or Celgene, a wholly owned subsidiary of Bristol-Myers Squibb Company, New York, NY, or BMS; a MUC1-EGFR ADC collaboration with Merck KGaA, Darmstadt Germany (operating in the United States and Canada under the name "EMD Serono"); and license agreement to develop and commercialize STRO-002 in Greater China with Tasly. Our XpressCF<sup>®</sup> and XpressCF+<sup>®</sup>™ platforms have also supported a spin-out company, Vaxcyte Inc., or Vaxcyte, focused on discovery and development of vaccines for the treatment and prophylaxis of infectious disease.

Since the commencement of our operations, we have devoted substantially all of our resources to performing research and development and manufacturing activities in support of our own product development efforts and those of our collaborators, raising capital to support and expand such activities and providing general and administrative support for these operations. We have funded our operations to date primarily from upfront, milestone and other payments under our collaboration agreements with BMS, Merck and EMD Serono, the issuance and sale of redeemable convertible preferred stock, our initial public offering, or IPO, follow-on public offerings of common stock and debt proceeds.

We do not have any products approved for commercial sale and have not generated any revenue from commercial product sales. We had a loss from operations of \$98.5 million and a net loss of \$105.5 million for the year ended December 31, 2021, which net loss included the non-operating, unrealized loss of \$4.5 million related to our holdings of Vaxcyte common stock. We had a loss from operations of \$71.1 million and net loss of \$32.1 million, due principally to an unrealized gain of \$41.5 million related to our holdings of Vaxcyte common stock, for the year ended December 31, 2020. Substantially all of our losses have resulted from expenses incurred in connection with our research and development programs and from general and administrative costs associated with our operations. We cannot assure you that we will have net income or that we will generate positive cash flow from operating activities in the future. As of December 31, 2021, we had an accumulated deficit of \$333.4 million. We do not expect to generate any revenue from commercial product sales unless and until we successfully complete development and obtain regulatory approval for one or more of our product candidates, which we expect will take a number of years. If we obtain regulatory approval for any of our product candidates, we expect to incur significant commercialization expenses related to product sales, marketing, manufacturing and distribution. We expect our operating expenses to significantly increase as we continue to develop, and seek regulatory approvals for, our product candidates, engage in other research and development activities, expand our pipeline of product candidates, continue to develop our manufacturing facility and capabilities, maintain and expand our intellectual property portfolio, seek regulatory and marketing approval for any product candidates that we may develop, acquire or in-license other assets or technologies, ultimately establish a sales, marketing and distribution infrastructure to commercialize any products for which we may obtain marketing approval, and operate as a public company. Our net losses may fluctuate significantly from quarter-to-quarter and year-to-year, depending on the timing of our clinical trials, our expenditures on other research and development activities and the timing of achievement and receipt of upfront, milestones and other collaboration agreement payments.

## **Impacts of the COVID-19 Pandemic**

The extent of the impact of COVID-19 on our operational and financial performance will depend on certain developments, including the duration and spread of the pandemic, impacts on our clinical studies, employee or industry events, and effects on our collaboration partners, suppliers, service providers and manufacturers, all of which are uncertain and cannot be predicted. The COVID-19 pandemic and its adverse effects have become more prevalent in the locations where we, our CROs, suppliers or third-party business partners conduct business. We are experiencing the impact of the COVID-19 pandemic on our business through increased cost and delays in the availability of materials routinely used in biologic therapeutic development and manufacturing, which has the potential to cause delays in our research, development and/or manufacturing activities, but overall patient enrollment and treatment remains on track. Additionally, the COVID-19 pandemic has had, and is expected to continue to have, an adverse impact on our operations, particularly as a result of preventive and precautionary measures that we, other businesses, and governments are taking. We may experience more pronounced and significant disruptions in our operations, liquidity, supply chain, facilities, and clinical trials in the future as well. With respect to our clinical trials, we have experienced minor delays in enrollment and occasional delays in data entry by trial sites, but overall enrollment and treatment remains on track. We may in the future experience more significant delays in enrollment, participant dosing, distribution of clinical trial materials, study monitoring and data analysis that could materially adversely impact our business, results of operations, revenue earned from our collaboration partners, and overall financial performance in future periods. Specifically, we may experience impact from changes in how we and companies worldwide conduct business due to the COVID-19 pandemic, including but not limited to restrictions on travel and in-person meetings, the speed and breadth of mass vaccinations for COVID-19 and the efficacy of such vaccines, delays in site activations and enrollment of clinical trials, prioritization of hospital resources toward pandemic effort, delays in review by the FDA and comparable foreign regulatory agencies, limitations on employee resources that would otherwise be focused on the conduct of our research, preclinical studies, clinical trials and manufacturing operations, including because of sickness of employees or their families, the desire of employees to avoid contact with large groups of people, an increased reliance on working from home or mass transit disruptions, and disruptions in our supply chain for our product candidates. Additionally, increased reliance on remote work by our employees as a result of the COVID-19 pandemic poses incremental increased cybersecurity risks as our employees' home networks are inherently less secure than our corporate networks. As of the filing date of this Form 10-K, the extent to which the COVID-19 pandemic may impact our financial condition, results of operations or guidance is uncertain. The effect of the COVID-19 pandemic will not be fully reflected in our results of operations and overall financial performance until future periods. See the section titled "Risk Factors" for further discussion of the possible impact of the ongoing COVID-19 pandemic on our business.

*A discussion and analysis of our financial condition, results of operations, and cash flows for the year ended December 31, 2019 is included in Item 7 of Part II "Management's Discussion and Analysis of Financial Condition and Results of Operations" in our Annual Report on Form 10-K for the year ended December 31, 2020 filed with the SEC on March 18, 2021.*

## **Financial Operations Overview**

### ***Revenue***

We do not have any products approved for commercial sale and have not generated any revenue from commercial product sales. Our total revenue to date has been generated principally from our collaboration and license agreements with BMS, Merck, and EMD Serono, and to a lesser extent, from manufacturing, supply and services and materials we provide to the above collaborators and to Vaxcyte.

We derive revenue from collaboration arrangements, under which we may grant licenses to our collaboration partners to further develop and commercialize our proprietary product candidates. We may also perform research and development activities under the collaboration agreements. Consideration under these contracts generally includes a nonrefundable upfront payment, development, regulatory and commercial milestones and other contingent payments, and royalties based on net sales of approved products. Additionally, the collaborations may provide options for the customer to acquire from us materials and reagents, clinical product supply or additional research and development services under separate agreements. We assess which activities in the collaboration agreements are considered distinct performance obligations that should be accounted for separately. We develop assumptions that require judgement to determine whether the license to our intellectual property is distinct from the research and development services or participation in activities under the collaboration agreements.

At the inception of each agreement, we determine the arrangement transaction price, which includes variable consideration, based on the assessment of the probability of achievement of future milestones and contingent payments and other potential consideration. We recognize revenue over time by measuring our progress towards the complete satisfaction of the relevant performance obligation using an appropriate input or output method based on the nature of the service promised to the customer.

For arrangements that include multiple performance obligations, we allocate the transaction price to the identified performance obligations based on the standalone selling price, or SSP, of each distinct performance obligation. In instances where SSP is not directly observable, we develop assumptions that require judgment to determine the SSP for each performance obligation identified in the contract. These key assumptions may include full-time equivalent, or FTE, personnel effort, estimated costs, discount rates and probabilities of clinical development and regulatory success.

Please see further discussion on the revenue recognition treatment of performance obligations under Critical Accounting Policies and Estimates.

### ***Operating Expenses***

#### ***Research and Development***

Research and development expenses represent costs incurred in performing research, development and manufacturing activities in support of our own product development efforts and those of our collaborators, and include salaries, employee benefits, stock-based compensation, laboratory supplies, outsourced research and development expenses, professional services and allocated facilities-related costs. We expense both internal and external research and development costs as they are incurred. Non-refundable advance payments for services that will be used or rendered for future research and development activities are recorded as prepaid expenses and recognized as expenses as the related services are performed.

We expect our research and development expenses to increase in the future as we advance our product candidates into and through preclinical studies and clinical trials, pursue regulatory approval of our product candidates, expand our pipeline of product candidates and continue to develop our manufacturing facility and capabilities. The process of conducting the necessary preclinical and clinical research to obtain regulatory approval is costly and time consuming. The actual probability of success for our product candidates may be affected by a variety of factors including: the safety and efficacy of our product candidates, early clinical data, investment in our clinical programs, the ability of collaborators to successfully develop our licensed product candidates, competition, manufacturing capability and commercial viability. We may never succeed in achieving regulatory approval for any of our product candidates. As a result of the uncertainties discussed above, we are

unable to determine the duration and completion costs of our research and development projects or when and to what extent we will generate revenue from the commercialization and sale of our product candidates.

The following table summarizes our research and development expenses incurred during the periods indicated. The internal costs include personnel, facility costs and research and scientific related activities associated with our pipeline. The external program costs reflect external costs attributable to our clinical development candidates and preclinical candidates selected for further development. Such expenses include third-party costs for preclinical and clinical studies and research, development and manufacturing services, and other consulting costs.

	Year ended December 31,	
	2021	2020
	(in thousands)	
<b>Internal costs:</b>		
Research and drug discovery	\$ 25,908	\$ 19,043
Process and product development	15,514	11,222
Manufacturing	31,336	23,455
Clinical development	6,009	2,637
Total internal costs	78,767	56,357
<b>External Program Costs:</b>		
Research and drug discovery	1,518	1,146
Toxicology and translational science	1,227	1,030
Process and product development	314	376
Manufacturing	12,822	11,925
Clinical development	9,752	6,127
Total external program costs	25,633	20,604
Total research and development expenses	\$ 104,400	\$ 76,961

#### **General and Administrative**

Our general and administrative expenses consist primarily of personnel costs, expenses for outside professional services, including legal, human resources, audit, accounting and tax services and allocated facilities-related costs. Personnel costs include salaries, employee benefits and stock-based compensation. We expect to incur additional expenses operating as a public company, including expenses related to compliance with the rules and regulations of the SEC and listing standards applicable to companies listed on the Nasdaq Global Market, additional insurance expenses, investor relations activities and other administrative and professional services. We also expect to increase the size of our administrative function and our general and administrative expenses to support the anticipated growth of our business, as we continue to advance our product candidates into and through the clinic.

#### **Interest Income**

Interest income consists primarily of interest earned on our invested funds.

#### **Unrealized Gain (Loss) on Equity Securities**

Unrealized gain (loss) on equity securities consists of the remeasurement of our investment in Vaxcyte common stock.

#### **Interest and Other Expense, Net**

Interest expense includes interest incurred on our debt and amortization of debt issuance costs including accretion of final payment. Additionally, the Company identified a financing component under the Merck 2018 Agreement and recorded interest expense associated with the upfront payment. Other income (expense) includes changes in values attributable to the arrangement with the Call Option Plan as defined in the notes to our financial statements included elsewhere in this report.

**Comparison of the Years Ended December 31, 2021 and 2020**

	Year ended December 31,		Change	
	2021	2020	\$	%
	(in thousands)			
Revenue	\$ 61,880	\$ 42,722	\$ 19,158	45 %
Operating expenses:				
Research and development	104,400	76,961	27,439	36 %
General and administrative	56,004	36,818	19,186	52 %
Total operating expenses	160,404	113,779	46,625	41 %
Loss from operations	(98,524)	(71,057)	(27,467)	39 %
Interest income	577	1,508	(931)	(62)%
Unrealized (loss) gain on equity securities	(4,454)	41,498	(45,952)	(111)%
Interest and other expense, net	(3,137)	(4,077)	940	(23)%
Net loss	<u>\$ (105,538)</u>	<u>\$ (32,128)</u>	<u>\$ (73,410)</u>	<u>228 %</u>

**Revenue**

We have recognized revenue as follows during the periods indicated:

	Year Ended December 31,		Change	
	2021	2020	\$	%
	(in thousands)			
Bristol-Myers Squibb Company ("BMS")	\$ 11,483	\$ 11,407	\$ 76	1 %
Merck Sharp & Dohme Corporation ("Merck") (1)	42,780	26,075	16,705	64 %
Merck KGaA, Darmstadt, Germany (operating in the United States and Canada under the name "EMD Serono")	4,576	5,042	(466)	(9)%
Vaxcyte (2)	3,041	198	2,843	1,436 %
Total revenue	<u>\$ 61,880</u>	<u>\$ 42,722</u>	<u>\$ 19,158</u>	<u>45 %</u>

(1)Merck was a related party until the closing of our public offering on May 14, 2020.

(2)Vaxcyte was a related party until the closing of its initial public offering on June 16, 2020.

Total revenue increased by \$19.2 million, or 45%, during the year ended December 31, 2021 as compared to the year ended December 31, 2020. This was due primarily to \$16.7 million from Merck, primarily related to increased revenue from performance obligations, with full recognition of revenue associated with the contingent third program upon the determination that the related performance obligation had terminated during the first quarter of 2021, and a cumulative catch-up in revenue as a result of the change in transaction price, due to a \$15.0 million contingent payment earned in the second quarter of 2021 for the initiation of the first IND-enabling toxicology study under the first program in the collaboration. There was also a \$4.1 million increase in contract research and manufacturing activities supporting materials supply. The Merck revenue increases noted above were partially offset by a \$2.8 million decrease in research and development services and a \$1.2 million decrease related to the financing component associated with the upfront payment. Revenue from Vaxcyte under our supply agreement increased by \$2.8 million, partially offset by an overall \$0.5 million decrease in revenue from EMD Serono.

**Research and Development Expense**

Research and development expense increased by \$27.4 million, or 36%, during the year ended December 31, 2021 as compared to the year ended December 31, 2020. The increase was due primarily to increases of \$11.2 million in personnel-related expenses due to higher headcount, \$6.3 million in laboratory supplies and production materials-related expenses, \$4.8 million in facilities-related expenses, \$3.4 million in clinical trial costs, \$1.5 million in consulting and outside services, and \$0.2 million in equipment and office-related expenses.

### **General and Administrative Expense**

General and administrative expense increased by \$19.2 million, or 52%, during the year ended December 31, 2021 as compared to the year ended December 31, 2020. The increase was due primarily to increases of \$11.4 million in personnel-related expenses due to higher headcount, \$3.2 million in insurance and external services, \$3.6 million in facilities-related expenses, and \$1.0 million in equipment and office-related expenses.

### **Interest Income**

Interest income decreased by \$0.9 million during the year ended December 31, 2021 as compared to the year ended December 31, 2020, due primarily to a \$2.3 million decrease in the amortization of premiums on investments, partially offset by an increase of \$1.4 million from higher average investment balances in 2021.

### **Unrealized (Loss) Gain on Equity Securities**

Unrealized (loss) on equity securities was \$4.5 million during the year ended December 31, 2021 as compared to an unrealized gain of \$41.5 million for the year ended December 31, 2020. The unrealized (loss) gain on equity securities in each period was entirely due to the remeasurement of the estimated fair value of our investment in Vaxcyte common stock.

### **Interest and Other Expense, Net**

Interest and other expense, net decreased by \$0.9 million during the year ended December 31, 2021 as compared to the year ended December 31, 2020, due primarily to a \$1.2 million decrease in interest expense associated with the financing component related to the 2018 Merck Agreement, partially offset by a \$0.3 million increase in interest expense related to our outstanding debt.

## **Liquidity and Capital Resources**

### **Sources of Liquidity**

To date, we have incurred significant net losses, and negative cash flows from operations. Our operations have been funded primarily by payments received from our collaborators, and net proceeds from equity sales and debt. As of December 31, 2021, we had \$229.5 million in cash, cash equivalents and marketable securities, outstanding debt of \$25.1 million and an accumulated deficit of \$333.4 million.

### **2021 Contingent Payment from Merck**

During the year ended December 31, 2021, we earned and received a \$15.0 million contingent payment from Merck for the initiation of an IND enabling toxicology study for the first program in our collaboration to develop novel cytokine derivative therapeutics for cancer.

### **2020 Public Offerings**

On May 14, 2020, we closed a public offering of 12,650,000 shares of our common stock at a public offering price of \$7.75 per share, which included the exercise in full of the underwriters' option to purchase 1,650,000 shares of common stock. Our net proceeds from this offering, after deducting underwriting discounts and commissions and other offering expenses, was approximately \$91.4 million.

On December 11, 2020, we closed a public offering of 6,900,000 shares of our common stock at a public offering price of \$21.00 per share, which included the exercise in full of the underwriters' option to purchase 900,000 shares of common stock. Our net proceeds from this offering, after deducting underwriting discounts and commissions and other offering expenses, was approximately \$135.8 million.



### **At-The-Market Sales**

During the year ended December 31, 2020, we sold an aggregate of 2,614,286 shares of our common stock through our At-the-Market ATM facility, or ATM Facility, pursuant to a sales agreement dated October 4, 2019 with Cowen and Company, LLC, as sales agent. The gross proceeds from these sales were approximately \$24.6 million, before deducting fees of approximately \$0.8 million, resulting in net proceeds of approximately \$23.8 million. During the year ended December 31, 2021, we did not sell any shares under an ATM facility.

### **Vaxcyte, Inc. Equity Ownership**

In June 2020, Vaxcyte closed an initial public offering of its common stock at a price per share of \$16.00. The Vaxcyte common stock held by us is measured at fair value at each reporting period based on the closing price of Vaxcyte's common stock on the last trading day of each reporting period, adjusted for a discount for lack of marketability due to the presence of a lock-up agreement during certain periods in 2020, with any unrealized gains and losses recorded in our statements of operations. The lock-up agreement expired in December 2020. As of December 31, 2021, we held 1,562,879 shares of Vaxcyte common stock with an estimated fair value of \$37.2 million.

### **Term Loan**

On February 28, 2020, or the Effective Date, we entered into a loan and security agreement, or the Loan and Security Agreement, with Oxford Finance LLC, or Oxford, as the collateral agent and a lender, and Silicon Valley Bank, as a lender, together with Oxford, the Lenders, pursuant to which the Lenders have agreed to lend us up to an aggregate of \$25.0 million, or the Term A Loan. Upon entering into the Loan and Security Agreement, we borrowed \$25.0 million from the Lenders, with approximately \$9.6 million of such amount applied to the repayment of the outstanding principal, interest and final payment fees owed pursuant to the prior loan and security agreement dated August 4, 2017.

The proceeds from the Term A Loan under the Loan and Security Agreement may be used to satisfy our future working capital needs and to fund our general business requirements. Our obligations under the Loan and Security Agreement are secured by all our assets, other than our intellectual property. We have also agreed not to encumber our intellectual property assets, except as permitted by the Loan and Security Agreement.

The Term A Loan matures on March 1, 2024, or the Maturity Date, and will be interest-only through March 1, 2022, followed by 24 equal monthly payments of principal and interest. The Term A Loan will bear interest at a floating per annum rate equal to the greater of (i) 8.07% or (ii) the sum of (a) the greater of (1) the thirty (30) day U.S. LIBOR rate reported in the Wall Street Journal on the last business day of the month that immediately precedes the month in which the interest will accrue or (2) 1.67%, plus (b) 6.40%.

We will be required to make a final payment of 3.83% of the original principal amount of the Term A Loan drawn, payable on the earlier of (i) the Maturity Date, (ii) the acceleration of the Term A Loan, or (iii) the prepayment of the Term A Loan, or the Final Payment. We may prepay all, but not less than all, of the Term A Loan upon 30 days' advance written notice to Oxford, provided that we will be obligated to pay a prepayment fee equal to (i) 3.00% of the principal amount of the Term A Loan prepaid on or before the first anniversary of the applicable funding date, or (ii) 2.00% of the principal amount of the Term A Loan prepaid between the first and second anniversary of the applicable funding date, or (iii) 1.00% of the principal amount of the Term A Loan prepaid thereafter, and prior to the Maturity Date, each, a Prepayment Fee.

The Loan and Security Agreement contains customary affirmative and restrictive covenants, including covenants regarding incurrence of additional indebtedness or liens, investments, transactions with affiliates, delivery of financial statements, maintenance of inventory, payment of taxes, maintenance of insurance, protection of intellectual property rights, dispositions of property, business combinations or acquisitions, among other customary covenants. We are also restricted from paying dividends or making other distributions or payments on our capital stock, subject to limited exceptions. The Loan and Security Agreement provides that an event of default will occur if, among other triggers, there occurs any circumstances that could reasonably be expected to result in a material adverse change in our business, or operations or condition (financial or otherwise) or a material impairment of the prospect of us to repay any portion of our obligations under the Loan and Security Agreement. The Loan and Security Agreement also includes customary representations and warranties, other events of default and termination provisions.

In connection with entering into the Loan and Security Agreement, we issued to the Lenders warrants exercisable for 81,257 shares of our common stock, or the Debt Warrants. The Debt Warrants are exercisable in whole or in part, immediately, and have a per share exercise price of \$9.23, which is the closing price of our common stock reported on the Nasdaq Global Market on the day prior to the Effective Date. The Debt Warrants will terminate on the earlier of February 28, 2030 or the closing of certain merger or consolidation transactions.

### **Leases**

In June 2021, we entered into a third amendment, or Third Amendment, to our manufacturing facility lease, dated May 18, 2011, as amended, by and between Alemany Plaza LLC, located at San Carlos, California, or San Carlos Lease, as an extension to the term of the San Carlos Lease for a period of five years, or the Lease Extension Period. Pursuant to the Third Amendment, the San Carlos Lease will expire on July 31, 2026, and it includes an option to renew the San Carlos Lease for an additional five years. The aggregate estimated base rent payments due over the Lease Extension Period is approximately \$4.2 million, subject to certain terms contained in the San Carlos Lease.

In June 2021, we entered into a first amendment, or the First Amendment, to our manufacturing facility lease, dated May 4, 2015, as amended, by and between 870 Industrial Road LLC, located at San Carlos, California, or the Industrial Lease, as an extension to the term of the Industrial Lease for a period of five years, or the Industrial Lease Extension Period. Pursuant to the first Amendment, the Industrial Lease will expire on June 30, 2026, and it includes an option to renew the Industrial Lease for an additional five years. The aggregate estimated base rent payments due over the Industrial Lease Extension Period is approximately \$4.3 million, subject to certain terms contained in the Industrial Lease.

In September 2020, the Company entered into a sublease agreement, or the Sublease with Five Prime Therapeutics, Inc., or the Sublessor, for approximately 115,466 square feet, in a building located in South San Francisco, California, or the Premises. The Company uses the Premises as its new corporate headquarters and to conduct (or expand) research and development activities. The Company commenced making monthly payments for the first 85,755 square feet of the Premises, or Initial Premises, in July 2021, with occupancy of such space commencing in August 2021. The Company was provided early access to the Initial Premises in the fourth quarter of 2020 to conduct certain planning and tenant improvement work. The Sublease is subordinate to the lease agreement, effective December 12, 2016, between the Sublessor and HCP Oyster Point III LLC, or the Landlord. The commencement date for the remaining 29,711 square feet of the Premises, or the Expansion Premises, is expected to be 24 months following the commencement date on the Initial Premises. However, the Company has the right to accelerate the commencement date on the Expansion Premises to an earlier date upon six months' prior written notice to the Sublessor. The Sublease for both the Initial Premises and Expansion Premises will expire on December 31, 2027. With a commencement date on the Initial Premises of July 1, 2021, the aggregate estimated base rent payments due over the term of the Sublease are approximately \$39.1 million, including the approximately \$5.2 million in potential financial benefit to the Company of base rent abatement to be provided by the Sublessor, subject to certain terms contained in the Sublease. The Sublease contains customary provisions requiring the Company to pay its pro rata share of utilities and a portion of the operating expenses and certain taxes, assessments and fees of the Premises and provisions allowing the Sublessor to terminate the Sublease upon the termination of the lease with the Landlord or if the Company fails to remedy a breach of certain of its obligations within specified time periods. Additionally, the Company posted a security deposit of \$0.9 million, which is reflected as restricted cash in non-current assets on the Company's balance sheet as of December 31, 2021 and 2020.

### ***Funding Requirements***

Based upon our current operating plan, we believe that our existing capital resources will enable us to fund our operating expenses and capital expenditure requirements through at least the next twelve months after the date of this filing. We have based this estimate on assumptions that may prove to be wrong, and we could utilize our available capital resources sooner than we currently expect. We will continue to require additional financing to advance our current product candidates into and through clinical development, to develop, acquire or in-license other potential product candidates, pay our obligations and to fund operations for the foreseeable future.

We may seek to raise any necessary additional capital through a combination of public or private equity offerings, debt financings, collaborations, strategic alliances, licensing arrangements, marketing and distribution arrangements, or other sources of financing. Adequate additional funding may not be available to us on acceptable terms, or at all. Any failure to raise capital as and when needed could have a negative impact on our financial condition and on our ability to pursue our business plans and strategies, and may cause us to delay, reduce the scope of or suspend one or more of our pre-clinical and clinical studies, research and development programs or commercialization efforts, and may necessitate us to delay, reduce or terminate planned activities in order to reduce costs. Due to the numerous risks and uncertainties associated with the development and commercialization of our product candidates and the extent to which we may enter into additional collaborations with third parties to participate in their development and commercialization, we are unable to estimate the amounts of increased capital outlays and operating expenditures associated with our current and anticipated clinical studies.

To the extent we raise additional capital through new collaborations, strategic alliances or licensing arrangements with third parties, we may have to relinquish valuable rights to our product candidates, future revenue streams, research programs or product candidates or to grant licenses on terms that may not be favorable to us. If we do raise additional capital through public or private equity or convertible debt offerings, the ownership interest of our existing stockholders will be diluted, and the terms of these securities may include liquidation or other preferences that adversely affect our stockholders' rights. If we raise additional capital through debt financing, we may be subject to covenants limiting or restricting our ability to take specific actions, such as incurring additional debt, making capital expenditures or declaring dividends.

## Cash Flows

The following table summarizes our cash flows during the periods indicated:

	Year Ended December 31,	
	2021	2020
	(in thousands)	
Cash used in operating activities	\$ (81,679 )	\$ (67,802 )
Cash (used in) provided by investing activities	(97,315 )	604
Cash provided by financing activities	3,256	269,247
Net (decrease) increase in cash, cash equivalents and restricted cash	<u>\$ (175,738 )</u>	<u>\$ 202,049</u>

### *Cash Flows from Operating Activities*

Cash used in operating activities for the year ended December 31, 2021 was \$81.7 million. Our net loss of \$105.5 million included \$4.5 million of unrealized loss on equity securities as a result of the remeasurement of the estimated fair value of our investment in Vaxcyte common stock, non-cash charges of \$23.2 million for stock-based compensation, \$4.8 million for depreciation and amortization, \$4.9 million for noncash lease expenses, \$2.8 million for the amortization of premiums on our marketable securities, and \$1.2 million in other non-cash charges. Cash used in operating activities also reflected a net change in operating assets and liabilities of \$17.6 million, due to an increase of \$6.9 million in accounts receivable from our collaborators, a decrease of \$15.2 million in our deferred revenue balance from revenue recognized under our collaboration agreements, an increase of \$4.0 million in prepaid expenses and other assets, and a decrease of \$2.7 million in our operating lease liability, which were partially offset by an increase of \$8.6 million in accounts payable and other liabilities due to timing of payments, and an increase of \$2.6 million in accrued compensation due to increased headcount.

Cash used in operating activities for the year ended December 31, 2020 was \$67.8 million. Our net loss of \$32.1 million included \$41.5 million of unrealized gain on equity securities as a result of the remeasurement of the estimated fair value of our investment in Vaxcyte common stock, and was partially offset by non-cash charges of \$11.9 million for stock-based compensation, \$4.3 million for depreciation and amortization, \$0.2 million related to revaluation of the vested options under the Call Option Plan, \$0.5 million for the amortization of premiums on our marketable securities, and \$0.3 million for the amortization of debt issuance costs. Cash used in operating activities also reflected a net change in operating assets and liabilities of \$11.5 million, due principally to a decrease of \$15.0 million in our deferred revenue balance from revenue recognized under our collaboration agreements, which was partially offset by an increase of \$2.8 million in accrued compensation due to increased headcount and bonuses resulting from certain company goal achievements and a decrease of \$0.7 million in accounts receivable from our collaborators.

### *Cash Flows from Investing Activities*

Cash used in investing activities of \$97.3 million for the year ended December 31, 2021 was primarily related to purchases of marketable securities of \$248.7 million and purchases of property and equipment of \$15.3 million, principally for leasehold improvements to the premises under the Sublease, offset partially by maturities and sales of marketable securities of \$166.7 million.

Cash provided by investing activities of \$0.6 million for the year ended December 31, 2020 was primarily related to purchases of marketable securities of \$130.7 million and purchases of property and equipment of \$7.1 million, principally for laboratory and manufacturing equipment, offset partially by maturities and sales of marketable securities of \$138.4 million.

### *Cash Flows from Financing Activities*

Cash provided by financing activities of \$3.3 million for the year ended December 31, 2021 was primarily related to \$2.5 million of proceeds received from the exercise of common stock options, and \$1.8 million of net proceeds received from participants in our employee equity plans, partially offset by a \$1.0 million tax payment related to the net share settlement of certain vested restricted stock units.

Cash provided by financing activities of \$269.2 million for the year ended December 31, 2020 was primarily related to \$251.4 million of net proceeds from the issuance of common stock from our public offering and the sales of common stock pursuant to our ATM Facility, \$25.0 million of gross proceeds from our debt refinancing, and \$2.8 million of net proceeds received from participants in our employee equity plans and from the exercise of common stock options, partially offset by a \$10.0 million repayment of the August 2017 Loan (as defined in Note 7 to our financial statements included elsewhere in this report).

### **Contractual Obligations and Other Commitments**

In addition to the contractual obligations and commitments as noted above and elsewhere in this Annual report with regards to the leases and term loans, we enter into agreements in the normal course of business, including with contract research organizations for clinical trials, contract manufacturing organizations for certain manufacturing services, and vendors for preclinical studies and other services and products for operating purposes, which are generally cancelable upon written notice.

### **Critical Accounting Policies and Estimates**

Our management's discussion and analysis of our financial condition and results of operations is based on our financial statements, which have been prepared in accordance with United States generally accepted accounting principles. The preparation of these financial statements requires us to make estimates and assumptions that affect the reported amounts of assets and liabilities and the disclosure of contingent assets and liabilities at the date of the financial statements, as well as the reported revenue generated and expenses incurred during the reporting periods. Our estimates are based on our historical experience and on various other factors that we believe are reasonable under the circumstances, the results of which form the basis for making judgments about the carrying value of assets and liabilities that are not readily apparent from other sources. Actual results may differ from these estimates under different assumptions or conditions.

While our significant accounting policies are described in the notes to our financial statements included elsewhere in this report, we believe that the following critical accounting policies are most important to understanding and evaluating our reported financial results.

#### ***Revenue Recognition***

We do not have any products approved for commercial sale and have not generated any revenue from commercial product sales. Our total revenue to date has been generated principally from our collaboration and license agreements with Celgene (now BMS), Merck, and EMD Serono, and to a lesser extent, from manufacturing, supply and services and materials we provide to the above collaborators and to Vaxcyte.

When we enter into collaboration agreements, we assess whether the arrangements fall within the scope of ASC 808, Collaborative Arrangements (ASC 808) based on whether the arrangements involve joint operating activities and whether both parties have active participation in the arrangement and are exposed to significant risks and rewards. To the extent that the arrangement falls within the scope of ASC 808, we assess whether the payments between us and our collaboration partner fall within the scope of other accounting literature. If we conclude that payments from the collaboration partner to us represent consideration from a customer, such as license fees and contract research and development activities, we account for those payments within the scope of ASC 606, Revenue from Contracts with Customers. However, if we conclude that our collaboration partner is not a customer for certain activities and associated payments, such as for certain collaborative research, development, manufacturing and commercial activities, we present such payments as a reduction of research and development expense or general and administrative expense, based on where we present the underlying expense.

#### ***Collaboration revenue***

We derive revenue from collaboration arrangements, under which we may grant licenses to our collaboration partners to further develop and commercialize our proprietary product candidates. We may also perform research and development activities under the collaboration agreements. Consideration under these contracts generally includes a nonrefundable upfront payment, development, regulatory and commercial milestones and other contingent payments, and royalties based on net sales of approved products. Additionally, the collaborations may

provide options for the customer to acquire from us materials and reagents, clinical product supply or additional research and development services under separate agreements.

We assess which activities in the collaboration agreements are considered distinct performance obligations that should be accounted for separately. We develop assumptions that require judgement to determine whether the license to our intellectual property is distinct from the research and development services or participation in activities under the collaboration agreements.

At the inception of each agreement, we determine the arrangement transaction price, which includes variable consideration, based on the assessment of the probability of achievement of future milestones and contingent payments and other potential consideration.

For arrangements that include multiple performance obligations, we allocate the transaction price to the identified performance obligations based on the standalone selling price, or SSP, of each distinct performance obligation. In instances where SSP is not directly observable, we develop assumptions that require judgment to determine the SSP for each performance obligation identified in the contract. These key assumptions may include full-time equivalent, or FTE, personnel effort, estimated costs, discount rates and probabilities of clinical development and regulatory success.

*Upfront Payments:* For collaboration arrangements that include a nonrefundable upfront payment, if the license fee and research and development services cannot be accounted for as separate performance obligations, the transaction price is deferred and recognized as revenue over the expected period of performance using a cost-based input methodology. We use judgement to assess the pattern of delivery of the performance obligation. In addition, amounts paid in advance of services being rendered may result in an associated financing component to the upfront payment. Accordingly, the interest on such borrowing cost component will be recorded as interest expense and revenue, based on an appropriate borrowing rate applied to the value of services to be performed by us over the estimated service performance period.

*License Grants:* For collaboration arrangements that include a grant of a license to our intellectual property, we consider whether the license grant is distinct from the other performance obligations included in the arrangement. For licenses that are distinct, we recognize revenues from nonrefundable, upfront payments and other consideration allocated to the license when the license term has begun and we have provided all necessary information regarding the underlying intellectual property to the customer, which generally occurs at or near the inception of the arrangement.

*Milestone and Contingent Payments:* At the inception of the arrangement and at each reporting date thereafter, we assess whether we should include any milestone and contingent payments or other forms of variable consideration in the transaction price using the most likely amount method. If it is probable that a significant reversal of cumulative revenue would not occur upon resolution of the uncertainty, the associated milestone value is included in the transaction price. At the end of each subsequent reporting period, we re-evaluate the probability of achievement of each such milestone and any related constraint and, if necessary, adjust our estimate of the overall transaction price. Since milestone and contingent payments may become payable to us upon the initiation of a clinical study or filing for or receipt of regulatory approval, we review the relevant facts and circumstances to determine when we should update the transaction price, which may occur before the triggering event. When we update the transaction price for milestone and contingent payments, we allocate the changes in the total transaction price to each performance obligation in the agreement on the same basis as the initial allocation. Any such adjustments are recorded on a cumulative catch-up basis in the period of adjustment, which may result in recognizing revenue for previously satisfied performance obligations in such period. Our collaborators generally pay milestones and contingent payments subsequent to achievement of the triggering event.

*Research and Development Services:* For amounts allocated to our research and development obligations in a collaboration arrangement, we recognize revenue over time using a cost-based input methodology, representing the transfer of goods or services as activities are performed over the term of the agreement.

*Materials Supply:* We provide materials and reagents, clinical materials and services to certain of our collaborators under separate agreements. The consideration for such services is generally based on FTE personnel effort used to manufacture those materials reimbursed at an agreed upon rate in addition to agreed-upon pricing for the provided materials. The amounts billed are recognized as revenue as the performance obligations are met by us.

### **Research and Development**

We record accrued expenses for estimated costs of our research and development activities conducted by third party service providers, which include outsourced research and development expenses, professional services and contract manufacturing activities. We record the estimated costs of research and development activities based upon the estimated amount of services provided but not yet invoiced, and include these costs in current liabilities in the balance sheets and within research and development expense in the statements of operations.

Nonrefundable advance payments for goods or services that will be used or rendered for future research and development activities are deferred and capitalized and recognized as an expense as the goods are delivered or the related services are performed.

For outsourced research and development expenses, such as professional fees payable to third parties for preclinical studies, clinical trials and research services and other consulting costs, we estimate the expenses based on the services performed, pursuant to contracts with research institutions that conduct and manage preclinical studies, clinical trials and research services on our behalf. We estimate these expenses based on discussions with internal management personnel and external service providers as to the progress or stage of completion of services and the contracted fees to be paid for such services. If the actual timing of the performance of services or the level of effort varies from the original estimates, we will adjust the accrual accordingly. Payments made to third parties under these arrangements in advance of the performance of the related services by the third parties are recorded as prepaid expenses until the services are rendered.

### **Stock-Based Compensation**

We recognize compensation costs related to stock-based awards granted to employees based on the estimated fair value of the awards on the date of grant. We account for forfeitures of stock-based awards as they occur. We estimate the grant date fair value, and the resulting stock-based compensation expense, using the Black-Scholes option-pricing model. The grant date fair value of the stock-based awards is generally recognized on a straight-line basis over the requisite service period, which is generally the vesting period of the respective awards.

The Black-Scholes option-pricing model requires the use of highly subjective assumptions to determine the fair value of stock-based awards, including the expected term and expected volatility of the underlying stock. We will continue to use judgment in evaluating the expected term and expected volatility utilized for our stock-based compensation calculations on a prospective basis.

The closing sale price per share of our common stock as reported on the Nasdaq Global Market on the date of grant is used to determine the exercise price per share of our stock-based awards to purchase common stock.

### **Income Taxes**

As of December 31, 2021, we had federal net operating loss, or NOL, carryforwards of \$281.7 million and federal general business credits from research and development expenses totaling \$25.1 million, as well as state NOL carryforwards of \$109.2 million and state research and development credits of \$17.2 million. If not utilized, the federal NOL carryforwards will expire at various dates beginning in 2032, and the federal credits will expire at various dates beginning in 2023. The state NOL carryforwards will expire at various dates beginning in 2030, if not utilized. The state research and development tax credits can be carried forward indefinitely.

Utilization of the net operating loss carryforwards may be subject to a substantial annual limitation due to the ownership change limitations provided by the Tax Reform Act of 1986, or the Tax Reform Act, as amended, and similar state provisions. The annual limitation may result in the expiration of NOLs and credits before utilization. We have performed a Section 382 study for the period of June 16, 2003 through December 31, 2020 and concluded that it is more likely than not that we experienced an ownership change on November 20, 2019. This change does not limit our ability to use our existing NOLs within the carryforward period provided by the Internal Revenue Code, subject to availability of taxable income. We may experience ownership changes in the future as a result of equity offerings or other shifts in our stock ownership, some of which are outside our control. If there is a subsequent event or further change in ownership, these losses may be subject to limitations, resulting in their expiration before they can be utilized.

We assess all material positions taken in any income tax return, including all significant uncertain positions, in all tax years that are still subject to assessment or challenge by relevant taxing authorities. Assessing an uncertain tax position begins with the initial determination of the position's sustainability and is measured at the largest amount of benefit that is greater than fifty percent likely of being realized upon ultimate settlement. As of each balance sheet date, unresolved uncertain tax positions must be reassessed, and we will determine whether (i) the factors underlying the sustainability assertion have changed and (ii) the amount of the recognized tax benefit is still appropriate. The recognition and measurement of tax benefits requires significant judgment. Judgments concerning the recognition and measurement of a tax benefit might change as new information becomes available.

### **Recent Accounting Pronouncements**

See Note 2 to our audited financial statements included elsewhere in this report for more information.



## Item 7A. Quantitative and Qualitative Disclosures about Market Risk

We are exposed to market risks in the ordinary course of our business. These risks primarily include interest rate sensitivities. The primary objective of our investment activities is to preserve our capital to fund our operations. We also seek to maximize income from our investments without assuming significant risk. To achieve our objectives, we maintain a portfolio of cash equivalents and investments in a variety of securities of high credit quality.

We had cash, cash equivalents and marketable securities of \$229.5 million and \$326.5 million as of December 31, 2021 and 2020, respectively, which consisted of money market funds, commercial paper, corporate debt securities, asset-backed securities, U.S. government agency securities and supranational debt securities. Such interest earning instruments carry a degree of interest rate risk; however, historical fluctuations in interest income have not been significant. Additionally, we had equity securities of \$37.2 million as of December 31, 2021, consisting solely of common stock of Vaxcyte.

Equity risk is the risk we will incur economic losses due to adverse changes in equity prices. Our potential exposure to changes in equity prices results from our Vaxcyte common stock holdings. Therefore, we are subject to market risk if such holdings materially decrease in value. A hypothetical 10 percent decrease in the market price for our equity investments as of December 31, 2021 would decrease the fair value by \$3.7 million. We intend to manage equity price risk going forward by continuously evaluating market conditions.

We do not enter into investments for trading or speculative purposes and have not used any derivative financial instruments to manage our interest rate risk exposure. We have not been exposed nor do we anticipate being exposed to material risks due to changes in interest rates. A hypothetical 10% change in market interest rates would not have a material impact on our financial statements. We do not believe that our cash, cash equivalents or marketable securities have significant risk of default or illiquidity.

As of December 31, 2021 and 2020, we had \$25.1 million and \$24.5 million, respectively, in debt outstanding, net of debt discount and accretion of final payment. Our debt with Oxford and SVB bears interest at a floating per annum rate equal to the greater of (i) 8.07% or (ii) the sum of (a) the greater of (1) the thirty (30) day U.S. LIBOR rate reported in the Wall Street Journal on the last business day of the month that immediately precedes the month in which the interest will accrue or (2) 1.67%, plus (b) 6.40%. This debt matures on March 1, 2024 and will be interest-only through March 1, 2022. Such interest-bearing debt carries a limited degree of interest rate risk. If overall interest rates had increased or decreased by 100 basis points during the periods presented our interest expense would not have been materially affected.

Item 8. *Financial Statements and Supplementary Data*

SUTRO BIOPHARMA, INC.  
ANNUAL REPORT ON FORM 10-K  
INDEX TO AUDITED FINANCIAL STATEMENTS

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## Report of Independent Registered Public Accounting Firm

To the Stockholders and the Board of Directors of Sutro Biopharma, Inc.

### Opinion on the Financial Statements

We have audited the accompanying balance sheets of Sutro Biopharma, Inc. (the Company) as of December 31, 2021 and 2020, the related statements of operations, comprehensive loss, stockholders' equity and cash flows for each of the three years in the period ended December 31, 2021, and the related notes (collectively referred to as the "financial statements"). In our opinion, the financial statements present fairly, in all material respects, the financial position of the Company at December 31, 2021 and 2020, and the results of its operations and its cash flows for each of the three years in the period ended December 31, 2021, in conformity with U.S. generally accepted accounting principles.

We also have audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States) (PCAOB), the Company's internal control over financial reporting as of December 31, 2021, based on criteria established in Internal Control-Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission (2013 framework) and our report dated February 28, 2022 expressed an unqualified opinion thereon.

### Basis for Opinion

These financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on the Company's financial statements based on our audits. We are a public accounting firm registered with the PCAOB and are required to be independent with respect to the Company in accordance with the U.S. federal securities laws and the applicable rules and regulations of the Securities and Exchange Commission and the PCAOB.

We conducted our audits in accordance with the standards of the PCAOB. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement, whether due to error or fraud. Our audits included performing procedures to assess the risks of material misstatement of the financial statements, whether due to error or fraud, and performing procedures that respond to those risks. Such procedures included examining, on a test basis, evidence regarding the amounts and disclosures in the financial statements. Our audits also included evaluating the accounting principles used and significant estimates made by management, as well as evaluating the overall presentation of the financial statements. We believe that our audits provide a reasonable basis for our opinion.

### Critical Audit Matter

The critical audit matter communicated below is matter arising from the current period audit of the financial statements that was communicated or required to be communicated to the audit committee and that: (1) relates to accounts or disclosures that are material to the financial statements and (2) involved our especially challenging, subjective or complex judgments. The communication of the critical audit matter does not alter in any way our opinion on the financial statements, taken as a whole, and we are not, by communicating the critical audit matter below, providing a separate opinion on the critical audit matter or on the accounts or disclosures to which it relates.

*Description of the Matter*

**Collaboration revenue**

The Company recognized collaboration revenue of \$61.9 million for the year ended December 31, 2021. As described in Note 2, the Company derives revenue from collaboration arrangements under which the Company may grant licenses to its collaboration partners to further development and commercialize its proprietary product candidates. The Company may perform research and development activities and consideration under the contracts generally includes nonrefundable upfront payments, development, regulatory and commercialization milestones, other contingent payments and royalties. The Company also provides materials and reagents, clinical materials and research and development services to collaborators. The Company receives consideration for these services based on full time equivalent personnel effort at agreed upon rates and agreed upon pricing for the materials. Management examines these research and development and material supply activities and bills its collaboration partners for eligible costs under the arrangements. Of the \$61.9 million recognized as revenue, \$24.2 million was recognized for the reimbursement of expenses for employee research and development activities and material supply activities with Merck & Co., Inc., BMS, EMD Serono, Inc., and Vaxcyte.

Auditing the Company's accounting for revenues from collaboration arrangements was challenging, as the revenue recorded within the Company's financial statements are based on a high-volume of research and development activities across multiple projects, which are subject to reimbursement.

*How We Addressed the Matter in Our Audit*

Our audit procedures included, among others, testing the eligibility of the Company's internal and external research and development activities against the terms of the agreements. We conducted meetings with program management to understand the nature of the activities performed under the collaboration agreements and to test the calculation of eligible costs for reimbursement. We also obtained external confirmations from collaboration partners to confirm the terms of the agreements.

/s/ Ernst & Young LLP

We have served as the Company's auditor since 2007.

Redwood City, California  
February 28, 2022

**SUTRO BIOPHARMA, INC.**

**BALANCE SHEETS**

(in thousands, except share and per share data)

	2021	December 31,	2020
<b>Assets</b>			
Current assets:			
Cash and cash equivalents	\$ 30,414	\$	206,152
Marketable securities	130,343		120,341
Investment in equity securities	37,181		41,644
Accounts receivable	12,454		5,559
Prepaid expenses and other current assets	8,123		4,486
Total current assets	218,515		378,182
Property and equipment, net	22,550		12,935
Operating lease right-of-use assets	29,041		-
Marketable securities, non-current	68,775		-
Other non-current assets	1,655		2,122
Restricted cash	872		872
Total assets	<u>\$ 341,408</u>	<u>\$</u>	<u>394,111</u>
<b>Liabilities and Stockholders' Equity</b>			
Current liabilities:			
Accounts payable	\$ 11,327	\$	5,544
Accrued compensation	11,417		8,823
Deferred revenue—current	5,496		14,603
Operating lease liability—current	1,037		-
Debt—current	9,375		-
Other current liabilities	3,084		627
Total current liabilities	41,736		29,597
Deferred revenue, non-current	-		6,100
Operating lease liability—non-current	31,224		-
Deferred rent	-		1,340
Debt—non-current	15,738		24,545
Other non-current liabilities	146		481
Total liabilities	88,844		62,063
Commitments and contingencies (Note 8)			
Stockholders' equity:			
Preferred stock, \$0.001 par value — 10,000,000 shares authorized as of December 31, 2021 and 2020; 0 shares issued and outstanding as of December 31, 2021 and 2020	-		-
Common stock, \$0.001 par value — 300,000,000 shares authorized as of December 31, 2021 and 2020; 46,327,131 and 45,752,116 shares issued and outstanding as of December 31, 2021 and 2020, respectively	46		46
Additional paid-in-capital	586,243		559,746
Accumulated other comprehensive (loss) income	(314 )		129
Accumulated deficit	(333,411 )		(227,873 )
Total stockholders' equity	252,564		332,048
<b>Total Liabilities and Stockholders' Equity</b>	<u>\$ 341,408</u>	<u>\$</u>	<u>394,111</u>

See accompanying notes to financial statements.

SUTRO BIOPHARMA, INC.

STATEMENTS OF OPERATIONS

(in thousands, except share and per share data)

	Year Ended December 31,		
	2021	2020	2019
Revenue (including amounts from related parties of \$0, \$2,813 and \$22,536 during the years ended December 31, 2021, 2020 and 2019, respectively)	\$ 61,880	\$ 42,722	\$ 42,736
Operating expenses			
Research and development	104,400	76,961	65,612
General and administrative	56,004	36,818	32,592
Total operating expenses	160,404	113,779	98,204
Loss from operations	(98,524 )	(71,057 )	(55,468 )
Interest income	577	1,508	4,074
Unrealized (loss) gain on equity securities	(4,454 )	41,498	-
Interest and other expense, net	(3,137 )	(4,077 )	(4,350 )
Net loss	\$ (105,538 )	\$ (32,128 )	\$ (55,744 )
Net loss per share, basic and diluted	\$ (2.29 )	\$ (0.99 )	\$ (2.43 )
Weighted-average shares used in computing basic and diluted net loss per share	46,119,089	32,573,469	22,958,577

See accompanying notes to financial statements.

SUTRO BIOPHARMA, INC.

STATEMENTS OF COMPREHENSIVE LOSS

(in thousands)

	Year Ended December 31,		
	2021	2020	2019
Net loss	\$ (105,538 )	\$ (32,128 )	\$ (55,744 )
Other comprehensive (loss) income:			
Unrealized (loss) gain on available-for-sale securities	(443 )	(36 )	212
Comprehensive loss	<u>\$ (105,981 )</u>	<u>\$ (32,164 )</u>	<u>\$ (55,532 )</u>

See accompanying notes to financial statements.

**SUTRO BIOPHARMA, INC.**  
**Statements of Stockholders' Equity**  
(in thousands, except share amounts)

	Common Stock Shares	Amount	23	Additional Paid-In- Capital	281,891	Accumulated Other Comprehensive (Loss) Income	(47 )	Accumulated Deficit	(150,328 )	Total Stockholders' Equity	131,539
<b>Balances at December 31, 2018</b>											
Adoption of Accounting Standards Update (ASU) No. 2014-09, Revenue from Contracts with Customers (Topic 606)	-	-	-	-	-	-	-	10,327	-	10,327	-
Exercise of common stock options	35,204	-	-	180	-	-	-	-	-	180	-
Issuance of common stock under Employee Stock Purchase Plan	131,939	-	-	1,260	-	-	-	-	-	1,260	-
Vesting of restricted stock units	114,103	-	-	-	-	-	-	-	-	-	-
Stock transaction associated with taxes withheld on restricted stock units	(30,461 )	-	-	(297 )	-	-	-	-	-	(297 )	-
Stock-based compensation expense	-	-	-	10,312	-	-	-	-	-	10,312	-
Net unrealized gain on available-for-sale securities	-	-	-	-	-	212	-	-	-	212	-
Net Loss	-	-	-	-	-	-	-	(55,744 )	-	(55,744 )	-
<b>Balances at December 31, 2019</b>	23,098,969	23	23	293,346	165	(195,745 )	-	-	-	97,789	1,861
Exercise of common stock options	171,354	-	-	1,861	-	-	-	-	-	1,861	-
Issuance of common stock under Employee Stock Purchase Plan	195,992	-	-	1,285	-	-	-	-	-	1,285	-
Vesting of restricted stock units	151,976	-	-	-	-	-	-	-	-	-	-
Stock transaction associated with taxes withheld on restricted stock units	(30,461 )	-	-	(314 )	-	-	-	-	-	(314 )	-
Stock-based compensation expense	-	-	-	11,917	-	-	-	-	-	11,917	-
Issuance of common stock warrants in connection with debt refinancing	-	-	-	619	-	-	-	-	-	619	-
Issuance of common stock in connection with public offerings, net of issuance costs of \$15,686	19,550,000	20	20	227,232	-	-	-	-	-	227,252	-
Issuance of common stock in connection with At-The-Market sale, net of issuance costs of \$777	2,614,286	3	3	23,800	-	-	-	-	-	23,803	(36 )
Net unrealized loss on available-for-sale securities	-	-	-	-	-	(36 )	-	-	-	(36 )	-
Net Loss	-	-	-	-	-	-	-	(32,128 )	-	(32,128 )	-
<b>Balances at December 31, 2020</b>	45,752,116	46	46	559,746	129	(227,873 )	-	-	-	332,048	2,485
Exercise of common stock options and common stock warrants	246,678	-	-	2,485	-	-	-	-	-	2,485	-
Return and retirement of common stock	(7,687 )	-	-	(7 )	-	-	-	-	-	(7 )	-
Issuance of common stock under Employee Stock Purchase Plan	145,809	-	-	1,765	-	-	-	-	-	1,765	-
Vesting of restricted stock units	238,724	-	-	-	-	-	-	-	-	-	-
Stock transaction associated with taxes withheld on restricted stock units	(48,509 )	-	-	(987 )	-	-	-	-	-	(987 )	-
Stock-based compensation expense	-	-	-	23,241	-	-	-	-	-	23,241	-
Net unrealized loss on available-for-sale securities	-	-	-	-	-	(443 )	-	-	-	(443 )	-
Net Loss	-	-	-	-	-	-	-	(105,538 )	-	(105,538 )	-
<b>Balances at December 31, 2021</b>	46,327,131	\$ 46	\$ 46	\$ 586,243	\$ (314)	\$ (333,411)	\$ (314)	\$ (333,411)	\$ (314)	\$ 252,564	\$ 252,564

See accompanying notes to financial statements.



**SUTRO BIOPHARMA, INC.**  
**STATEMENTS OF CASH FLOWS**  
(in thousands)

	2021	Year Ended December 31,	
		2020	2019
<b>Operating activities</b>			
Net loss	\$ (105,538 )	\$ (32,128 )	\$ (55,744 )
Adjustments to reconcile net loss to net cash used in operating activities:			
Depreciation and amortization	4,844	4,297	4,777
Amortization of premium (accretion of discount) on marketable securities	2,781	490	(1,457 )
Stock-based compensation	23,241	11,917	10,312
Noncash lease expenses	4,929	-	-
Unrealized loss (gain) on equity securities	4,454	(41,498 )	-
Remeasurement of liability awards	(12 )	19	(115 )
Other	1,242	587	468
Changes in operating assets and liabilities:			
Accounts receivable	(6,895 )	739	(3,809 )
Prepaid expenses and other assets	(3,959 )	(80 )	(1,441 )
Accounts payable	6,433	(947 )	2,253
Accrued compensation	2,594	2,806	(200 )
Other liabilities	2,141	22	186
Deferred rent	-	931	(67 )
Deferred revenue	(15,207 )	(14,957 )	(20,186 )
Change in operating lease liability	(2,727 )	-	-
Net cash used in operating activities	(81,679 )	(67,802 )	(65,023 )
<b>Investing activities</b>			
Purchases of marketable securities	(248,727 )	(130,741 )	(196,226 )
Maturities of marketable securities	148,250	116,385	128,576
Sales of marketable securities	18,476	22,000	20,000
Purchases of equipment and leasehold improvements	(15,323 )	(7,129 )	(3,481 )
Proceeds from exercise of options for Vaxcyte shares	9	89	-
Net cash (used in) provided by investing activities	(97,315 )	604	(51,131 )
<b>Financing activities</b>			
Proceeds from sales of common stock, net of issuance costs	-	251,415	(327 )
Proceeds from debt refinancing	-	25,000	-
Payments of debt	-	(10,000 )	(5,000 )
Proceed from exercise of common stock options	2,485	1,861	180
Taxes paid related to net share settlement of restricted stock units	(987 )	(314 )	(297 )
Return and retirement of common stock	(7 )	-	-
Proceeds from employee stock purchase plan	1,765	1,285	1,260
Net cash provided by (used in) financing activities	3,256	269,247	(4,184 )
Net (decrease) increase in cash, cash equivalents and restricted cash	(175,738 )	202,049	(120,338 )
Cash, cash equivalents and restricted cash at beginning of year	207,024	4,975	125,313
Cash, cash equivalents and restricted cash at end of year	<u>\$ 31,286</u>	<u>\$ 207,024</u>	<u>\$ 4,975</u>
<b>Supplemental disclosure of cash flow information</b>			
Cash paid for interest	<u>\$ 2,046</u>	<u>\$ 1,675</u>	<u>\$ 1,049</u>
Income tax paid	<u>\$ 103</u>	<u>\$ -</u>	<u>\$ -</u>
<b>Supplemental Disclosures of Non-cash Investing and Financing Information</b>			
Purchase of property and equipment included in accounts payable	<u>\$ 370</u>	<u>\$ 546</u>	<u>\$ 270</u>
Remeasurement of operating lease right-of-use assets for lease modification	<u>\$ 4,227</u>	<u>\$ -</u>	<u>\$ -</u>
Offering costs included in accounts payable	<u>\$ -</u>	<u>\$ 361</u>	<u>\$ -</u>
Embedded interest associated with program fees	<u>\$ 610</u>	<u>\$ 1,852</u>	<u>\$ 3,144</u>
Warrants issued to lenders	<u>\$ -</u>	<u>\$ 619</u>	<u>\$ -</u>

See accompanying notes to financial statements.

## SUTRO BIOPHARMA, Inc.

### Notes to Financial Statements

#### 1. Organization and Principal Activities

##### *Description of Business*

Sutro Biopharma, Inc. (the "Company") is a clinical stage drug discovery, development and manufacturing company focused on leveraging its integrated cell-free protein synthesis and site-specific conjugation platform, XpressCF<sup>®</sup>, to create a broad variety of optimally designed, next-generation protein therapeutics, initially for cancer. The Company was incorporated on April 21, 2003, and is headquartered in South San Francisco, California.

The Company operates in one business segment, the development of biopharmaceutical products.

##### *Liquidity*

The Company has incurred significant losses and has negative cash flows from operations. As of December 31, 2021, there was an accumulated deficit of \$333.4 million. Management expects to continue to incur additional substantial losses in the foreseeable future as a result of the Company's research and development and other operational activities.

As of December 31, 2021, the Company had unrestricted cash, cash equivalents and marketable securities of \$229.5 million, which is available to fund future operations. The Company will need to raise additional capital to support the completion of its research and development activities and to support its operations.

The Company believes that its unrestricted cash, cash equivalents and marketable securities as of December 31, 2021 will enable the Company to maintain its operations for a period of at least 12 months following the filing date of these financial statements.

#### 2. Basis of Presentation and Summary of Significant Accounting Policies

##### *Basis of Presentation and Use of Estimates*

The accompanying financial statements have been prepared in accordance with U.S. generally accepted accounting principles ("U.S. GAAP"). The preparation of financial statements in conformity with U.S. GAAP requires management to make estimates and assumptions that affect the amounts reported in the financial statements and accompanying notes. The Company bases its estimates on historical experience and market-specific or other relevant assumptions that it believes are reasonable under the circumstances. The amounts of assets and liabilities reported in the Company's balance sheets and the amounts of expenses and income reported for each of the periods presented are affected by estimates and assumptions, which are used for, but are not limited to, determining research and development periods under collaboration arrangements, stock-based compensation expense, valuation of marketable securities, impairment of long-lived assets, income taxes and certain accrued liabilities. Actual results could differ from such estimates or assumptions.

The full extent to which the COVID-19 pandemic will directly or indirectly impact the Company's business, results of operations and financial condition, including revenue, expenses, manufacturing, clinical trials, research and development costs and employee-related amounts, will depend on future developments that are highly uncertain, including as a result of new information that may emerge concerning COVID-19 and the actions taken to contain or treat it, as well as the economic impact on local, regional, national and international customers, suppliers, service providers and markets. The Company has made estimates of the impact of COVID-19 within its financial statements and there may be changes to those estimates in future periods. Actual results could differ from such estimates or assumptions.

### **Recently Adopted Accounting Pronouncements**

In June 2016, the Financial Accounting Standards Board (“FASB”) issued Accounting Standards Updates (“ASU”) 2016-13 (Topic 326), Financial Instruments Credit Losses. The guidance modifies the measurement and recognition of credit losses for most financial assets and certain other instruments. The amendment updates the guidance for measuring and recording credit losses on financial assets measured at amortized cost by replacing the “incurred loss” model with an “expected loss” model. The Company adopted ASU 2016-13 in the third quarter of 2021 using the modified retrospective adoption approach. As a result of this adoption, the Company presents these financial assets, which include accounts receivable and available-for-sale debt securities, at the net amount the Company expects to collect. The amendment also requires the Company to record credit losses related to available-for-sale debt securities as an allowance through net income rather than reducing the carrying amount under the historical, other-than-temporary-impairment model. The adoption of ASU 2016-13 did not have a material impact on the Company’s financial statements and related disclosures for the year ended December 31, 2021.

In February 2016, the FASB issued ASU 2016-02 (Topic 842), Leases (Accounting Standards Codification, or “ASC”, 842). ASC 842 supersedes the lease recognition requirements in ASC 840, Leases. ASC 842 clarifies the definition of a lease and requires lessees to recognize right-of-use assets and lease liabilities for all leases, including those classified as operating leases under previous lease accounting guidance. The Company adopted ASC 842 on July 1, 2021, effective as of January 1, 2021. There was no impact on the Company’s accumulated deficit as of January 1, 2021 as a result of the adoption of this standard. Results for the period ended December 31, 2021 are presented under Topic 842. Other prior period amounts are not adjusted and continue to be reported in accordance with the Company’s historic accounting under previous lease guidance, ASC Topic 840: Leases (“Topic 840”). The Company elected the package of practical expedients permitted under the transition guidance of the new standard, which allowed the Company to carry forward its historical assessment on whether a contract is or contains a lease, lease classification, and initial direct costs. Upon adoption on January 1, 2021, the Company recognized operating lease right-of-use (“ROU”) assets of \$29.7 million, and current and non-current operating lease liabilities of \$2.9 million and \$27.8 million, respectively. In connection with the adoption of this standard, deferred rent of \$1.3 million and prepaid rent of \$0.3 million, which was previously recorded in prepaid expenses and other current assets on the balance sheet as of December 31, 2020, were derecognized. Finance lease assets and liabilities were not material. The adoption of ASC 842 did not have a material impact on the Company’s Statements of Operations and Statements of Cash flows.

### **Recent Accounting Pronouncements Not Yet Adopted**

In March 2020, the FASB issued ASU 2020-04, “Reference Rate Reform (Topic 848): Facilitation of the Effects of Reference Rate Reform on Financial Reporting”, which provides optional expedients and exceptions for a limited period of time to ease the potential burden in accounting treatments related to contracts, hedging relationships and other transactions affected by reference rate reform if certain criteria are met. Adoption of the expedients and exceptions is elective and is permitted upon issuance of the guidance through December 31, 2022. The Company does not expect that the new guidance will have material impact on its financial position, results of operations and cash flows.

### **Cash, Cash Equivalents, Marketable Securities and Restricted Cash**

The Company considers all highly liquid investments with original maturities of 90 days or less from the date of purchase to be cash equivalents. Investments with original maturities of greater than 90 days from the date of purchase but less than one year from the balance sheet date, or where the Company's intent is to use the investments to fund current operations or to make them available for current operations are classified as current, while investments with maturities in one year or beyond one year from the balance sheet date are classified as long-term investments.

Available-for-sale marketable securities are carried at fair value, with unrealized gains and losses reported as a component of accumulated other comprehensive income (loss). Realized gains and losses are included in interest income in the Company's Statements of Operations. There were no material realized gains or losses in the periods presented. The cost of securities sold is based on the specific-identification method.

The Company evaluates, on a quarterly basis, its marketable securities for potential impairment. For marketable securities in an unrealized loss position, the Company assesses whether such declines are due to credit loss based on factors such as changes to the rating of the security by a ratings agency, market conditions and supportable forecasts of economic and market conditions, among others. If a credit loss exists, the Company assesses whether it has plans to sell the security or it is more likely than not it will be required to sell any marketable security before recovery of its amortized cost basis. If either condition is met, the security's amortized cost basis is written down to fair value and is recognized through interest and other expense, net.

If neither condition is met, declines as a result of credit losses, if any, are recognized as an allowance for credit loss, limited to the amount of unrealized loss, through interest and other expense, net. Any portion of unrealized loss that is not a result of a credit loss, is recognized in other comprehensive income (loss).

The Company invests in money market funds, commercial paper, corporate debt securities, asset-based securities and U.S. government agency securities with high credit ratings. The Company has established guidelines regarding diversification of its investments and their maturities, with the objectives of maintaining safety and liquidity while maximizing yield.

Under certain agreements, the Company has pledged cash and cash equivalents as collateral. Restricted cash related to such agreements was \$0.9 million and \$0.9 million, respectively, as of December 31, 2021 and 2020.

A reconciliation of cash, cash equivalents, and restricted cash reported within the Company's Balance Sheets to the amount reported within the accompanying Statements of Cash Flows was as follows:

	2021	December 31, 2020	2019
		(in thousands)	
Cash and cash equivalents	\$ 30,414	\$ 206,152	\$ 4,960
Restricted cash	872	872	15
Total cash, cash equivalents and restricted cash shown in the statements of cash flows	<u>\$ 31,286</u>	<u>\$ 207,024</u>	<u>\$ 4,975</u>

### **Concentrations of Credit Risk**

Cash and cash equivalents and marketable securities consist of financial instruments that potentially subject the Company to a concentration of credit risk, to the extent of the amounts recorded on the balance sheets. The Company minimizes the amount of credit exposure by investing cash that is not required for immediate operating needs in money market funds, government obligations and/or commercial paper with short maturities.

The Company performs a regular review of its collaborators' credit risk and payment histories when circumstances warrant, including payments made subsequent to year-end. When appropriate, the Company provides for an allowance for credit risks by reserving for specifically identified doubtful accounts, although historically the Company has not experienced credit losses from its accounts receivable.

### **Investments in Equity Securities**

Subsequent to the closing of the initial public offering ("IPO") of Vaxcyte, Inc. in June 2020, the fair value of Vaxcyte's common stock became readily determinable. As a result, beginning June 2020, Vaxcyte common stock held by the Company is measured at fair value at each reporting period based on the closing price of Vaxcyte's common stock on the last trading day of each reporting period, with any unrealized gains and losses recorded in the Company's statements of operations.

### **Property and Equipment, Net**

Property and equipment are stated at cost, less accumulated depreciation and amortization. Depreciation is determined using the straight-line method over the estimated useful lives of the respective assets, generally three to five years. Leasehold improvements are amortized on a straight-line basis over the shorter of their estimated useful lives or the term of the lease. Maintenance and repairs are charged to expense as incurred and costs of improvement are capitalized.

### **Impairment of Long-Lived Assets**

The Company reviews long-lived assets, including property and equipment, leasehold improvements and right-of-use assets for impairment whenever events or changes in business circumstances indicate that the carrying amount of the assets may not be fully recoverable. An impairment loss would be recognized when the estimated, undiscounted future cash flows expected to result from the use of the asset and its eventual disposition are less than its carrying amount. Impairment, if any, is measured as the amount by which the carrying amount of a long-lived asset exceeds its fair value.

The Company did not recognize any impairment charges during the years ended December 31, 2021, 2020 and 2019. As of December 31, 2021 and 2020, management believes that no revision to the remaining useful lives or write down of the remaining long-lived assets is required.

### **Leases**

The Company determines if an arrangement is or contains a lease at contract inception by assessing whether the arrangement contains an identified asset and whether the lessee has the right to control such asset. The Company is required to classify leases as either finance or operating leases and to record a ROU asset and a lease liability for all leases with a term greater than 12 months regardless of the lease classification. The lease classification will determine whether the lease expense is recognized based on an effective interest rate method or on a straight-line basis over the term of the lease. The Company determines the initial classification and measurement of its ROU assets and lease liabilities at the lease commencement date and thereafter, if modified. The Company does not have material finance leases.

For leases with a term greater than 12 months, the Company records the related ROU asset and lease liability at the present value of lease payments over the term of the lease. The term of the Company's leases equals the non-cancellable period of the lease, including any rent-free periods provided by the lessor, and also includes options to extend or terminate the lease that the Company is reasonably certain to exercise. The ROU asset equals the carrying amount of the related lease liability, adjusted for any lease payments made prior to lease commencement and lease incentives provided by the lessor. Variable lease payments are expensed as incurred and do not factor into the measurement of the applicable ROU asset or lease liability.

The Company has elected, for all classes of underlying assets, not to recognize ROU assets and lease liabilities for leases with a term of 12 months or less. Lease cost for short-term leases is recognized on a straight-line basis over the lease term. The Company has also elected to not separate lease and non-lease components for its leases and, as a result, accounts for lease and non-lease components as one component.

The Company's leases do not provide a readily determinable implicit rate. Therefore, the Company estimates its incremental borrowing rate to discount the lease payments based on information available at lease commencement. The Company determines its incremental borrowing rate based on the rate of interest that the Company would have to pay to borrow, on a collateralized basis over a similar term, an amount equal to the lease payments in a similar economic environment.

Lease payments may be fixed or variable; however, only fixed payments are included in the Company's lease liability calculation. Lease costs for the Company's operating leases are recognized on a straight-line basis within operating expenses over the lease term. The Company's lease agreements may contain variable non-lease components such as common area maintenance, operating expenses or other costs, which are expensed as incurred.

### **Revenue Recognition**

On January 1, 2019, the Company adopted Accounting Standards Update (ASU) No. 2014-09 (Topic 606), Revenue from Contracts with Customers ("ASC 606"). Under ASC 606, an entity recognizes revenue when its customer obtains control of promised goods or services, in an amount that reflects the consideration that the entity expects to receive in exchange for those goods or services. To determine revenue recognition for arrangements that an entity determines are within the scope of ASC 606, the entity performs the following five steps: (i) identify the contract(s) with a customer; (ii) identify the performance obligations in the contract; (iii) determine the transaction price; (iv) allocate the transaction price to the performance obligations in the contract; and (v) recognize revenue when (or as) the entity satisfies a performance obligation.

When the Company enters into collaboration agreements, it assesses whether the arrangements fall within the scope of ASC 808, Collaborative Arrangements (ASC 808) based on whether the arrangements involve joint operating activities and whether both parties have active participation in the arrangement and are exposed to significant risks and rewards. To the extent that the arrangement falls within the scope of ASC 808, the Company assesses whether the payments between the Company and its collaboration partner fall within the scope of other accounting literature. If it concludes that payments from the collaboration partner to the Company represent consideration from a customer, such as license fees and contract research and development activities, the Company accounts for those payments within the scope of ASC 606, Revenue from Contracts with Customers. However, if the Company concludes that its collaboration partner is not a customer for certain activities and associated payments, such as for certain collaborative research, development, manufacturing and commercial activities, the Company presents such payments as a reduction of research and development expense or general and administrative expense, based on where the Company presents the underlying expense.

The Company has no products approved for commercial sale and has not generated any revenue from commercial product sales. The total revenue to date has been generated principally from collaboration and license agreements and to a lesser extent, from manufacturing, supply and services and materials the Company provides to its collaboration partners.

### *Collaboration Revenue*

The Company derives revenue from collaboration arrangements, under which the Company may grant licenses to its collaboration partners to further develop and commercialize its proprietary product candidates. The Company may also perform research and development activities under the collaboration agreements. Consideration under these contracts generally includes a nonrefundable upfront payment, development, regulatory and commercial milestones and other contingent payments, and royalties based on net sales of approved products. Additionally, the collaborations may provide options for the customer to acquire from the Company materials and reagents, clinical product supply or additional research and development services under separate agreements.

The Company assesses which activities in the collaboration agreements are considered distinct performance obligations that should be accounted for separately. The Company develops assumptions that require judgement to determine whether the license to the Company's intellectual property is distinct from the research and development services or participation in activities under the collaboration agreements.

At the inception of each agreement, the Company determines the arrangement transaction price, which includes variable consideration, based on the assessment of the probability of achievement of future milestones and contingent payments and other potential consideration. The Company recognizes revenue over time by measuring its progress towards the complete satisfaction of the relevant performance obligation using an appropriate input or output method based on the nature of the service promised to the customer.

For arrangements that include multiple performance obligations, the Company allocates the transaction price to the identified performance obligations based on the standalone selling price, or SSP, of each distinct performance obligation. In instances where SSP is not directly observable, the Company develops assumptions that require judgment to determine the SSP for each performance obligation identified in the contract. These key assumptions may include FTE, personnel effort, estimated costs, discount rates and probabilities of clinical development and regulatory success.

*Upfront Payments:* For collaboration arrangements that include a nonrefundable upfront payment, if the license fee and research and development services cannot be accounted for as separate performance obligations, the transaction price is deferred and recognized as revenue over the expected period of performance using a cost-based input methodology. The Company uses judgement to assess the pattern of delivery of the performance obligation. In addition, amounts paid in advance of services being rendered may result in an associated financing component to the upfront payment. Accordingly, the interest on such borrowing cost component will be recorded as interest expense and revenue, based on an appropriate borrowing rate applied to the value of services to be performed by the Company over the estimated service performance period.

*License Grants:* For collaboration arrangements that include a grant of a license to the Company's intellectual property, the Company considers whether the license grant is distinct from the other performance obligations included in the arrangement. For licenses that are distinct, the Company recognizes revenues from nonrefundable, upfront payments and other consideration allocated to the license when the license term has begun and the Company has provided all necessary information regarding the underlying intellectual property to the customer, which generally occurs at or near the inception of the arrangement.

*Milestone and Contingent Payments:* At the inception of the arrangement and at each reporting date thereafter, the Company assesses whether it should include any milestone and contingent payments or other forms of variable consideration in the transaction price using the most likely amount method. If it is probable that a significant reversal of cumulative revenue would not occur upon resolution of the uncertainty, the associated milestone value is included in the transaction price. At the end of each subsequent reporting period, the Company re-evaluates the probability of achievement of each such milestone and any related constraint and, if necessary, adjusts its estimate of the overall transaction price. Since milestone and contingent payments may become payable to the Company upon the initiation of a clinical study or filing for or receipt of regulatory approval, the Company reviews the relevant facts and circumstances to determine when the Company should update the transaction price, which may occur before the triggering event. When the Company updates the transaction price for milestone and contingent payments, the Company allocates the changes in the total transaction price to each performance obligation in the agreement on the same basis as the initial allocation. Any such adjustments are recorded on a cumulative catch-up basis in the period of adjustment, which may result in recognizing revenue for previously satisfied performance obligations in such period. The Company's collaborators generally pay milestones and contingent payments subsequent to achievement of the triggering event.

*Research and Development Services:* For amounts allocated to the Company's research and development obligations in a collaboration arrangement, the Company recognizes revenue over time using a cost-based input methodology, representing the transfer of goods or services as activities are performed over the term of the agreement.

*Materials Supply:* The Company provides materials and reagents, clinical materials and services to certain of its collaborators under separate agreements. The consideration for such services is generally based on FTE personnel effort used to manufacture those materials reimbursed at an agreed upon rate in addition to agreed-upon pricing for the provided materials. The amounts billed are recognized as revenue as the performance obligations are met by the Company.

### ***Stock-Based Compensation***

The Company maintains a stock-based compensation plan as a long-term incentive for employees, consultants, and members of the Company's Board of Directors. The plan allows for the issuance of restricted stock units, non-statutory and incentive stock options to employees and non-statutory stock options ("NSOs") to nonemployees. The Company also maintains an employee stock purchase plan.

Share-based payments, including purchases under the Company's employee stock purchase plan, are measured using fair-value-based measurements and recognized as compensation expense over the service period in which the awards are expected to vest. The Company's fair-value-based measurements of awards to employees and directors as of the grant date utilize the single-option award-valuation approach, and the Company uses the straight-line method for expense attribution. The fair-value-based measurements of options granted to nonemployees are remeasured at each period end until the options vest and are amortized to expense as earned. The Company accounts for forfeitures of stock-based awards as they occur. The valuation model used for calculating the estimated fair value of stock awards is the Black-Scholes option-pricing model. The Black-Scholes model requires the Company to make assumptions and judgments about the variables used in the calculations, including the expected term (weighted-average period of time that the options granted are expected to be outstanding), the expected volatility of the Company's common stock, the related risk-free interest rate and the expected dividends.

### ***Research and Development***

The Company records accrued expenses for estimated costs of the research and development activities conducted by third party service providers, which include outsourced research and development expenses, professional services and contract manufacturing activities. The Company records the estimated costs of research and development activities based upon the estimated amount of services provided but not yet invoiced, and includes these costs in current liabilities in the balance sheets and within research and development expense in the statements of operations.

Nonrefundable advance payments for goods or services that will be used or rendered for future research and development activities are deferred and capitalized and recognized as an expense as the goods are delivered or the related services are performed.

For outsourced research and development expenses, such as professional fees payable to third parties for preclinical studies, clinical trials and research services and other consulting costs, the Company estimates the expenses based on the services performed, pursuant to contracts with research institutions that conduct and manage preclinical studies, clinical trials and research services on the Company's behalf. The Company estimates these expenses based on discussions with internal management personnel and external service providers as to the progress or stage of completion of services and the contracted fees to be paid for such services. If the actual timing of the performance of services or the level of effort varies from the original estimates, the Company will adjust the accrual accordingly. Payments made to third parties under these arrangements in advance of the performance of the related services by the third parties are recorded as prepaid expenses until the services are rendered.

### ***Income Taxes***

The Company provides for income taxes under the asset and liability method. Current income tax expense or benefit represents the amount of income taxes expected to be payable or refundable for the current year. Deferred income tax assets and liabilities are determined based on differences between the financial statement reporting and tax bases of assets and liabilities and net operating loss and credit carryforwards, and are measured using the enacted tax rates and laws that will be in effect when such items are expected to reverse. Deferred income tax assets are reduced, as necessary, by a valuation allowance when management determines it is more likely than not that some or all of the tax benefits will not be realized.



The Company accounts for uncertain tax positions in accordance with Accounting Standards Codification (“ASC”) 740-10, *Accounting for Uncertainty in Income Taxes*. The Company assesses all material positions taken in any income tax return, including all significant uncertain positions, in all tax years that are still subject to assessment or challenge by relevant taxing authorities. Assessing an uncertain tax position begins with the initial determination of the position’s sustainability and is measured at the largest amount of benefit that is greater than fifty percent likely of being realized upon ultimate settlement. As of each balance sheet date, unresolved uncertain tax positions must be reassessed, and the Company will determine whether (i) the factors underlying the sustainability assertion have changed and (ii) the amount of the recognized tax benefit is still appropriate. The recognition and measurement of tax benefits requires significant judgment. Judgments concerning the recognition and measurement of a tax benefit might change as new information becomes available.

The Company includes any penalties and interest expense related to income taxes as a component of Interest and other income (expense), net, as necessary.

#### **Fair Value Measurements**

Fair value is defined as the exchange price that would be received for an asset or paid to transfer a liability, or an exit price, in the principal or most advantageous market for that asset or liability in an orderly transaction between market participants on the measurement date, and establishes a fair value hierarchy that requires an entity to maximize the use of observable inputs, where available, and minimize the use of unobservable inputs when measuring fair value. The Company determined the fair value of financial assets and liabilities using the fair value hierarchy that describes three levels of inputs that may be used to measure fair value, as follows:

Level 1—Quoted prices in active markets for identical assets and liabilities;

Level 2—Inputs other than Level 1 that are observable, either directly or indirectly, such as quoted prices for similar assets or liabilities, quoted prices in markets that are not active, or other inputs that are observable or can be corroborated by observable market data for substantially the full term of the assets or liabilities; and

Level 3—Unobservable inputs that are supported by little or no market activity and that are significant to the fair value of the assets or liabilities.

The carrying amounts of accounts receivable, prepaid expenses, accounts payable, accrued liabilities and accrued compensation and benefits approximate fair value due to the short-term nature of these items.

The fair value of the Company’s outstanding loan (See Note 7) is estimated using the net present value of the payments, discounted at an interest rate that is consistent with market interest rate, which is a Level 2 input. The estimated fair value of the Company’s outstanding loan approximates the carrying amount, as the loan bears a floating rate that approximates the market interest rate.

#### **Net Loss Per Share**

Basic net loss per share is calculated by dividing the net loss by the weighted-average number of shares of common stock outstanding for the period, without consideration for potential dilutive common shares. Basic net loss per share is the same as diluted net loss per share as the inclusion of all potentially dilutive securities would have been anti-dilutive given the net loss of the Company.

### 3. Fair Value Measurements

The following table sets forth the fair value of the Company's financial assets and liabilities measured on a recurring basis by level within the fair value hierarchy:

	Total	December 31, 2021		
		Level 1 (in thousands)	Level 2	Level 3
<b>Assets:</b>				
Money market funds	\$ 29,451	\$ 29,451	\$ -	\$ -
Commercial paper	22,580	-	22,580	-
Corporate debt securities	74,861	-	74,861	-
Equity securities	37,181	37,181	-	-
Asset-backed securities	32,957	-	32,957	-
U.S. government securities	47,420	47,420	-	-
Supranational debt securities	21,300	-	21,300	-
<b>Total</b>	<b>\$ 265,750</b>	<b>\$ 114,052</b>	<b>\$ 151,698</b>	<b>\$ -</b>

	Total	December 31, 2020		
		Level 1 (in thousands)	Level 2	Level 3
<b>Assets:</b>				
Money market funds	\$ 204,632	\$ 204,632	\$ -	\$ -
Commercial paper	42,208	-	42,208	-
Corporate debt securities	25,716	-	25,716	-
Equity securities	41,644	41,644	-	-
Asset-backed securities	12,632	-	12,632	-
U.S. government securities	39,785	39,785	-	-
<b>Total</b>	<b>\$ 366,617</b>	<b>\$ 286,061</b>	<b>\$ 80,556</b>	<b>\$ -</b>

Where applicable, the Company uses quoted market prices in active markets for identical assets to determine fair value. This pricing methodology applies to Level 1 investments, which are comprised of money market funds, U.S. government securities and the shares of Vaxcyte common stock held by the Company.

If quoted prices in active markets for identical assets are not available, then the Company uses quoted prices for similar assets or inputs other than quoted prices that are observable, either directly or indirectly. These investments are included in Level 2 and consist of commercial paper, corporate debt securities, asset-backed securities and supranational debt securities. These assets are valued using market prices when available, adjusting for accretion of the purchase price to face value at maturity.

A financial instrument's categorization within the valuation hierarchy is based upon the lowest level of input that is significant to the fair value measurement. The Company's assessment of the significance of a particular input to the fair value measurement in its entirety requires management to make judgments and consider factors specific to the asset or liability.

In certain cases where there is limited activity or less transparency around inputs to valuation, securities are classified as Level 3 within the valuation hierarchy. As of December 31, 2021 and 2020, the Company did not hold any securities that were classified as Level 3 within the valuation hierarchy.

#### **Investments in Equity Securities**

Subsequent to the closing of the initial public offering ("IPO") of Vaxcyte in June 2020, the fair value of Vaxcyte's common stock became readily determinable. As a result, beginning June 2020, Vaxcyte common stock held by the Company is measured at fair value at each reporting period based on the closing price of Vaxcyte's common stock on the last trading day of each reporting period, with any unrealized gains and losses recorded in the Company's statements of operations.

As of December 31, 2021 and 2020, the Company held 1,562,879 and 1,567,324 shares, respectively, of Vaxcyte common stock with an estimated fair value of \$37.2 million and \$41.6 million, respectively. The Company recognized an unrealized (loss) gain of (\$4.5) million and \$41.5 million for the year ended December 31, 2021 and 2020, respectively, which resulted from the change in estimated fair value of Vaxcyte common stock, adjusted by a \$9,000 and \$146,000 payment received for call option exercises and a revaluation of a prior preferred stock warrant converted to common stock for the year ended December 31, 2021 and 2020, respectively.

#### 4. Cash Equivalents and Marketable Securities

Cash equivalents and marketable securities consisted of the following:

	Amortized Cost Basis	December 31, 2021		Fair Value
		Unrealized Gains	Unrealized Losses	
(in thousands)				
Money market funds	\$ 29,451	\$ -	\$ -	\$ 29,451
Commercial paper	22,580	-	-	22,580
Corporate debt securities	75,012	-	(151)	74,861
Asset-based securities	32,975	-	(18)	32,957
U.S. government securities	47,504	-	(84)	47,420
Supranational debt securities	21,361	-	(61)	21,300
Total	228,883	-	(314)	228,569
Less amounts classified as cash equivalents	(29,451)	-	-	(29,451)
Total marketable securities	\$ 199,432	\$ -	\$ (314)	\$ 199,118

	Amortized Cost Basis	December 31, 2020		Fair Value
		Unrealized Gains	Unrealized Losses	
(in thousands)				
Money market funds	\$ 204,632	\$ -	\$ -	\$ 204,632
Commercial paper	42,208	-	-	42,208
Corporate debt securities	25,669	48	(1)	25,716
Asset-based securities	12,593	39	-	12,632
U.S. government securities	39,743	44	(2)	39,785
Total	324,845	131	(3)	324,973
Less amounts classified as cash equivalents	(204,632)	-	-	(204,632)
Total marketable securities	\$ 120,213	\$ 131	\$ (3)	\$ 120,341

As of December 31, 2021 and 2020, \$68.8 million and zero, respectively, of marketable securities had maturities of more than one year and are classified as long-term assets.

There were \$176.5 million and \$14.7 million of investments in an unrealized loss position of \$0.3 million and \$3,000 as of December 31, 2021 and 2020, respectively. During the years ended December 31, 2021, 2020 and 2019, the Company did not record any other-than-temporary impairment charges on its available-for-sale securities. Based on the Company's procedures under the expected credit loss model, including an assessment of unrealized gains on the portfolio after December 31, 2021, the Company concluded that the unrealized losses for its marketable securities were not attributable to credit and therefore an allowance for credit losses for these securities has not been recorded as of December 31, 2021. Also, based on the scheduled maturities of the investments, the Company was more likely than not to hold these investments for a period of time sufficient for a recovery of the Company's cost basis.

The Company recognized no material gains or losses on its cash equivalents and current and non-current marketable securities as of December 31, 2021 and as a result, the Company did not reclassify any amounts out of accumulated other comprehensive income for the year then ended.

## 5. Collaboration and License Agreements and Supply Agreements

The Company has entered into collaboration and license agreements and supply agreements with various pharmaceutical and biotechnology companies. The Company analyzes its agreements to determine whether it should account for the agreements within the scope of ASC 808, and, if so, it analyzes whether it should account for any elements under ASC 606.

The Company's accounts receivable balances may contain billed and unbilled amounts from upfront payments, milestones and other contingent payments, as well as reimbursable costs from collaboration and license agreements and supply agreements. The Company has not experienced credit loss from its accounts receivable and, therefore, has not recorded a reserve for estimated credit losses as of December 31, 2021.

In accordance with its agreements, the Company recognized revenue as follows:

	2021	Year Ended December 31, 2020		2019
		(in thousands)		
Bristol-Myers Squibb Company ("BMS") (1)	\$ 11,483	\$ 11,407	\$ 11,321	
Merck Sharp & Dohme Corporation ("Merck") (2)	42,780	26,075	21,458	
Merck KGaA, Darmstadt, Germany (operating in the United States and Canada under the name "EMD Serono")	4,576	5,042	8,879	
Vaxcyte (3)	3,041	198	1,078	
Total revenue	\$ 61,880	\$ 42,722	\$ 42,736	

(1) In January 2019, BMS announced the entry into a definitive agreement to acquire Celgene and the transaction was completed in November 2019.

(2) Merck was a related party until the closing of the Company's public offering on May 14, 2020.

(3) Vaxcyte was a related party until the closing of its initial public offering on June 16, 2020.

The following table presents the changes in the Company's deferred revenue balance from its agreements during the year ended December 31, 2021:

	Year ended December 31, 2021 (in thousands)	
Deferred revenue—December 31, 2020	\$	20,703
Additions to deferred revenue		23,402
Recognition of revenue in current period		(38,609 )
Deferred revenue—December 31, 2021	\$	5,496

The Company's balance of deferred revenue contains a license option payment and the transaction price from collaboration agreements allocated to performance obligations which are partially unsatisfied. The Company expects to recognize approximately \$5.5 million of the deferred revenue over the next twelve months.

There have been no material changes to the Company's agreements during the year ended December 31, 2021, except as described below.

### Collaboration with BMS

#### BMS Agreement

In November 2019, BMS acquired Celgene, and Celgene became a wholly owned subsidiary of BMS. In connection with such acquisition, BMS assumed the rights and obligations of the 2014 Celgene Agreement, 2017 Celgene Agreement and 2018 Celgene Master Services Agreement. Throughout this Annual Report, the Company refers to Celgene as BMS and the Company's agreements with Celgene as the BMS Agreement and the 2018 BMS Master Services Agreement.

In September 2014, the Company signed a Collaboration and License Agreement (the “BMS Agreement”) with BMS to discover and develop bispecific antibodies and/or antibody-drug conjugates (“ADCs”), focused primarily on the field of immuno-oncology, using the Company’s proprietary integrated cell-free protein synthesis platform, XpressCF®. In August 2017, the Company entered into an amended and restated collaboration and license agreement with BMS to refocus the collaboration on four programs that were advancing through preclinical development, including an ADC program targeting B cell maturation antigen (“BCMA ADC”).

In May 2019, the U.S. Food and Drug Administration cleared the investigational new drug (“IND”) application for the BCMA ADC, which was discovered and is being manufactured by the Company and is the first collaboration program IND. BMS has worldwide development and commercialization rights with respect to the BCMA ADC. The Company will continue to be responsible for clinical supply manufacturing and certain development services for the BCMA ADC and is eligible to receive from BMS aggregate development and regulatory contingent payments of up to \$275.0 million, if approved in multiple indications, and tiered royalties ranging from mid to high single digit percentages on worldwide sales of any resulting commercial products.

As of December 31, 2021 and 2020, there was no balance of deferred revenue related to payments received by the Company under the BMS Agreement.

#### **2018 BMS Master Services Agreement**

In March 2018, the Company entered into a Master Development and Clinical Manufacturing Services Agreement (the “2018 BMS Master Services Agreement”) with BMS, wherein BMS requested the Company to provide development, manufacturing and supply chain management services, including clinical product supply.

As of December 31, 2021 and 2020, there was \$0.6 million and \$1.2 million, respectively, of deferred revenue under the 2018 BMS Master Services Agreement.

Revenues under the BMS Agreement and the 2018 BMS Master Services Agreement were as follows:

	2021	Year ended December 31, 2020	2019
		(in thousands)	
Ongoing performance related to unsatisfied performance obligations	\$ —	\$ 2,974	\$ 3,936
Research and development services	940	646	571
Materials supply	10,543	7,787	6,814
Total revenue	<u>\$ 11,483</u>	<u>\$ 11,407</u>	<u>\$ 11,321</u>

#### **Collaboration with Merck**

##### **2018 Merck Agreement**

In July 2018, the Company entered into an agreement (the “2018 Merck Agreement”) with Merck for access to the Company’s technology and the identification and preclinical research and development of two target programs, with an option for Merck to engage the Company to continue these activities for a third program, upon the payment of an additional amount, focusing on cytokine derivatives for cancer and autoimmune disorders with an initial transaction price of \$60.0 million. The option to expand activities to a third program expired in January 2021.

Under ASC 606, the Company determined there was a financing component associated with the \$60.0 million upfront payment and has calculated total interest expense of \$7.3 million as of December 31, 2021, on the unearned revenue portion beyond one year from the effective date of the agreement, which amount was recognized as interest expense and revenue over the service period for the first and second target programs.

In March 2020, Merck exercised its option to extend the research term of the collaboration’s first cytokine-derivative program by one year, which, pursuant to the terms of the 2018 Merck Agreement, triggered a payment of \$5.0 million. The \$5.0 million was, in prior periods, considered to be a fully constrained variable consideration. Removal of the constraint on this variable consideration resulted in a change to the total transaction price, from

\$60.0 million to \$65.0 million. The Company allocated the updated transaction price to all identified performance obligations on the same basis as the initial allocation upon inception of the 2018 Merck Agreement, with any adjustments recorded as a cumulative catch-up in the current period.

In the second quarter of 2021, the Company earned a \$15.0 million contingent payment for the initiation by Merck of the first IND-enabling toxicology study under the first cytokine-derivative program in the collaboration. The \$15.0 million was, in prior periods, considered to be a fully constrained variable consideration. Removal of the constraint on this variable consideration resulted in a change to the total transaction price, from \$65.0 million to \$80.0 million. The Company allocated the updated transaction price to all identified performance obligations on the same basis as the initial allocation upon inception of the 2018 Merck Agreement, with any adjustments recorded as a cumulative catch-up in the period ended December 31, 2021. As a result of the change in transaction price, the Company recognized substantially all of the \$15.0 million contingent payment, with a remaining \$0.3 million related to the Joint Steering Committee, ("JSC") performance obligation, as a cumulative catch-up in revenue in the period ended December 31, 2021.

In September 2021, the Company entered into an amendment to the 2018 Merck Agreement (the "2021 Amendment") to extend the research term for the first program in the 2018 Merck Agreement to discover and develop novel cytokine derivative therapeutics for cancer and autoimmune disorders. Under the terms of the 2021 Amendment, the Company received a payment of \$2.5 million and may receive up to an additional \$7.5 million upon the achievement of certain developmental milestones. Pursuant to ASC 606, the Company concluded that the 2021 Amendment constitutes a contract modification which is to be accounted for as a separate contract from the 2018 Merck Agreement. From the \$2.5 million payment received, \$1.9 million was recognized as revenue on a proportion of performance basis in the year ended December 31, 2021, related to the Company's identified performance obligations under the 2021 Amendment. The additional \$7.5 million is considered to be fully constrained variable consideration.

In December 2021, Merck did not extend the research term for the second research program of the collaboration and that research program reverted to the Company. The first program of the collaboration is focused on two distinct cytokine derivative molecules for the treatment of cancer. The Company is also eligible to receive aggregate contingent payments of up to approximately \$0.5 billion for the target program selected by Merck, assuming the development and sale of the therapeutic candidate and all possible indications identified under the collaboration. If one or more products from the target program is developed for non-oncology or a single indication, the Company will be eligible for reduced aggregate milestone payments. In addition, the Company is eligible to receive tiered royalties ranging from mid-single digit to low teen percentages on the worldwide sales of any commercial products that may result from the collaboration.

As of December 31, 2021 and 2020, there was a total of \$0.9 million and \$18.5 million, respectively, of deferred revenue related to the 2018 Merck Agreement and 2021 Amendment.

### **2020 Merck Master Services Agreement**

In August 2020, the Company entered into a Pre-Clinical and Clinical Supply Agreement (the “2020 Merck Master Services Agreement”) with Merck, wherein Merck requested the Company to provide development, manufacturing and supply chain management services, including clinical product supply, upon completion of the research programs under the 2018 Merck Agreement.

As of both December 31, 2021 and 2020, there was no deferred revenue under the 2020 Merck Master Services Agreement.

Revenues under the 2018 Merck Agreement and the 2020 Merck Master Services Agreement were as follows:

	2021	Year ended December 31, 2020 (in thousands)	2019
Ongoing performance related to unsatisfied performance obligations	\$ 35,098	\$ 18,474	\$ 14,736
Research and development services	2,666	5,485	3,578
Financing component on unearned revenue	610	1,852	3,144
Materials supply	4,406	264	–
Total revenue	<u>\$ 42,780</u>	<u>\$ 26,075</u>	<u>\$ 21,458</u>

### **Collaboration with EMD Serono**

#### **EMD Serono Agreements**

The Company signed a Collaboration Agreement and a License Agreement with EMD Serono in May 2014 and September 2014, respectively, which were entered into in contemplation of each other and therefore treated as a single agreement for accounting purposes. The Collaboration Agreement was subsumed into the License Agreement (the “MDA Agreement”), which agreement is to develop ADCs for multiple cancer targets. Under the MDA Agreement, a novel bispecific ADC product candidate targeting EGFR and MUC1, known as M1231, is undergoing development.

The Company is eligible to receive up to \$52.5 million for M1231 under the MDA Agreement, primarily from pre-commercial contingent payments. Relatedly, the Company earned a \$2.0 million contingent payment in the second quarter of 2021 related to a patient enrollment achievement in the Phase 1 dose escalation portion of a study of M1231. In August 2020, the Company earned a \$1.0 million clinical supply milestone payment under the MDA Agreement. In September 2019, the Company earned a \$1.5 million contingent payment under the MDA Agreement upon designation by EMD Serono of a specific bispecific antibody drug conjugate as a clinical development candidate with their approval to advance it to IND-enabling studies. In addition, the Company is eligible to receive tiered royalties ranging from low-to-mid single digit percentages, along with certain additional one-time royalties, on worldwide sales of any commercial products that may result from the MDA Agreement.

As of both December 31, 2021 and 2020, there was no deferred revenue related to payments received by the Company under the MDA Agreement.

#### **2019 EMD Serono Supply Agreement**

In April 2019, the Company entered into an ADC Product Preclinical and Phase I Clinical Supply Agreement (the “2019 EMD Serono Supply Agreement”) with EMD Serono, wherein EMD Serono requested the Company to provide development, manufacturing and supply chain management services, including clinical product supply.

As of December 31, 2021 and 2020, there was zero and \$1 million, respectively, of deferred revenue related to payments received by the Company under the 2019 EMD Serono Supply Agreement.

Revenues under the EMD Serono agreements were as follows:

	2021	Year ended December 31, 2020 (in thousands)	2019
Ongoing performance related to unsatisfied performance obligations	\$ —	\$ —	\$ 2,266
Contingent payment / milestone earned	2,000	1,000	1,500
Research and development services	851	1,316	2,890
Materials supply	1,725	2,726	2,223
Total revenue	<u>\$ 4,576</u>	<u>\$ 5,042</u>	<u>\$ 8,879</u>

#### ***Vaxcyte Supply Agreement***

In May 2018, the Company entered into a Supply Agreement (the "Supply Agreement") with Vaxcyte, wherein Vaxcyte engaged the Company to provide research and development services and to supply extracts and custom reagents, as requested by Vaxcyte. The pricing is based on an agreed upon cost plus arrangement.

During 2020, upon Vaxcyte's request and their agreement to reimburse the related costs, the Company entered into agreements with third-party contract manufacturers ("CMOs") to conduct process transfers to allow for such CMOs to manufacture and supply extract and custom reagents for Vaxcyte. For the year ended December 31, 2021 and 2020, the agreed-upon reimbursements by Vaxcyte of the costs associated with such arrangements, principally for pass-through costs from the CMOs, were \$8.9 million and \$0.5 million, respectively, and were accounted for by the Company as a reduction to research and development expense based on the Company's conclusion that Vaxcyte was not a customer for such activities and associated payments.

Revenues under the Vaxcyte Supply Agreement were as follows:

	2021	Year ended December 31, 2020 (in thousands)	2019
Research and development services	\$ 1,131	\$ 184	\$ —
Materials supply	1,910	14	1,078
Total revenue	<u>\$ 3,041</u>	<u>\$ 198</u>	<u>\$ 1,078</u>

#### ***BioNova Option Agreement***

In October 2021, the Company entered into an agreement with BioNova to confer BioNova the option to obtain exclusive rights to develop and commercialize STRO-001 in China, Hong Kong, Macau and Taiwan, referred to as Greater China. BioNova will pursue the clinical development, regulatory approval, and commercialization of STRO-001 in multiple indications, including non-Hodgkin's lymphoma, multiple myeloma, and leukemia in the licensed territory. The Company will retain development and commercial rights of STRO-001 globally outside of Greater China, including the United States.

Under the BioNova Option Agreement, BioNova paid the Company an initial licensing option payment of \$4.0 million, with potential payments totaling up to \$200 million related to option exercise, development, regulatory, and commercial milestones. The Company will provide STRO-001 to BioNova under appropriate clinical and commercial supply service agreements. Upon commercialization, the Company is eligible to receive tiered royalties ranging from low- to mid-teen percentages based on annual net sales of STRO-001 in Greater China for at least ten years following the first commercial sale of STRO-001 in Greater China.



The Company identified a combined performance obligation under the initial license option agreement, which consists of four interrelated promises: generating a recommended dose of STRO-001 for multiple myeloma and Non-Hodgkin's lymphoma, providing licensed know-how and regulatory filings necessary to prepare an IND; providing initial clinical supply in the People's Republic of China; and participating in the JSC. These promises are considered to be interdependent and not distinct from each other, representing a combined output. The transaction price at inception included the refundable payment of \$4.0 million and was considered constrained at the inception of the agreement since the Company could not conclude it was probable that a significant reversal in the amount of revenue recognized would not occur. BioNova will have the right to exercise the license option for an additional payment of \$12.0 million. As of December 31, 2021, there was \$4.0 million of deferred revenue related to the payment received by the Company under the BioNova Option Agreement and BioNova had not yet exercised the license option.

#### ***Tasly License Agreement***

In December 2021, the Company entered into a license agreement with Tasly, to grant Tasly an exclusive license to develop and commercialize STRO-002 in Greater China. Tasly will pursue the clinical development, regulatory approval, and commercialization of STRO-002 in multiple indications, including ovarian cancer, non-small cell lung cancer, triple-negative breast cancer, and other indications in Greater China. The Company will retain development and commercial rights of STRO-002 globally outside of Greater China, including the United States.

Under the Tasly License Agreement, Tasly is obligated to make to the Company an initial nonrefundable upfront payment of \$40.0 million, with additional potential payments totaling up to \$345 million related to development, regulatory and commercialization contingent payments and milestones. The Company will provide STRO-002 to Tasly under appropriate clinical and commercial supply service agreements. Upon commercialization, the Company will receive tiered royalties, ranging from low- to mid-teen percentages based on annual net sales of STRO-002 in Greater China for at least ten years following the first commercial sale of STRO-002 in Greater China.

The Company determined that the Tasly License Agreement falls within the scope of ASC 808, as both parties are active participants in the activities and are exposed to significant risks and rewards dependent on the success of the commercialization of indications for STRO-002 in Greater China. The Company concluded that the Tasly License Agreement contained the following units of account: i) licensed know-how and Sutro patents, license to trademark rights, and initial regulatory data and information necessary to prepare an IND; and ii) collaboration governance and information sharing activities, such as JSC participation and ongoing regulatory and pharmacovigilance support.

The promises related to the licensed know-how and Sutro patents, license to trademark rights, and initial regulatory data and information necessary to prepare an IND are considered to be interdependent and not distinct from each other, representing a combined output. The Company determined that these promises are capable of being distinct from the collaboration governance and information sharing activities discussed below and further determined that this unit of account is a vendor-customer relationship and will account for it in accordance with ASC 606. The transaction price at inception included fixed consideration consisting of the upfront payment of \$40.0 million. All potential future milestones and other payments were considered constrained at the inception of the Tasly License Agreement since the Company could not conclude it was probable that a significant reversal in the amount of revenue recognized would not occur. Since there is only one performance obligation accounted for under ASC 606, no allocation of the transaction price was necessary.

The Company determined that the unit of account consisting of collaboration governance and information sharing activities, such as JSC participation and ongoing regulatory and pharmacovigilance support, do not represent a customer-vendor relationship between the Company and Tasly. These promises are considered to be interdependent and not distinct from each other, representing a combined output. However, the Company determined that these promises are capable of being distinct from the intellectual property and data license promises discussed above. As such, based on the nature of the agreement and collaborative activities, the Company determined that the costs associated with these governance and information sharing activities performed under the agreement will be included in research and development expenses in the statements of operations, with any reimbursement of costs by Tasly reflected as a reduction of such expenses. During the year ended December 31, 2021, the Company did not recognize a reduction of research and development expenses under the Tasly License Agreement.

On December 24, 2021, the effective date of the Tasly License Agreement, the Company satisfied its only performance obligation related to the \$40.0 million upfront payment by delivering to Tasly the license, know-how and data required under the Tasly License Agreement. Following the satisfaction of such performance obligation, under the Tasly License Agreement, Tasly is obligated to pay the Company the \$40.0 million upfront payment. In February 2022, Tasly indicated to the Company that it would like to discuss and renegotiate the terms of the Tasly License Agreement. As any renegotiation could affect the amount and timing of Tasly's obligations under the terms of the Tasly License Agreement, including the upfront payment, the Company has concluded that it will not recognize the \$40.0 million upfront payment as revenue in December 2021.

## 6. Property and Equipment, Net

Property and equipment, net, consists of the following:

	December 31,	
	2021	2020
	(in thousands)	
Computer equipment and software	\$ 1,353	\$ 1,291
Furniture and office equipment	237	680
Laboratory equipment	30,231	30,814
Leasehold improvements	23,649	15,896
Construction in progress	506	1,081
Total	55,976	49,762
Less accumulated depreciation and amortization	(33,426 )	(36,827 )
Total property and equipment, net	<u>\$ 22,550</u>	<u>\$ 12,935</u>

Depreciation and amortization expense amounted to \$4.8 million, \$4.3 million and \$4.8 million for the years ended December 31, 2021, 2020 and 2019, respectively.

## 7. Loan and Security Agreement

In August 2017, the Company entered into a loan and security agreement with Oxford Finance LLC ("Oxford") and Silicon Valley Bank ("SVB") under which it borrowed \$15.0 million (the "August 2017 Loan"). The loan was due in 30 monthly installments from March 2019 through its repayment in August 2021, with interest-only monthly payments until March 2019. The Company commenced repayment of the loan in March 2019. The interest charges on the loan were based on a floating rate that equaled the greater of 7.39% or the sum of the 30-day U.S. Dollar London Interbank Offered Rate ("LIBOR") plus 6.40%. In connection with the August 2017 Loan, the Company issued to Oxford and SVB a warrant to purchase the Company's Series D-2 redeemable convertible preferred stock (the "2017 Warrant"). The 2017 Warrants were later converted into warrants to purchase Series E redeemable convertible preferred stock in May and July 2018, and upon the Company's IPO on October 1, 2018, all Series E redeemable convertible preferred stock warrants were converted to warrants to purchase 46,359 shares of common stock. The estimated fair value upon issuance of the 2017 Warrant of \$0.3 million was recorded as a debt discount on the associated borrowings on the Company's balance sheet. The debt discount was amortized to interest expense over the expected repayment period of the loan using the effective-interest method.

On February 28, 2020, (the "Effective Date"), the Company entered into a loan and security agreement (the "Loan and Security Agreement") with Oxford as the collateral agent and a lender, and SVB as a lender (together with Oxford, the "Lenders"), pursuant to which the Lenders agreed to lend the Company up to an aggregate of \$25.0 million (the "Term A Loan"). Upon entering into the Loan and Security Agreement, the Company borrowed \$25.0 million from the Lenders, with approximately \$9.6 million of such amount applied to the repayment of the outstanding principal, interest and final payment fees owed pursuant to the August 2017 Loan. As such, the August 2017 Loan has been paid in full. The Company accounted for the issuance of the Loan and Security Agreement and repayment of the August 2017 Loan as a debt modification. The associated unamortized debt discount on the August 2017 Loan and new lender fees from the debt issuance will be amortized as interest expense using the effective interest method until the maturity date of the Term A Loan.

The Company's obligations under the Loan and Security Agreement are secured by all assets of the Company, other than its intellectual property. The Company has also agreed not to encumber its intellectual property assets, except as permitted by the Loan and Security Agreement.

The Term A Loan matures on March 1, 2024 (the "Maturity Date") and will be interest-only through March 1, 2022, followed by 24 equal monthly payments of principal and interest. The Term A Loan will bear interest at a floating per annum rate equal to the greater of (i) 8.07% or (ii) the sum of (a) the greater of (1) the thirty (30) day U.S. LIBOR rate reported in the Wall Street Journal on the last business day of the month that immediately precedes the month in which the interest will accrue or (2) 1.67%, plus (b) 6.40%.

The Company will be required to make a final payment of 3.83% of the original principal amount of the Term A Loan, or \$1.0 million, payable on the earlier of (i) the Maturity Date, (ii) the acceleration of the Term A Loan, or (iii) the prepayment of the Term A Loan (the "Final Payment"). The final payment amount is accreted as interest expense until the Maturity Date using the effective interest method. The Company may prepay all, but not less than all, of the Term A Loan upon 30 days' advance written notice to Oxford, provided that the Company will be obligated to pay a prepayment fee equal to (i) 3.00% of the principal amount of the Term A Loan prepaid on or before the first anniversary of the applicable funding date, or (ii) 2.00% of the principal amount of the Term A Loan prepaid between the first and second anniversary of the applicable funding date, or (iii) 1.00% of the principal amount of the Term A Loan prepaid thereafter, and prior to the Maturity Date (each, a "Prepayment Fee").

The Loan and Security Agreement contains customary affirmative and restrictive covenants, including covenants regarding incurrence of additional indebtedness or liens, investments, transactions with affiliates, delivery of financial statements, maintenance of inventory, payment of taxes, maintenance of insurance, protection of intellectual property rights, dispositions of property, business combinations or acquisitions, among other customary covenants. The Company is also restricted from paying dividends or making other distributions or payments on its capital stock, subject to limited exceptions. The Loan and Security Agreement provides that an event of default will occur if, among other triggers, there occurs any circumstances that could reasonably be expected to result in a material adverse change in the business, or operations or condition (financial or otherwise) of the Company or a material impairment of the prospect of the Company to repay any portion of its obligations under the Agreement. The Agreement also includes customary representations and warranties, other events of default and termination provisions.

In connection with entering into the Loan and Security Agreement, the Company issued to the Lenders warrants exercisable for 81,257 shares of the Company's common stock (the "2020 Warrants"). The 2020 Warrants are exercisable in whole or in part, immediately, and have a per share exercise price of \$9.23, which is the closing price of the Company's common stock reported on the Nasdaq Global Market on the day prior to the Effective Date. The 2020 Warrants will terminate on the earlier of February 28, 2030 or the closing of certain merger or consolidation transactions. The estimated fair value upon issuance of the Warrants of \$0.6 million is recorded as a debt discount on the associated borrowings on the Company's balance sheet. The debt discount is being amortized to interest expense over the expected repayment period of the loan using the effective-interest method.

As of December 31, 2021 and 2020, accrued interest expense was \$0.2 million and \$0.2 million, respectively.

During years ended December 31, 2021, 2020 and 2019, the Company recorded interest expense related to loans outstanding of \$2.6 million, \$2.3 million and \$1.1 million, respectively, with average interest rates of 8.07%, 8.08% and 8.72%, respectively, and interest related to the accretion of debt discount of \$0.6 million, \$0.5 million and \$0.2 million, respectively.

Long-term debt and net premium (amortization) balances are as follows:

	2021	December 31, (in thousands)	2020
Principal amount of debt	\$	25,000	\$ 25,000
Net premium / (amortization) associated with accretion of final payment and other debt issuance costs		113	(455 )
Debt, current and non-current		25,113	24,545
Less: Debt, current portion		(9,375 )	-
Debt, non-current portion	\$	<u>15,738</u>	<u>\$ 24,545</u>

Future minimum payments of principal and estimated payments of interest on the Company's Loan and Security Agreement as of December 31, 2021 are as follows:

Year Ending December 31:	Amount (in thousands)
2022	\$ 11,166
2023	13,312
2024	4,126
Total future maturities	28,604
Less amount representing interest	(2,646 )
Less final payment	(958 )
Total principal amount of debt	<u>\$ 25,000</u>

## 8. Commitments and Contingencies

### Leases

In June 2021, the Company entered into a third amendment (the "Third Amendment") to its manufacturing facility lease, dated May 18, 2011, as amended, by and between Alemany Plaza LLC, located in San Carlos, California (the "San Carlos Lease"), as an extension to the term of the San Carlos Lease for a period of five years (the "Lease Extension Period"). Pursuant to the Third Amendment, the San Carlos Lease will expire on July 31, 2026, and it includes an option to renew the San Carlos Lease for an additional five years. The aggregate estimated base rent payments due over the Lease Extension Period is approximately \$4.2 million, subject to certain terms contained in the San Carlos Lease.

In June 2021, the Company entered into a first amendment (the "First Amendment") to its manufacturing support facility lease, dated May 4, 2015, as amended, by and between 870 Industrial Road LLC, located in San Carlos, California (the "Industrial Lease"), as an extension to the term of the Industrial Lease for a period of five years (the "Industrial Lease Extension Period"). Pursuant to the first Amendment, the Industrial Lease will expire on June 30, 2026, and it includes an option to renew the Industrial Lease for an additional five years. The aggregate estimated base rent payments due over the Industrial Lease Extension Period is approximately \$4.3 million, subject to certain terms contained in the Industrial Lease.

In September 2020, the Company entered into a sublease agreement (the "Sublease") with Five Prime Therapeutics, Inc. (the "Sublessor"), for approximately 115,466 square feet, in a building located in South San Francisco, California (the "Premises"). The Company uses the Premises as its new corporate headquarters and to conduct (or expand) research and development activities. The Company commenced making monthly payments for the first 85,755 square feet of the Premises ("Initial Premises") in July 2021, with occupancy of such space commencing in August 2021. The Company was provided early access to the Initial Premises commencing in the fourth quarter of 2020 to conduct certain planning and tenant improvement work. The Sublease is subordinate to the lease agreement, effective December 12, 2016, between the Sublessor and HCP Oyster Point III LLC (the "Landlord"). The commencement date for the remaining 29,711 square feet of the Premises (the "Expansion Premises") is expected to be 24 months following the commencement date on the Initial Premises, although the Company has the right to accelerate the commencement date on the Expansion Premises to an earlier date upon six months' prior written notice to the Sublessor. The Sublease for both the Initial Premises and Expansion Premises will expire on December 31, 2027. With a commencement date on the Initial Premises of July 1, 2021,

the aggregate estimated base rent payments due over the term of the Sublease are approximately \$39.1 million, including the approximately \$5.2 million in potential financial benefit to the Company of base rent abatement to be provided by Sublessor, subject to certain terms contained in the Sublease. The Sublease contains customary provisions requiring the Company to pay its pro rata share of utilities and a portion of the operating expenses and certain taxes, assessments and fees of the Premises and provisions allowing the Sublessor to terminate the Sublease upon the termination of the lease with the Landlord or if the Company fails to remedy a breach of certain of its obligations within specified time periods. Additionally, the Company posted a security deposit of \$0.9 million, which is reflected as restricted cash in non-current assets on the Company's balance sheet as of December 31, 2021 and 2020.

The Company recognizes rent expense for these operating leases on a straight-line basis over the lease period. The components of lease costs, which the Company includes in operating expenses in the statements of operations, were as follows (in thousands):

	<b>Year ended December 31, 2021</b>
Operating lease cost	\$ 8,355
Short-term lease cost	117
Variable lease cost	2,089
<b>Total lease cost</b>	<b>\$ 10,561</b>

During the year ended December 31, 2021, the Company recorded operating lease expense of \$8.4 million and paid \$6.2 million of operating lease payments related to the lease liabilities, which the Company includes in net cash used in operating activities in the statements of cash flows.

As of December 31, 2021, the weighted-average remaining lease term was 5.7 years and the weighted-average discount rate used to determine the operating lease liability was 10.8%.

As of December 31, 2021, the maturities of the Company's operating lease liabilities were as follows (in thousands):

<b>Year Ending December 31,</b>	<b>Amount (in thousands)</b>
2022 <sup>(1)</sup>	\$ 1,657
2023	8,002
2024	9,219
2025	9,533
2026	8,994
Thereafter	8,289
<b>Total lease payments</b>	<b>45,694</b>
Less: imputed interest	(13,433 )
<b>Operating lease liabilities</b>	<b>32,261</b>
Less: current portion	(1,037 )
<b>Total lease liabilities, non-current</b>	<b>\$ 31,224</b>

(1) Includes approximately \$5.2 million in potential financial benefit to the Company of base rent abatement to be provided by sublessor for months 7 – 18 of the sublease period, subject to certain terms contained in the Sublease.

Under the historical guidance of ASC 840, the deferred rent balance on December 31, 2020 totaled \$1.3 million and the future minimum lease payments for the Company's operating leases on December 31, 2020 were as follows (in thousands):

Year Ending December 31,	Amount (in thousands)
2021	\$ 5,742
2022 <sup>(1)</sup>	5,183
2023	6,310
2024	7,476
2025 and beyond	24,034
Total future minimum lease payments	<u>\$ 48,745</u>

(1) Excludes approximately \$5.2 million in potential financial benefit to the Company of base rent abatement to be provided by sublessor for months 7 – 18 of the sublease period, subject to certain terms contained in the Sublease.

Rent expense was \$4.7 million and \$3.6 million for the years ended December 31, 2020 and 2019, respectively.

#### **Indemnification & Other**

In the ordinary course of business, the Company may provide indemnifications of varying scope and terms to vendors, lessors, business partners, board members, officers, and other parties with respect to certain matters, including, but not limited to, losses arising out of breach of such agreements, services to be provided by the Company, negligence or willful misconduct of the Company, violations of law by the Company, or from intellectual property infringement claims made by third parties. In addition, the Company has entered into indemnification agreements with directors and certain officers and employees that will require the Company, among other things, to indemnify them against certain liabilities that may arise by reason of their status or service as directors, officers or employees. No demands have been made upon the Company to provide indemnification under such agreements, and thus, there are no claims that the Company is aware of that could have a material effect on the Company's balance sheets, statements of operations, or statements of cash flows. The Company currently has directors' and officers' liability insurance.

In addition, the Company enters into agreements in the normal course of business, including with contract research organizations for clinical trials, contract manufacturing organizations for certain manufacturing services, and vendors for preclinical studies and other services and products for operating purposes, which are generally cancelable upon written notice.

#### **9. Related-Party Transactions**

Upon the Company's public offering on May 14, 2020, Merck's ownership of the Company's outstanding equity interest decreased to less than 10%. As a result, starting May 14, 2020, the Company ceased to reflect balances and transactions associated with Merck as being with a related party in its financial statements. Transactions with Merck for the years ended December 31, 2021, 2020 and 2019 are described in Note 5.

As discussed in Note 2, Vaxcyte closed its IPO of its common stock on June 16, 2020, resulting in the Company's ownership of Vaxcyte's outstanding equity being less than 4.0%. As a result, starting on June 16, 2020, the Company ceased to reflect any balances and transactions associated with Vaxcyte being a related party in its financial statements. Transactions with Vaxcyte for the years ended December 31, 2021, 2020 and 2019 are described in Note 5.

#### **10. Stockholders' Equity**

##### **Common Stock**

Holders of common stock are entitled to one vote per share on all matters to be voted upon by the stockholders of the Company.

As of December 31, 2021 and 2020, the Company had reserved common stock, on an if-converted basis, for issuance as follows:

	<b>December 31,</b>	
	<b>2021</b>	<b>2020</b>
Common stock options issued and outstanding	6,512,086	5,439,295
Common stock awards issued and outstanding	2,403,826	666,375
Remaining shares reserved for issuance under 2018 Equity Incentive Plan and 2021 Equity Inducement Plan	1,504,641	1,710,824
Shares reserved for issuance under 2018 Employee Stock Purchase Plan	673,251	361,539
Warrants to purchase common stock	127,616	153,070
Total	<u>11,221,420</u>	<u>8,331,103</u>

### **Preferred Stock**

As of December 31, 2021, the Company had 10,000,000 shares of preferred stock authorized with a par value of \$0.001. No shares of preferred stock were outstanding as of December 31, 2021 and 2020.

### **Warrants**

In August 2017, the Company issued warrants to Oxford and SVB to purchase an aggregate of 682,230 shares of Series D-2 redeemable convertible preferred stock at an exercise price of \$0.6596 per share in connection with the issuance of the August 2017 Loan. If there was a subsequent convertible preferred stock or other senior equity securities financing with a per share price less than the Series D-2 redeemable convertible preferred per share price, then the warrant would automatically convert to a warrant to purchase such class of shares, based on the per share price of such equity. Given that the price per share of the Series E redeemable convertible preferred stock described above was less than the price per share of the Series D-2 redeemable convertible preferred stock, the 2017 Warrant converted into a warrant to purchase a total of 1,682,871 shares of Series E redeemable convertible preferred stock at an exercise price of \$0.2674 per share. The warrant is exercisable from the original date of issuance and has a 10-year term.

The Company adjusted the warrant liability for changes in fair value until the completion of its IPO on October 1, 2018, at which time certain convertible preferred stock warrants were converted into warrants for the purchase of common stock and the related convertible preferred stock warrant liability was reclassified to additional paid-in capital and others expired. On October 1, 2018, 1,232,220 shares of the Series C redeemable convertible preferred warrants were canceled, and the remaining 687,928 shares were converted to 25,453 shares of warrants to purchase common stock on a 1-for-0.0370 basis at an exercise price of \$12.9649. The common stock warrant was outstanding and exercisable as of December 31, 2020. In November 2021, this common stock warrant was fully net exercised into 9,308 shares of common stock. All Series E redeemable convertible preferred warrants were converted to 46,359 shares of warrants to purchase common stock on a 1-for-0.0275 basis.

In February 2020, in connection with entering into the Loan and Security Agreement, the Company issued to Oxford and SVB the 2020 Warrants, which are exercisable for 54,171 shares and 27,086 shares, respectively, of the Company's common stock. The 2020 Warrants are exercisable in whole or in part, immediately, and have a per share exercise price of \$9.23, which is the closing price of the Company's common stock reported on the Nasdaq Global Market on the day prior to the Effective Date. The 2020 Warrants will terminate on the earlier of February 28, 2030 or the closing of certain merger or consolidation transactions.

## **11. Equity Incentive Plans, Employee Stock Purchase Plan and Stock-Based Compensation**

### **2004 Equity Incentive Plan, 2018 Equity Incentive Plan and 2021 Equity Inducement Plan**

In September 2018, the Company adopted the 2018 Equity Incentive Plan ("2018 Plan"), which became effective on September 25, 2018. As a result, the Company will not grant any additional awards under the 2004 Equity Incentive Plan ("2004 Plan"). The terms of the 2004 Plan and applicable award agreements will continue to govern any outstanding awards thereunder. In addition to the shares of common stock reserved for future issuance under the 2004 Plan that were added to the 2018 Plan upon its effective date, the Company initially reserved 2,300,000 shares of common stock for issuance under the 2018 Plan. In addition, the number of shares of common stock reserved for issuance under the 2018 Plan will automatically increase on the first day of January for a period of up to ten years, commencing on January 1, 2019, in an amount equal to 5% of the total number of

shares of the Company's capital stock outstanding on the immediately preceding December 31 (rounded to the nearest whole share), or a lesser number of shares determined by the Company's board of directors. As a result, common stock reserved for issuance under the 2018 Plan was increased by 2,287,605 shares on January 1, 2021.

In August 2021, the Company adopted the 2021 Equity Inducement Plan ("2021 Plan"), which became effective on August 4, 2021. Upon its effective date, the Company initially reserved 750,000 shares of common stock for issuance pursuant to non-qualified stock options and restricted stock units ("RSUs") under the 2021 Plan. In accordance with Rule 5635(c)(4) of the Nasdaq listing rules, equity awards under the 2021 Plan may only be made to an employee if he or she is granted such equity awards in connection with his or her commencement of employment with the Company and such grant is an inducement material to his or her entering into employment with the Company or such subsidiary. In addition, awards under the 2021 Plan may only be made to employees who have not previously been an employee or member of the Board (or any parent or subsidiary of the Company) or following a bona fide period of non-employment of the employee by the Company (or a parent or subsidiary of the Company). At all times the Company will reserve and keep available a sufficient number of shares as will be required to satisfy the requirements of all outstanding awards granted under the 2021 Plan.

As of December 31, 2021, the Company had 1,504,641 shares available for grant under the 2018 Plan and the 2021 Plan.

The following table summarizes option activities under the Company's 2004 Plan, 2018 Plan and 2021 Plan:

	Outstanding Options	Weighted- Average Exercise Price	Weighted- Average Remaining Contract Term (Years)	Aggregate Intrinsic Value (in thousands)
Balances at December 31, 2020	5,439,295	\$ 11.93	7.75	\$ 53,202
Granted	1,449,834	\$ 20.27		
Exercised	(237,370)	\$ 10.47		
Canceled/Forfeited	(139,673)	\$ 10.94		
Balances at December 31, 2021	6,512,086	\$ 13.86	7.39	\$ 14,955
Exercisable at December 31, 2021	3,866,289	\$ 12.91	6.63	\$ 9,170

The aggregate intrinsic value was calculated as the difference between the exercise prices of the underlying stock option awards and the estimated fair value of the Company's common stock on the date of exercise. For the years ended December 31, 2021, 2020 and 2019, the aggregate intrinsic value of stock options exercised was \$2.8 million, \$1.2 million and \$0.2 million, respectively, determined at the date of the option exercise.

#### Employee Stock Options Valuation

For determining stock-based compensation expense, the fair-value-based measurement of each employee stock option was estimated as of the date of grant using the Black-Scholes option pricing model with assumptions as follows:

	Year Ended December 31,		
	2021	2020	2019
Expected term (in years)	5.3-6.1	3.1-7.0	4.5-7.0
Expected volatility	80.9%-84.9%	73.2%-87.4%	72.7%-74.9%
Risk-free interest rate	0.6%-1.3%	0.2%-1.6%	1.4%-2.6%
Expected dividend	-	-	-

*Expected Term*—The expected term represents the period that the stock-based awards are expected to be outstanding. The Company used the "simplified" method to determine the expected term of options granted, which calculates the expected terms as the average of the weighted-average vesting term and the contractual term of the option.



*Expected Volatility*—Since the Company has limited information available on the volatility of its common stock due to its short trading history, the expected volatility was estimated based on the average historical volatilities of common stock of comparable publicly traded entities over a period equal to the expected term of the stock option grants. The Company will continue to apply this process until a sufficient amount of historical information regarding the volatility of its own stock price becomes available.

*Risk-Free Interest Rate*—The risk-free interest rate is based on the U.S. Treasury yield in effect at the time of grant for zero-coupon U.S. Treasury notes with maturities approximately equal to the expected term of the options.

*Expected Dividend*—The Company has never paid dividends on its common stock. Therefore, the Company used an expected dividend of zero.

Using the Black-Scholes option-valuation model, the weighted-average estimated grant-date fair value of employee stock options granted during the years ended December 31, 2021, 2020 and 2019 was \$14.24, \$5.59 and \$6.71 per share, respectively.

#### **Restricted Stock Units**

Restricted stock units (“RSUs”) are share awards that entitle the holder to receive freely tradable shares of the Company’s common stock upon vesting. The RSUs cannot be transferred and the awards are subject to forfeiture if the holder’s employment terminates prior to the release of the vesting restrictions. The RSUs generally vest over a four-year period provided the employee remains continuously employed with the Company. The fair value of the RSUs is equal to the closing price of the Company’s common stock on the grant date.

A summary of the status and activity of non-vested RSUs for the year ended December 31, 2021 is as follows:

	<b>Number of Shares</b>		<b>Weighted Average Grant-Date Fair Value</b>
Non-vested December 31, 2020	666,375	\$	9.83
Granted	2,094,250		20.31
Released	(238,724 )		11.23
Canceled	(118,075 )		17.66
Non-vested December 31, 2021	<u>2,403,826</u>	<u>\$</u>	<u>18.43</u>

#### **2018 Employee Stock Purchase Plan**

In September 2018, the Company adopted the 2018 Employee Stock Purchase Plan (“ESPP”), in order to enable eligible employees to purchase shares of the Company’s common stock. The Company initially reserved 230,000 shares of common stock for sale under the ESPP. The aggregate number of shares reserved for sale under the ESPP will increase automatically on January 1st of each of the first ten calendar years after the effective date by the number of shares equal to the lesser of 1% of the total outstanding shares of the Company’s common stock as of the immediately preceding December 31 (rounded to the nearest whole share) or a number of shares as may be determined by the Company’s board of directors. As a result, common stock reserved for issuance under the ESPP was increased by 457,521 shares on January 1, 2021. The aggregate number of shares issued over the term of the Company’s ESPP, subject to stock-splits, recapitalizations or similar events, may not exceed 2,300,000 shares of the Company’s common stock.

The fair value of the ESPP shares is estimated using the Black-Scholes option pricing model. For the years ended December 31, 2021, 2020 and 2019, the fair value of ESPP shares was estimated using the following assumptions:

	Year Ended December 31,		
	2021	2020	2019
Expected term (in years)	0.5	0.5	0.5
Expected volatility	65.9-111.4%	63.0%-111.4%	63.0%-83.2%
Risk-free interest rate	0.1 %	0.1%-1.9%	1.9%-2.5%
Expected dividend	-	-	-

During the years ended December 31, 2021, 2020 and 2019, 145,809, 195,992, and 131,939 shares, respectively, had been purchased. As of December 31, 2021, 673,251 shares were available for future issuance under the ESPP.

#### **Stock-Based Compensation Expense**

The Company believes that the fair value of the stock options, RSUs and ESPP shares is more reliably measurable than the fair value of services received.

Total stock-based compensation expense recognized was as follows:

	Year Ended December 31,		
	2021	2020	2019
	(in thousands)		
Research and development expense:			
Stock options	\$ 2,208	\$ 1,405	\$ 903
Restricted stock units	4,280	770	623
ESPP	638	512	389
Subtotal	7,126	2,687	1,915
General and administrative expense:			
Stock options	11,045	7,098	6,815
Restricted stock units	4,920	2,021	1,464
ESPP	150	111	118
Subtotal	16,115	9,230	8,397
Total	\$ 23,241	\$ 11,917	\$ 10,312

As of December 31, 2021, unrecognized stock-based compensation expense related to the unvested stock options and RSUs granted was \$24.7 million and \$36.3 million, respectively. The remaining unrecognized compensation cost is expected to be recognized over a weighted-average period of 2.5 years and 3.2 years, respectively. As of December 31, 2021, there is \$0.1 million of unrecognized stock-based compensation expense related to the ESPP.

#### **Call Option Plan**

In February 2017, the Company adopted a Call Option Plan to grant selected employees, officers, directors and consultants (collectively, the "Participants") options to purchase shares of the common stock of Vaxcyte. As of December 31, 2021, the Company has reserved 266,724 shares of Vaxcyte common stock for issuance under the program, under which call options covering 248,944 and 17,780 shares were granted in February 2017 and August 2019, respectively. The call options granted in February 2017 vested 25% on each of January 1, 2017, 2018, 2019, and 2020, and expire one year from the vesting date. The call options granted in August 2019 vest 25% on each of January 1, 2019, 2020, 2021, and 2022, and expire one year from the vesting date.

A summary of the status of the call options at December 31, 2021 and 2020 is as follows:

	December 31, 2021 Shares	December 31, 2020 Shares
Options vested and exercised	262,279	257,834
Options vested and outstanding	-	-
Options unvested and outstanding	4,445	8,890
Total options granted	<u>266,724</u>	<u>266,724</u>

The amounts recognized as compensation expense related to the Call Option Plan for the years ended December 31, 2021, 2020 and 2019 were \$97,000, \$109,000 and \$78,000, respectively. The amounts recognized as other expense or income related to the remeasurement of the vested call options for the years ended December 31, 2021, 2020 and 2019 were \$109,000 of other income and \$76,000 and \$153,000 of other expense, respectively. As of December 31, 2021 and 2020, the liability attributable to the Call Option Plan was \$97,000 and \$109,000, respectively.

## 12. Income Taxes

Provision for income taxes was zero, \$0.1 million and zero for the years ended December 31, 2021, 2020 and 2019, respectively. The Company has established a full valuation allowance against its net deferred tax assets due to the uncertainty surrounding the realization of such assets. All losses to date have been incurred domestically.

The effective tax rate of the Company's provision (benefit) for income taxes differs from the federal statutory rate as follows:

	Year Ended December 31,		
	2021	2020	2019
Federal statutory rate	21.0 %	21.0 %	21.0 %
State tax	-	(0.1)	-
Change in valuation allowance	(24.7)	(34.7)	(22.7)
Tax credits	3.7	9.3	4.9
Stock compensation	(0.2)	(1.9)	(1.3)
ASC 606 adoption	-	-	(3.9)
Other	0.2	6.1	2.0
Total	<u>0.0 %</u>	<u>(0.3)%</u>	<u>0.0 %</u>

The components of the Company's deferred tax assets consist of the following:

	December 31	
	2021	2020
	(in thousands)	
Deferred tax assets:		
Net operating loss carryforwards	\$ 67,719	\$ 47,549
Research and development credits	31,864	25,175
Deferred revenue	-	3,629
Accruals and other	3,973	2,965
Operating lease liability	7,266	-
Stock based compensation	3,910	3,495
Fixed asset basis	1,008	917
Total deferred tax assets	115,740	83,730
Less: valuation allowance	(100,646)	(74,432)
Gross deferred tax assets	15,094	9,298
Deferred tax liabilities:		
Operating lease right-of-use asset	(6,716)	-
Vaxcyte investment	(8,378)	(9,298)
Total deferred tax liabilities	(15,094)	(9,298)
Total net deferred tax assets	<u>\$ -</u>	<u>\$ -</u>

Realization of the future tax benefits is dependent on the Company's ability to generate sufficient taxable income within the carryforward period. Due to the Company's history of operating losses and future sources of taxable income, the Company believes that the recognition of the deferred tax assets is currently not more likely than not to be realized and, accordingly, have provided a full valuation allowance against net deferred tax assets. For the year ended December 31, 2021, 2020 and 2019, the net increase in the valuation allowance was \$26.2 million, \$11.1 million and \$12.6 million, respectively.

As of December 31, 2021, the Company had federal net operating loss carryforwards of \$281.7 million and federal general business credits from research and development expenses totaling \$25.1 million, as well as state net operating loss carryforwards of \$109.2 million and state research and development credits of \$17.2 million.

The federal net operating loss carryforwards will expire at various dates beginning in 2032, and the federal credits will expire at various dates beginning in 2023, if not utilized. The state net operating loss carryforwards will expire at various dates beginning in 2030, if not utilized. The state research and development tax credits can be carried forward indefinitely.

Events which cause limitations in the amount of net operating losses that the Company may utilize in any one year include, but are not limited to, a cumulative ownership change of more than 50%, as defined, over a three-year testing period. Such limitations may result in limitations upon the Company's ability to utilize the losses in future periods. The Company has performed a Section 382 study for the period of June 16, 2003 through December 31, 2020, and concluded that it is more likely than not that the Company experienced an ownership change on November 20, 2019. This change does not limit the Company's ability to use its existing net operating losses within the carryforward period provided by the Internal Revenue Code, subject to availability of taxable income. However, if there is subsequent event or further change in ownership, these losses may be subject to limitations, resulting in their expiration before they can be utilized.

The Company files U.S. federal and state tax returns with varying statutes of limitations. Due to net operating loss and credit carryforwards, all of the tax years since inception through the 2020 tax year remain subject to examination by the U.S. federal and some state authorities. The actual amount of any taxes due could vary significantly depending on the ultimate timing and nature of any settlement. The amount of unrecognized tax benefits, if recognized, that would affect the effective tax rate is \$6.4 million, \$4.9 million and \$3.8 million as of December 31, 2021, 2020 and 2019, respectively. One or more of these unrecognized tax benefits could be subject to a valuation allowance if and when recognized in a future period, which could impact the timing of any related effective tax rate benefit. The Company believes that the amount by which the unrecognized tax benefits may increase or decrease within the next 12 months is not estimable.

The Company has elected to recognize, if incurred, interest and penalties related to liabilities for uncertain tax positions as a part of income tax expense. No such interest and penalties have been incurred to date.

The Company determines its uncertain tax positions based on a determination of whether and how much of a tax benefit taken by the Company in its tax filings is more likely than not to be sustained upon examination by the relevant income tax authorities.

A reconciliation of the beginning and ending amounts of unrecognized tax benefits is as follows:

	2021	December 31 2020 (in thousands)	2019
Gross unrecognized tax benefit at January 1	\$ 4,902	\$ 3,783	\$ 2,795
Additions for tax positions taken in the current year	1,492	1,090	1,005
Additions / (Reductions) for tax positions of prior years	15	29	(17)
Gross unrecognized tax benefit at December 31	<u>\$ 6,409</u>	<u>\$ 4,902</u>	<u>\$ 3,783</u>

### 13. Net Loss Per Share

The following table sets forth the computation of the Company's basic and diluted net loss per share.

	2021	Year Ended December 31, 2020	2019
	(in thousands, except share and per share amounts)		
<b>Numerator:</b>			
Net loss	<u>\$ (105,538)</u>	<u>\$ (32,128)</u>	<u>\$ (55,744)</u>
<b>Denominator:</b>			
Shares used in computing net loss per share	46,119,089	32,573,469	22,958,577
Net loss per share, basic and diluted	<u>\$ (2.29)</u>	<u>\$ (0.99)</u>	<u>\$ (2.43)</u>

The following common stock equivalents were excluded from the computation of diluted net loss per share for the years ended December 31, 2021, 2020 and 2019 because including them would have been antidilutive:

	2021	Year Ended December 31, 2020	2019
Common stock options issued and outstanding	6,512,086	5,439,295	3,872,664
Restricted stock units issued and outstanding	2,403,826	666,375	335,799
Warrants to purchase common stock	127,616	153,070	71,813
Shares to be issued under ESPP	54,759	55,299	41,421
Total	<u>9,098,287</u>	<u>6,314,039</u>	<u>4,321,697</u>

**Item 9. Changes in and Disagreements with Accountants on Accounting and Financial Disclosure**

None.

**Item 9A. Controls and Procedures****Conclusions Regarding the Effectiveness of Disclosure Controls and Procedures**

As of December 31, 2021, management, with the participation of our Chief Executive Officer (our principal executive officer) and Chief Financial Officer (our principal accounting officer), performed an evaluation of the effectiveness of the design and operation of our disclosure controls and procedures as defined in Rules 13a-15(e) and 15d-15(e) of the Exchange Act. Our disclosure controls and procedures are designed to ensure that information required to be disclosed in the reports we file or submit under the Exchange Act is recorded, processed, summarized and reported within the time periods specified in the SEC's rules and forms, and that such information is accumulated and communicated to our management, including the Chief Executive Officer and the Chief Financial Officer, to allow timely decisions regarding required disclosures.

Disclosure controls and procedures include, without limitation, controls and procedures designed to ensure that information required to be disclosed by us in the reports we file or submit under the Exchange Act is accumulated and communicated to our management, including our Chief Executive Officer and Chief Financial Officer, as appropriate to allow timely decisions regarding required disclosure. Any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving the desired control objective and management necessarily applies its judgment in evaluating the cost-benefit relationship of possible controls and procedures. Based on this evaluation, our Chief Executive Officer and Chief Financial Officer concluded that, as of December 31, 2021, the design and operation of our disclosure controls and procedures were effective at a reasonable assurance level.

**Management's Annual Report on Internal Control Over Financial Reporting**

Our management is responsible for establishing and maintaining adequate internal control over financial reporting. Internal control over financial reporting is defined in Rules 13a-15(f) and 15d-15(f) promulgated under the Exchange Act as a process designed by, or under the supervision of, our Chief Executive Officer and Chief Financial Officer and effected by our board of directors, management and other personnel to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with U.S. GAAP. Our internal control over financial reporting includes those policies and procedures that:

- pertain to the maintenance of records that, in reasonable detail, accurately and fairly reflect our transactions and dispositions of our assets;
- provide reasonable assurance that transactions are recorded as necessary to permit preparation of financial statements in accordance with U.S. GAAP, and that our receipts and expenditures are being made only in accordance with authorizations of our management and directors; and
- provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use or disposition of our assets that could have a material effect on our financial statements.

Because of its inherent limitations, internal control over financial reporting may not prevent or detect misstatements. Therefore, even those systems determined to be effective can provide only reasonable assurance with respect to financial statement preparation and presentation. Projections of any evaluation of effectiveness to future periods are subject to the risk that controls may become inadequate because of changes in conditions, or that the degree of compliance with the policies or procedures may deteriorate. Additionally, in designing disclosure controls and procedures, our management necessarily was required to apply its judgment in evaluating the cost-benefit relationship of possible disclosure controls and procedures. The design of any disclosure controls and procedures also is based in part upon certain assumptions about the likelihood of future events, and there can be no assurance that any design will succeed in achieving its stated goals under all potential future conditions.

Our management, with the participation of our Chief Executive Officer and Chief Financial Officer, assessed the effectiveness of our internal control over financial reporting as of December 31, 2021. In making this assessment, management used the criteria set forth by the Committee of Sponsoring Organizations of the Treadway Commission (COSO) in its 2013 Internal Control – Integrated Framework. Based on our assessment, our management has concluded that, as of December 31, 2021, our internal control over financial reporting is effective based on those criteria. The effectiveness of our internal control over financial reporting as of December 31, 2021 has been audited by Ernst & Young LLP, an independent registered public accounting firm, as stated in their report which is included in this Item 9A of this Annual Report on Form 10-K.

#### **Changes in Internal Control over Financial Reporting**

There were no changes in our internal control over financial reporting identified in connection with the evaluation required by Rule 13a-15(d) and 15d-15(d) of the Exchange Act that occurred during the quarter ended December 31, 2021 that have materially affected, or are reasonably likely to materially affect, our internal controls over financial reporting.

## Report of Independent Registered Public Accounting Firm

To the Stockholders and the Board of Directors of Sutro Biopharma, Inc.

### Opinion on Internal Control Over Financial Reporting

We have audited Sutro Biopharma, Inc.'s internal control over financial reporting as of December 31, 2021, based on criteria established in Internal Control—Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission (2013 framework) (the COSO criteria). In our opinion, Sutro Biopharma, Inc.'s (the Company) maintained, in all material respects, effective internal control over financial reporting as of December 31, 2021, based on the COSO criteria.

We also have audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States) (PCAOB), the balance sheets of Sutro Biopharma, Inc. (the Company) as of December 31, 2021 and 2020, the related statements of operations, comprehensive loss, stockholders' equity and cash flows for each of the three years in the period ended December 31, 2021, and the related notes and our report dated February 28, 2022 expressed an unqualified opinion thereon.

### Basis for Opinion

The Company's management is responsible for maintaining effective internal control over financial reporting and for its assessment of the effectiveness of internal control over financial reporting included in the accompanying Management's Report on Internal Control over Financial Reporting. Our responsibility is to express an opinion on the Company's internal control over financial reporting based on our audit. We are a public accounting firm registered with the PCAOB and are required to be independent with respect to the Company in accordance with the U.S. federal securities laws and the applicable rules and regulations of the Securities and Exchange Commission and the PCAOB.

We conducted our audit in accordance with the standards of the PCAOB. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether effective internal control over financial reporting was maintained in all material respects.

Our audit included obtaining an understanding of internal control over financial reporting, assessing the risk that a material weakness exists, testing and evaluating the design and operating effectiveness of internal control based on the assessed risk, and performing such other procedures as we considered necessary in the circumstances. We believe that our audit provides a reasonable basis for our opinion.

### Definition and Limitations of Internal Control Over Financial Reporting

A company's internal control over financial reporting is a process designed to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles. A company's internal control over financial reporting includes those policies and procedures that (1) pertain to the maintenance of records that, in reasonable detail, accurately and fairly reflect the transactions and dispositions of the assets of the company; (2) provide reasonable assurance that transactions are recorded as necessary to permit preparation of financial statements in accordance with generally accepted accounting principles, and that receipts and expenditures of the company are being made only in accordance with authorizations of management and directors of the company; and (3) provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use, or disposition of the company's assets that could have a material effect on the financial statements.

Because of its inherent limitations, internal control over financial reporting may not prevent or detect misstatements. Also, projections of any evaluation of effectiveness to future periods are subject to the risk that controls may become inadequate because of changes in conditions, or that the degree of compliance with the policies or procedures may deteriorate.

/s/ Ernst & Young LLP  
Redwood City, California  
February 28, 2022



**Item 9B. Other Information**

None.

**Item 9C. Disclosure Regarding Foreign Jurisdictions that Prevent Inspections**

None.

## PART III

### **Item 10. Directors, Executive Officers and Corporate Governance**

The information required by this Item will be set forth in our proxy statement with respect to our 2022 Annual Meeting of Stockholders, or Proxy Statement, to be filed with the Securities and Exchange Commission within 120 days after our fiscal year end and is incorporated herein by reference.

### **Item 11. Executive Compensation**

The information required by this Item will be set forth in the Proxy Statement to be filed with the Securities and Exchange Commission within 120 days after our fiscal year end and is incorporated herein by reference.

### **Item 12. Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters**

The information required by this Item will be set forth in the Proxy Statement to be filed with the Securities and Exchange Commission within 120 days after our fiscal year end and is incorporated herein by reference.

### **Item 13. Certain Relationships and Related Transactions and Director Independence**

The information required by this Item will be set forth in the Proxy Statement to be filed with the Securities and Exchange Commission within 120 days after our fiscal year end and is incorporated herein by reference.

### **Item 14. Principal Accountant Fees and Services**

The information required by this item will be set forth in the Proxy Statement to be filed with the Securities and Exchange Commission within 120 days after our fiscal year end and is incorporated herein by reference.

PART IV

**Item 15. Exhibits and Financial Statement Schedules**

*(1) Financial Statements:*

The financial statements required by Item 15(a) are filed as part of this Annual Report on Form 10-K under Item 8 “Financial Statements and Supplementary Data.”

*(2) Financial Statement Schedules*

The financial statement schedules required by Item 15(a) are omitted because they are not applicable, not required or the required information is included in the financial statements or notes thereto as filed in Item 8 of this Annual Report on Form 10-K.

*(3) Exhibits.*

Exhibit Number	Exhibit Description	Form	Incorporated by Reference			Filed Herewith
			Number	Exhibit	Date	
3.1	<a href="#">Amended and Restated Certificate of Incorporation of Sutro Biopharma, Inc.</a>	10-Q	<a href="#">001-38662</a>	3.1	11/14/2018	
3.2	<a href="#">Amended and Restated Bylaws of Sutro Biopharma, Inc.</a>	10-Q	<a href="#">001-38662</a>	3.2	11/14/2018	
4.1	<a href="#">Third Amended and Restated Investors' Rights Agreement, dated May 24, 2018, by and among the Registrant and certain of its stockholders.</a>	S-1	<a href="#">333-227103</a>	4.2a	8/29/2018	
4.2	<a href="#">Omnibus Amendment Agreement, dated July 26, 2018, by and among the Registrant and certain of its stockholders.</a>	S-1	<a href="#">333-227103</a>	4.2b	8/29/2018	
4.3	<a href="#">Form of Warrant to Purchase Shares of Common Stock.</a>	S-1	<a href="#">333-227103</a>	4.3	8/29/2018	
4.5	<a href="#">Description of Registrant's Securities</a>	10-K	<a href="#">001-38662</a>	4.5	3/16/2020	
10.1	<a href="#">Form of Indemnity Agreement by and between the Registrant and its directors and officers</a>	S-1/A	<a href="#">333-227103</a>	10.1	9/17/2018	
10.2†	<a href="#">2018 Equity Incentive Plan and form of award agreements thereunder</a>	S-1/A	<a href="#">333-227103</a>	10.4	9/17/2018	
10.3†	<a href="#">Amended Form of Restricted Stock Unit Agreement under the 2018 Equity Incentive Plan.</a>	10-Q	<a href="#">001-38662</a>	10.1	11/8/2019	
10.4†	<a href="#">Amended Form of Performance Stock Unit Agreement under the 2018 Equity Incentive Plan.</a>	10-Q	<a href="#">001-38662</a>	10.2	11/8/2019	
10.5	<a href="#">Sales Agreement, dated October 4, 2019, by and between the Registrant and Cowen and Company, LLC</a>	S-3	<a href="#">333-234101</a>	1.2	10/4/2019	

10.6†	<a href="#">2018 Employee Stock Purchase Plan and form of award agreements thereunder</a>	S-1/A	<a href="#">333-227103</a>	10.5	9/17/2018	
10.7†	<a href="#">2004 Stock Plan, as amended, and forms of award agreements.</a>	S-1	<a href="#">333-227103</a>	10.2	8/29/2018	
10.8†	<a href="#">2017 Call Option Plan and forms of award agreements.</a>	S-1	<a href="#">333-227103</a>	10.3	8/29/2018	
10.9†	<a href="#">Exclusive Patent License and Research Collaboration Agreement, dated July 23, 2018, by and between the Registrant and Merck Sharp &amp; Dohme Corp., a subsidiary of Merck &amp; Co., Inc., Kenilworth, NJ.</a>	S-1/A	<a href="#">333-227103</a>	10.15	9/17/2018	
10.11†	<a href="#">Offer Letter, dated December 11, 2012, by and between the Registrant and Edward C. Albini.</a>					X
10.12†	<a href="#">Offer Letter, dated December 29, 2008, by and between the Registrant and William J. Newell, as amended.</a>	S-1	<a href="#">333-227103</a>	10.6	8/29/2018	
10.14†	<a href="#">Offer Letter, dated November 12, 2010, by and between the Registrant and Trevor Hallam, as amended.</a>	S-1	<a href="#">333-227103</a>	10.8	8/29/2018	
10.16	<a href="#">Standard Industrial/Commercial Multi-Tenant Lease-Net, dated May 18, 2011, by and between the Registrant and Lydia Tseng and/or Alemany Plaza LLC, as amended.</a>	S-1	<a href="#">333-227103</a>	10.10	8/29/2018	
10.17†	<a href="#">Amended and Restated Collaboration and License Agreement, dated August 2, 2017, by and among Celgene Corporation, Celgene Alpine Investment Company II, LLC, and the Registrant, as amended.</a>	S-1/A	<a href="#">333-227103</a>	10.11	9/17/2018	
10.18†	<a href="#">License Agreement, dated September 16, 2014, by and between Merck KGaA, Darmstadt, Germany (operating in the United States and Canada under the name "EMD Serono") and the Registrant, as amended.</a>	S-1	<a href="#">333-227103</a>	10.12	8/29/2018	
10.19†	<a href="#">Amended and Restated Exclusive Agreement, dated October 3, 2007, between The Board of Trustees of The Leland Stanford Junior University and Fundamental Applied Biology, Inc., as amended.</a>	S-1/A	<a href="#">333-227103</a>	10.13	9/17/2018	
10.20	<a href="#">Loan and Security Agreement, dated February 28, 2020, among Oxford Finance LLC, Silicon Valley Bank, and the Registrant.</a>	10-K	<a href="#">001-38662</a>	10.20	3/16/2020	

10.21	<a href="#">Form of Warrant to Oxford Finance LLC pursuant to the Loan and Security Agreement.</a>	10-K	<a href="#">001-38662</a>	10.21	3/16/2020	
10.22	<a href="#">Form of Warrant to Silicon Valley Bank pursuant to the Loan and Security Agreement.</a>	10-K	<a href="#">001-38662</a>	10.22	3/16/2020	
10.23	<a href="#">Sublease Agreement, dated September 3, 2020, by and between the Company and Five Prime Therapeutics, Inc.</a>	10-Q	<a href="#">001-38662</a>	10.1	11/5/2020	
10.24†	<a href="#">Severance and Change in Control Plan of the Company</a>	10-K	<a href="#">001-38662</a>	10.24	3/18/2021	
10.25	<a href="#">Third Amendment to Lease 888-894 Industrial Road, San Carlos, CA</a>	10-Q	<a href="#">001-38662</a>	10.2	8/9/2021	
10.26†	<a href="#">2021 Equity Inducement Plan Document</a>	S-8	<a href="#">333-258603</a>	99.1	8/9/2021	
10.27	<a href="#">Second Amendment to the Exclusive Patent License and Research Collaboration Agreement</a>	10-Q	<a href="#">001-38662</a>	10.2	11/10/2021	
10.28	<a href="#">Option Agreement, dated October 9, 2021, by and between the Registrant and BioNova Pharmaceuticals Limited.</a>					X
10.29	<a href="#">License Agreement, dated December 24, 2021, by and between the Registrant and Tasly Biopharmaceuticals Co., Ltd.</a>					X
10.30	<a href="#">Offer Letter, dated May 23, 2021, by and between the Registrant and Jane Chung.</a>					X
10.31	<a href="#">Offer Letter, dated December 11, 2015, by and between the Registrant and Arturo Molina.</a>					X
21.1	<a href="#">Subsidiaries of the Registrant.</a>	S-1	<a href="#">333-227103</a>	21.1	8/29/2018	
23.1	<a href="#">Consent of independent registered public accounting firm.</a>					X
24.1	<a href="#">Power of Attorney. Reference is made to the signature page hereto.</a>					X

31.1	<a href="#">Certification of Principal Executive Officer Pursuant to Rules 13a-14(a) and 15d-14(a) under the Securities Exchange Act of 1934, as Adopted Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.</a>	X
31.2	<a href="#">Certification of Principal Financial Officer Pursuant to Rules 13a-14(a) and 15d-14(a) under the Securities Exchange Act of 1934, as Adopted Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.</a>	X
32.1**	<a href="#">Certification of Principal Executive Officer Pursuant to 18 U.S.C. Section 1350, as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.</a>	X
32.2**	<a href="#">Certification of Principal Financial Officer Pursuant to 18 U.S.C. Section 1350, as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.</a>	X
101.INS	Inline XBRL Instance Document	X
101.SCH	Inline XBRL Taxonomy Extension Schema Document	X
101.CAL	Inline XBRL Taxonomy Extension Calculation Linkbase Document	X
101.DEF	Inline XBRL Taxonomy Extension Definition Linkbase Document	X
101.LAB	Inline XBRL Taxonomy Extension Label Linkbase Document	X
101.PRE	Inline XBRL Taxonomy Extension Presentation Linkbase Document	X
104	Cover Page Interactive Data File (embedded within the Inline XBRL document)	X

\*\* This certification is deemed not filed for purposes of section 18 of the Exchange Act or otherwise subject to the liability of that section, nor shall it be deemed incorporated by reference into any filing under the Securities Act or the Exchange Act.

‡ Indicates management contract or compensatory plan.

† Confidential treatment has been granted for portions of this exhibit pursuant to Rule 406 of the Securities Act, or Rule 24b-2 of the Exchange Act. The Registrant has omitted and filed separately with the SEC the confidential portions of this exhibit.

**Item 16. Form 10-K Summary.**

Registrants may voluntarily include a summary of information required by Form 10-K under Item 16. We have elected not to include such summary.

**SIGNATURES**

Pursuant to the requirements of Section 13 or 15(d) the Securities Exchange Act of 1934, the registrant has duly caused this Registration Statement to be signed on its behalf by the undersigned, thereunto duly authorized.

SUTRO BIOPHARMA, INC.

Date: February 28, 2022

By: /s/ William J. Newell

Name: William J. Newell

Title: Chief Executive Officer

Date: February 28, 2022

By: /s/ Edward C. Albini

Name: Edward C. Albini

Title: Chief Financial Officer



## POWER OF ATTORNEY

Each person whose individual signature appears below hereby authorizes and appoints William J. Newell and Edward C. Albini and each of them, with full power of substitution and resubstitution, as his or her true and lawful attorney-in-fact and agent to act in his or her name, place and stead and to execute in the name and on behalf of each person, individually and in each capacity stated below, and to file any and all amendments to this Annual Report on Form 10-K and to file the same, with all exhibits thereto, and other documents in connection therewith, with the Securities and Exchange Commission, granting unto said attorney-in-fact and agents full power and authority to do and perform each and every act and thing, ratifying and confirming all that said attorney-in-fact and agents or his substitute or substitutes may lawfully do or cause to be done by virtue thereof. Pursuant to the requirements of the Securities Exchange Act of 1934, this report has been signed below by the following persons on behalf of the registrant and in the capacities and on the dates indicated.

/s/ William J. Newell William J. Newell	President, Chief Executive Officer and Director <i>(Principal Executive Officer)</i>	February 28, 2022
/s/ Edward C. Albini Edward C. Albini	Chief Financial Officer and Corporate Secretary <i>(Principal Financial and Accounting Officer)</i>	February 28, 2022
/s/ Michael Dybbs, Ph.D. Michael Dybbs, Ph.D.	Director	February 28, 2022
/s/ John G. Freund, M.D. John G. Freund, M.D.	Director	February 28, 2022
/s/ Joseph M. Lobacki Joseph M. Lobacki	Director	February 28, 2022
/s/ Connie Matsui Connie Matsui	Director	February 28, 2022
/s/ James Panek James Panek	Director	February 28, 2022
/s/ Daniel H. Petree Daniel H. Petree	Director	February 28, 2022
/s/ Shalini Sharp Shalini Sharp	Director	February 28, 2022
/s/ Jon M. Wigginton, M.D. Jon M. Wigginton, M.D.	Director	February 28, 2022
/s/ Heidi Hunter Heidi Hunter	Director	February 28, 2022





**Biologics by Design.  
Imagine.**

December 11, 2012

Edward Albini  
[Private Address]

Dear Ed:

I am pleased to offer you a position with Sutro Biopharma, Inc. (the "Company"), as a Chief Financial Officer reporting to Bill Newell, CEO. If you decide to join us, you will receive an annual salary of \$260,000, which will be paid semi-monthly in accordance with the Company's normal payroll procedures. Furthermore, in each calendar year during your employment with the Company, you will be eligible to receive an annual bonus dependent on performance objectives, which will be based on company objectives established by the Company's Board of Directors in their discretion. Your target bonus will be equal to thirty percent (30%) of your base salary, assuming the achievement of such performance objectives as determined solely by the Company's Board of Directors. You will be eligible for bonus consideration for 2013. Any bonus that you earn will be paid to you within two and one-half (2-1/2) months of the end of the calendar year in which it is earned, and shall be paid in cash, less any usual, required withholding. As an employee, you will also be eligible to receive certain employee benefits including health insurance, life insurance and disability insurance, with reasonable and customary coverages and deductibles or co-payments. You should note that the Company may modify job titles, salaries and benefits from time to time as it deems necessary.

In addition, if you decide to join the Company, it will be recommended at the first meeting of the Company's Board of directors following your start date that the Company grant you an option to purchase 1,658,864 shares of the Company's Common Stock at a price per share equal to the fair market value per share of the Common Stock on the date of grant, as determined by the Company's Board of Directors. Twenty-five percent (25%) of the shares subject to the option shall vest 12 months after the date your vesting begins subject to your continuing employment with the Company, and no shares shall vest before such date. The remaining shares shall vest monthly over the next 36 months in equal monthly amounts subject to you continuing employment with the company. This option grant shall be subject to the terms and conditions of the company's Stock Option Plan and Stock Option Agreement, including vesting requirements. No right to any stock is earned or accrued until such time that vesting occurs, nor does the grant confer any right to continue vesting or employment.

If your employment with the Company is terminated by the Company due to an Involuntary Termination (as defined below), you will receive: (i) continued payment of your base salary (less applicable tax withholdings) for nine (9) months following such termination, such amounts to be paid in accordance with the Company's normal payroll policies; (ii) nine (9) months of accelerated vesting on all outstanding Company stock options; and (iii) reimbursement for premiums paid for continued health benefits for you (and any eligible dependents) under the Company's health plans until the earlier of (A) nine (9) months or (B) the date upon which you and your eligible dependents become covered under similar plans; provided, however, that you validly elect to continue coverage under the Consolidated Omnibus Budget Reconciliation Act of 1985, as amended. Requests for such reimbursement must be submitted promptly following the date such expenses are incurred, but in no event later than forty-five (45) days

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from such date, in accordance with the Company's reimbursement policies, as in effect from time to time. Reimbursements will be made as soon as administratively practicable following approval of the reimbursement (or, if later, following the date you are first entitled to such reimbursements under this paragraph).

If your employment with the Company is terminated by the Company due to an Involuntary Termination (as defined below) and such termination occurs on or within twelve (12) months following a Change of Control (as defined below), then, you will receive accelerated vesting as to 100% of any then non-exercisable option shares under any of your option grants. In addition, in such circumstances all the time periods in the preceding paragraph shall be increased from nine (9) months to 12 months.

The receipt of any benefits pursuant to the two prior paragraphs above will be subject to you signing and not revoking a separation agreement and release of claims substantially in the form attached to this offer letter as Exhibit A (the "Release"), provided that such release becomes effective no later than sixty (60) days following your termination date or such earlier date required by the Release (such deadline, the "Release Deadline"). If the Release does not become effective by the Release Deadline, you will forfeit any rights to severance or benefits under this letter, and in no event will severance payments or benefits be paid or provided until the Release actually becomes effective. In the event your termination occurs at a time during the calendar year where the Release could become effective in the calendar year following the calendar year in which your termination occurs, then any severance payments or benefits under this letter that would be considered Deferred Compensation Separation Benefits (as defined on Exhibit B hereto) will be paid on the first payroll date to occur during the calendar year following the calendar year in which such termination occurs, or, if later, (i) the Release Deadline, (ii) such time as required by the payment schedule applicable to each payment or benefit as set forth in Exhibit B, or (iii) such time as required by this paragraph.

For the purposes of this offer letter, "Involuntary Termination" means (i) your involuntary discharge by the Company for reasons other than Cause (as defined below); or (ii) your voluntary resignation within ninety (90) days following the end of the Cure Period (as defined below) as a result of the occurrence of any of the following without your consent: (a) a material diminution in your authority, duties or responsibilities; or (b) a material diminution in your base compensation (other than a reduction generally applicable to executive officers of the Company implemented for expense management purposes); provided, however, that you must provide written notice to the Company of the condition that could constitute an "Involuntary Termination" event pursuant to the provisions of section (ii) of this paragraph within ninety (90) days of the initial existence of such condition and such condition must not have been remedied by the Company within thirty (30) days (the "Cure Period") of such written notice.

"Change of Control" means the occurrence of any of the following events: (i) the closing of a consolidation or merger of the Company with or into any other corporation in which the holders of the Company's outstanding shares immediately before such consolidation or merger do not, immediately after such consolidation or merger, retain stock representing a majority of the voting power of the surviving corporation of such consolidation or merger; or (ii) a sale of all or substantially all of the assets of the Company. Notwithstanding the foregoing, in no event shall (A) an initial public offering of Common Stock pursuant to a registration statement filed with the Securities and Exchange Commission; (B) any equity financing (including the issuance of convertible debt) of the Company in a single transaction or a series of transactions; or (C) a transaction whose primary purpose is to change the state of the Company's incorporation and/or to create a holding company that will be owned in substantially the same proportions by the persons who held the Company's securities before such transaction constitute a Change of Control for purposes of this offer letter.

"Cause" means (i) an unauthorized use or disclosure of the Company's confidential information or trade secrets, which use or disclosure causes material harm to the Company; (ii) a deliberate material failure in the performance of your duties as Chief Financial Officer or any other duties as pertaining to employees of the Company generally; (iii) conviction of, or pleas of "guilty" or "no contest" to, a felony under the laws of the United States or any state thereof; (iv) gross misconduct; or (v) a continued failure to perform assigned duties customarily performed

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by a Chief Financial Officer of a corporation of similar size, after receiving written notification of such failure from the Board of Directors or the Chief Executive Officer.

The Company is excited about your joining and looks forward to a beneficial and productive relationship. Nevertheless, you should be aware that your employment with the Company is for no specified period and constitutes at-will employment. As a result, you are free to resign at any time, for any reason or for no reason. Similarly, the Company is free to conclude its employment relationship with you at any time, with or without cause, and with or without notice. We request that, in the event of resignation, you give the Company at least two week's notice.

The Company reserves the right to conduct background investigations and/or reference checks on all of its potential employees. Your job offer, therefore, is contingent upon a clearance of such a background investigation and/or reference check, if any.

For purposes of federal immigration law, you will be required to provide to the Company documentary evidence of your identity and eligibility for employment in the United States. Such documentation must be provided to us within three (3) business days of your date of hire, or our employment relationship with you may be terminated.

We also ask that, if you have not already done so, you disclose to the Company any and all agreements relating to your prior employment that may affect your eligibility to be employed by the Company or limit the manner in which you may be employed. It is the Company's understanding that any such agreements will not prevent you from performing the duties of your position and you represent that such is the case. Moreover, you agree that, during the term of your employment with the company, you will not engage in any other employment, occupation, consulting or other business activity directly related to the business in which the Company is now involved or becomes involved during the term of your employment, nor will you engage in any other activities that conflict with your obligations to the Company. Similarly, you agree not to bring any third party confidential information to the Company, including that of your former employer, and that in performing your duties for the Company you will not in any way utilize any such information.

As a Company employee, you will be expected to abide by the company's rules and standards. Specifically, you will be required to sign an acknowledgment that you have read and that you understand the Company's rules of conduct, which are included in the Company Handbook.

As a condition of your employment, you are also required to sign and comply with an At-Will Employment, Confidential Information, Invention Assignment and Arbitration Agreement which requires, among other provisions, the assignment of patent rights to any invention made during your employment at the Company, and non-disclosure of company proprietary information. In the event of any dispute or claim relating to or arising out of our employment relationship, you and the Company agree that (i) any and all disputes between you and the Company shall be fully and finally resolved by binding arbitration, (ii) you are waiving any and all rights to a jury trial but all court remedies will be available in arbitration, (iii) all disputes shall be resolved by a neutral arbitrator who shall issue a written opinion, (iv) the arbitration shall provide for adequate discovery, and (v) the Company shall pay all but the first \$125 of the arbitration fees. Please note that we must receive your signed Agreement before your first day of employment.

Notwithstanding anything to the contrary in this letter, any severance or other benefits to which you may become entitled to pursuant to this letter will be subject to the terms provided in Exhibit B hereto.

To accept the Company's offer, please sign and date this letter in the space provided below. If you accept our offer, your first day of employment will be a mutually agreed upon date between you and the Company. This letter, along with any agreements relating to proprietary rights between you and the Company, set forth the terms of your employment with the Company and supersede any prior representations or agreements including, but not limited to, any representations made during your recruitment, interviews or pre-employment negotiations, whether written or oral. This letter, including, but not limited to, its at-will employment provision, may not be modified or amended

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except by a written agreement signed by the CEO of the Company and you. This offer of employment will terminate if it is not accepted, signed and returned by December 14, 2012.

We look forward to your favorable reply and to working with you at Sutro Biopharma.

*[signature page follows]*

To indicate your acceptance of the Company's offer, please sign and date this letter in the space provided below and return it to me. A duplicate original is enclosed for your records.

Sincerely,

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—  
William J. Newell  
Chief Executive Officer

Agreed to and accepted:

Signature:\_\_\_

Printed Name:\_\_\_

Date:\_\_\_

Enclosures:

Exhibit A: General Release of All Claims

Exhibit B: Section 409A Provisions

At-Will Employment, Confidential Information, Invention Assignment and Arbitration Agreement

Sutro Biopharma 2013 Benefits Guide

**EXHIBIT A**

**GENERAL RELEASE OF ALL CLAIMS**

In consideration of the severance benefits to be provided to Edward Albini by Sutro Biopharma, Inc. (the "Company"), pursuant to the terms of the letter you entered into with the Company dated as of December 11, 2012 (the "Agreement"), you, on your own behalf and on behalf of your heirs, executors, administrators, and assigns, hereby fully and forever release and discharge the Company and its directors, officers, employees, agents, successors,

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predecessors, subsidiaries, parent, stockholders, employee benefit plans and assigns (together called "the Releasees"), from all known and unknown claims and causes of action including, without limitation, any claims or causes of action arising out of or relating in any way to your employment with the Company, including the termination of that employment.

Eight days after you sign (and do not revoke) this General Release of All Claims ("Release"), provided that it is not signed earlier than your cessation of employment, you will be entitled to the severance benefits or change of control benefits set forth in the Agreement, subject to any other requirements set forth therein or on Exhibit B thereto, that are conditioned on this Release.

You understand and agree that this Release is a full and complete waiver of all claims, including (without limitation) claims to attorneys' fees or costs, claims of wrongful discharge, constructive discharge, breach of contract, breach of the covenant of good faith and fair dealing, harassment, retaliation, discrimination, violation of public policy, defamation, invasion of privacy, interference with a leave of absence, personal injury, fraud or emotional distress and any claims of discrimination or harassment based on sex, age, race, national origin, disability or any other basis under Title VII of the Civil Rights Act of 1964, the Fair Labor Standards Act, the Equal Pay Act of 1963, the Americans With Disabilities Act, the Age Discrimination in Employment Act of 1967 (ADEA), the *California Labor Code*, the California Fair Employment and Housing Act, the California Family Rights Act, the Family Medical Leave Act or any other federal or state law or regulation relating to employment or employment discrimination. You further understand and agree that this waiver includes all claims, known and unknown, to the greatest extent permitted by applicable law.

You also hereby agree that nothing contained in this Release shall constitute or be treated as an admission of liability or wrongdoing by the Releasees or you.

In addition, you hereby expressly waive any and all rights and benefits conferred upon you by the provisions of Section 1542 of the *Civil Code of the State of California*, which states as follows:

A general release does not extend to claims which the creditor does not know or suspect to exist in his or her favor at the time of executing the release, which if known by him or her must have materially affected his or her settlement with the debtor.

If any provision of this Release is found to be unenforceable, it shall not affect the enforceability of the remaining provisions and the court shall enforce all remaining provisions to the full extent permitted by law.

You agree to provide, at the Company's expense, including reimbursement of your time and/or the reasonable fees and expenses of your counsel, reasonable cooperation and complete and accurate information to the Company (voluntarily, without requiring a subpoena or other compulsion of law) in the event of litigation against the Company and/or its officers or directors. You also agree that you will not assist any person in bringing or pursuing any claim or action of any kind against the Company, unless pursuant to subpoena or other compulsion of law.

This Release constitutes the entire agreement between you and Releasees with regard to the subject matter of this Release. It supersedes any other agreements, representations or understandings, whether oral or written and whether express or implied, which relate to the subject matter of this Release except as otherwise set forth in the Agreement. However, this Release covers only those claims that arose prior to the execution of this Release. Execution of this Release does not bar any claim that arises hereafter, including (without limitation) a claim for breach of the Agreement.

You understand that you have the right to consult with an attorney before signing this Release. You have 21 days after receipt of this Release to review and consider this Release, discuss it with an attorney of your own choosing, and decide to execute it or not execute it. You also understand that you may revoke this Release during a period of

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seven days after you sign it and that this Release will not become effective for seven days after you sign it (and then only if you do not revoke it). In any event, this Release is not to be signed, and will not become effective, prior to your cessation of employment. In order to revoke this Release, within seven days after you execute this Release you must deliver to William Newell at the Company a letter stating that you are revoking it.

You understand that if you choose to revoke this Release within seven days after you sign it, you will not receive the severance benefits set forth in the Agreement that are conditioned on this Release and the Release will have no effect.

You agree not to disclose to others the terms of this Release, except that you may disclose such information to your spouse and to your attorney or accountant in order for such attorney or accountant to render services to you related to this Release.

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You state that before signing this Release, you:

- Have read it,
- Understand it,
- Know that you are giving up important rights,
- Are aware of your right to consult an attorney before signing it, and
- Have signed it knowingly and voluntarily.

Date: \_\_\_\_\_

By: \_\_\_\_\_  
Edward Albini

TO BE SIGNED UPON CESSATION OF EMPLOYMENT

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## EXHIBIT B

### SECTION 409A

(a) Notwithstanding anything to the contrary in the letter, no Deferred Compensation Separation Benefits (as defined below) will become payable under the letter until you have a "separation from service" within the meaning of Section 409A of the Internal Revenue Code of 1986, as amended (the "Code"), and any proposed or final regulations and guidance promulgated thereunder ("Section 409"). Further, if you are a "specified employee" within the meaning of Section 409A at the time of your termination (other than due to death), and the severance or other benefits payable to you, if any, pursuant to the letter, when considered together with any other severance payments or separation benefits, are considered deferred compensation under Section 409A (together, the "Deferred Compensation Separation Benefits"), such Deferred Compensation Separation Payments that are otherwise payable within the first six (6) months following your termination of employment will become payable on the first payroll date that occurs on or after the date six (6) months and one (1) day following the date of your termination of employment (or such later date as is required to avoid the imposition of additional tax under Section 409A). All subsequent Deferred Compensation Separation Benefits, if any, will be payable in accordance with the payment schedule applicable to each payment or benefit. Notwithstanding anything herein to the contrary, if you die following your termination but prior to the six (6) month anniversary of your termination (or any later delay date), then any payments delayed in accordance with this paragraph will be payable in a lump sum as soon as administratively practicable after the date of your death and all other Deferred Compensation Separation Benefits will be payable in accordance with the payment schedule applicable to each payment or benefit. Each payment and benefit payable under the letter is intended to constitute separate payments for purposes of Section 1.409A-2(b)(2) of the Treasury Regulations.

(b) Any amount paid under the letter that satisfies the requirements of the "short-term deferral" rule set forth in Section 1.409A-1(b)(4) of the Treasury Regulations shall not constitute Deferred Compensation Separation Benefits for purposes of section (a) above.

(c) Any amount paid under the letter that qualifies as a payment made as a result of an involuntary separation from service pursuant to Section 1.409A-1(b)(9)(iii) of the Treasury Regulations that does not exceed the Section 409A Limit shall not constitute Deferred Compensation Separation Benefits for purposes of section (a) above. For purposes of this section (c), "Section 409A Limit" will mean the lesser of two (2) times: (i) your annualized compensation based upon the annual rate of pay paid to you during the Company's taxable year preceding the Company's taxable year of your termination of employment as determined under Treasury Regulation 1.409A-1(b)(9)(iii)(A)(1) and any Internal Revenue Service guidance issued with respect thereto; or (ii) the maximum amount that may be taken into account under a qualified plan pursuant to Section 401(a)(17) of the Code for the year in which your employment is terminated.

(d) Reimbursement. To the extent that any taxable reimbursements of expenses or in-kind benefits are provided, they shall be made in accordance with Section 409A, including, but not limited to the following provisions:

- i) The amount of any such expense reimbursement or in-kind benefit provided during a service provider's taxable year shall not affect any expenses eligible for reimbursement in any other taxable year;
  - ii) The reimbursement of the eligible expense shall be made no later than the last day of the service provider's taxable year that immediately follows the taxable year in which the expense was incurred; and
  - iii) The right to any reimbursement shall not be subject to liquidation or exchange for another benefit or payment.
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(e) The foregoing provisions are intended to comply with the requirements of Section 409A so that none of the severance payments and benefits to be provided under the letter will be subject to the additional tax imposed under Section 409A, and any ambiguities herein will be interpreted to so comply. You and the Company agree to work together in good faith to consider amendments to the letter and to take such reasonable actions which are necessary, appropriate or desirable to avoid imposition of any additional tax or income recognition prior to actual payment to you under Section 409A.

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**CERTAIN CONFIDENTIAL INFORMATION CONTAINED IN THIS DOCUMENT, MARKED BY [\*], HAS BEEN OMITTED BECAUSE IT IS NOT MATERIAL AND WOULD LIKELY CAUSE COMPETITIVE HARM TO SUTRO BIOPHARMA, INC. IF PUBLICLY DISCLOSED.**

### **OPTION AND LICENSE AGREEMENT**

THIS OPTION AND LICENSE AGREEMENT (this "Agreement"), entered into as of October 9, 2021 (the "Effective Date"), is entered into by and between BioNova Pharmaceuticals Limited, a company incorporated under the laws of Hong Kong, having its registered office at Unit 417, 4<sup>th</sup> floor, Lippo Centre Tower Two, No. 89 Queensway Admiralty, Hong Kong ("BioNova"), and Sutro Biopharma, Inc., with its headquarters at 111 Oyster Point Boulevard, South San Francisco, CA 94080, U.S.A. ("Sutro").

### **INTRODUCTION**

WHEREAS, BioNova wishes to obtain from Sutro and Sutro wishes to grant to BioNova certain rights and licenses under intellectual property owned or controlled by Sutro to Develop, Manufacture and Commercialize Licensed Products in the Field in the Territory (each as defined below), subject to the terms and conditions set forth herein.

NOW, THEREFORE, in consideration of the premises and the mutual promises and conditions hereinafter set forth, and other good and valuable consideration, the receipt and sufficiency of which are hereby acknowledged, the Parties, intending to be legally bound, do hereby agree as follows:

### **ARTICLE I DEFINITIONS**

Unless the context clearly indicates otherwise, the following terms used in this Agreement will have the meanings set forth in this ARTICLE I:

Section I.1. "Abandoning Party" has the meaning set forth in Section 9.2(c).

Section I.2. "Accounting Standards" means, with respect to a Person, generally accepted accounting principles ("GAAP") as practiced in a jurisdiction where a Party conducts its business, International Financial Reporting Standards ("IFRS"), or applicable international standards followed by such Person.

Section I.3. "Acquired Competing Product" has the meaning set forth in Section 3.9(c).

Section I.4. "Action" means any claim, action, cause of action or suit (whether in contract or tort or otherwise), litigation (whether at law or in equity, whether civil or criminal), assessment,

arbitration, investigation, hearing, charge, complaint, demand, notice or proceeding of, to, from, by or before any Governmental Authority.

Section I.5. “Active Ingredient” means those active materials that provide pharmacological activity in a pharmaceutical or biologic product (excluding formulation components such as coatings, stabilizers, excipients or solvents, adjuvants or controlled release technologies). Drug delivery vehicles, adjuvants and excipients will not be deemed to be Active Ingredients.

Section I.6. “ADC” means an antibody drug conjugate whereby [\*]

Section I.1. “Adverse Event” or “AE” has the meaning set forth in the PRC Measures for the Administration of Reporting and Surveillance of Drug Adverse Events (effective as of July 1, 2011) or the equivalent applicable Laws in any relevant Region, and generally means any untoward medical occurrence associated with the use of a product in human subjects, whether or not considered related to such product. An AE does not necessarily have a causal relationship with a product, that is, an AE can be any unfavorable and unintended sign (including an abnormal laboratory finding), symptom, or disease temporally associated with the use of such product.

Section I.2. “Affiliate” means, with respect to any specified Person, any other Person that controls, is controlled by, or is under common control with such first Person. For purposes of this definition only, “control” means (a) to possess, directly or indirectly, the power to direct or cause the direction of the management or policies of a Person, whether through ownership of voting securities or by contract relating to voting rights or corporate governance; or (b) to own, directly or indirectly, more than fifty percent (50%) of the outstanding voting securities or other ownership interests of such Person.

Section I.3. “Agreement” has the meaning set forth in the Preamble.

Section I.4. “Alliance Manager” has the meaning set forth in Section 7.6(a).

Section I.5. “Anti-Corruption Laws” means laws, regulations, or orders prohibiting the provision of a financial or other advantage for a corrupt purpose or otherwise in connection with the improper performance of a relevant function, including without limitation, the US Foreign Corrupt Practices Act (FCPA), the Anti-Unfair Competition Law of the PRC and the Criminal Law of the PRC, and similar laws governing corruption and bribery, whether public, commercial or both, including industry codes dealing with government procurement, conflicts of interest, corruption or bribery, in each case to the extent applicable in the applicable country, region or territory.

Section I.6. “Auditor” has the meaning set forth in Section 8.7(a).

Section I.7. “Binding Orders” has the meaning set forth in Section 5.1(c).

Section I.8. “BioNova” has the meaning set forth in the Preamble.

Section I.9. “BioNova Indemnified Party” has the meaning set forth in Section 12.1.

Section I.10. "BioNova Technology" means any and all Sole Inventions and interest in any Joint Inventions or Joint Patents that are Controlled by BioNova or any of its Affiliates or its or their Sublicensees at any time during the Term that are necessary or reasonably useful to Develop, Manufacture or Commercialize, or otherwise to research, make, have made, use, offer for sale, sell, have sold, and import the Licensed Compound or Licensed Products.

Section I.11. "Biosimilar Product" means with respect to a particular Licensed Product sold by BioNova or any of its Affiliates or Sublicensees in a Region in the Territory, a product sold by a Third Party (other than a Sublicensee or any other Third Party in a chain of distribution originating from BioNova or any of its Affiliates or Sublicensees) in such Region in the Territory that (a) (i) [\*], or (ii) [\*], and (b) [\*].

Section I.12. "Breaching Party" has the meaning set forth in Section 14.3(a).

Section I.13. "Business Day" means any day, other than a Saturday or a Sunday, on which the banks in each of Shanghai, Hong Kong, and New York are open for business.

Section I.14. "Calendar Quarter" means each of the three month periods ending on March 31, June 30, September 30, and December 31 of any Calendar Year; provided, however: (a) the first Calendar Quarter of the Term will extend from the Effective Date to the end of the Calendar Quarter in which the Effective Date occurs; and (b) the last Calendar Quarter will extend from the beginning of the Calendar Quarter in which this Agreement expires or terminates until the effective date of such expiration or termination.

Section I.15. "Calendar Year" means, for the first Calendar Year, the period beginning on the Effective Date and ending on December 31, 2021, and for each Calendar Year thereafter each twelve (12)-month period commencing on January 1, and ending on December 31, except that the last Calendar Year will commence on January 1 of the year in which this Agreement expires or terminates and end on the effective date of such expiration or termination.

Section I.16. "Change of Control" means, with respect to a Person, (a) a merger, reorganization or consolidation of such Person with a third party that results in the voting securities of such Person outstanding immediately prior thereto, or any securities into which such voting securities have been converted or exchanged, ceasing to represent more than fifty percent (50%) of the combined voting power of the surviving entity or the parent of the surviving entity immediately after such merger or consolidation, (b) a transaction or series of related transactions in which a third party, together with its Affiliates, becomes the direct or indirect beneficial owner of more than fifty percent (50%) of the combined voting power of the outstanding securities of such Person, or (c) the sale or other transfer to a third party of all or substantially all of such Person's assets. Notwithstanding the foregoing, any transaction or series of transactions effected for the primary purpose of financing the operations of the applicable Person (including the issuance or sale of securities for financing purposes) or changing the form or jurisdiction of organization of such Person will not be deemed a "Change of Control" for purposes of this Agreement.



Section I.17.“Clinical Study” means a study in which human subjects or patients are dosed with a drug, whether approved or investigational.

Section I.18.“Clinical Supply” has the meaning set forth in Section 5.1.

Section I.19.“Clinical Transfer Price” has the meaning set forth in Section 5.1.

Section I.20.“CMC” means the information referred to as “Chemistry, Manufacturing and Controls” information pertaining to a Licensed Product as may be required by a Regulatory Authority to be included or referenced in any IND for a candidate Licensed Product or in any application for Marketing Authorization with respect to such Licensed Product, provided it is understood that any information relating to Expression Technology shall be provided through the Disclosure Process.

Section I.21.“CMC Data” means any data included in the CMC portion of a Regulatory Filing or in any supporting development reports thereto, in each case, with respect to any Licensed Product in any country in the world, except that required access by any Regulatory Authority in any country or region in the Territory to any information relating to Expression Technology shall be provided through the Disclosure Process.

Section I.22.“Code” means Title 11 of the U.S. Code.

Section I.23.“Combination” means any Combination Product or Combination Therapy.

Section I.24.“Combination Product” means a product that (a) [\*]; or (b) [\*].

Section I.25.“Combination Therapy” means any therapy or treatment regimen that comprises, or is a combination of (a) a Licensed Product, and (b) [\*], where (a) and (b) [\*]

Section I.26.“Commercial Supply Agreement” has the meaning set forth in Section 5.2.

Section I.27.“Commercialization”, “Commercializing” or “Commercialize” means any and all activities related to the pre-marketing, launching, marketing, promotion (including advertising and detailing), packaging and having packaged, labeling, bidding, tendering and listing, pricing and reimbursement, distribution, storage, handling, offering for sale, selling, having sold, importing and exporting for sale, having imported and exported for sale, distribution, having distributed, customer service and support, and post-marketing safety surveillance and reporting of a product (including the Licensed Product), but not including Development or Manufacturing.

Section I.28.“Commercially Reasonable Efforts” means, in respect of a Party’s obligation under this Agreement, the level of efforts and resources (measured as of the time that such efforts and resources are required to be used under this Agreement) that are commonly used by a company in the biopharmaceutical industry of a similar size and profile as such Party to Develop, Manufacture or Commercialize, as the case may be, a product owned by such company or to which it has rights, which product is at a similar stage in its development or product life and is of a similar market and profitability potential to the Licensed Product and taking into account all materially relevant factors, including the intellectual property protection of the product, product labeling or anticipated labeling, market potential,

financial return, medical and clinical considerations, regulatory environments and competitive market conditions, market exclusivity, and other technical legal, scientific, medical or commercial factors that such a company would reasonably deem to be relevant.

Section I.29. "Competitive Product" means [\*]

Section I.30. "Confidential Information" means (a) all trade secrets or confidential or proprietary information (including any tangible materials embodying any of the foregoing) of the disclosing Party or its Affiliates provided or disclosed to the other Party or any of its Affiliates in connection with this Agreement or disclosed in connection with the Confidentiality Agreement, and (b) the terms and conditions of this Agreement, which are the Confidential Information of each Party; provided, however, that Confidential Information will not include information that:

(i) is published by a Third Party or otherwise is or hereafter becomes part of the public domain by public use, publication, general knowledge or the like through no breach of this Agreement on the part of the receiving Party;

(ii) is in the receiving Party's possession prior to disclosure by the disclosing Party hereunder, and not through a prior disclosure by the disclosing Party, without any obligation of confidentiality with respect to such information (as evidenced by the receiving Party's or such Affiliate's written records or other competent evidence);

(iii) is subsequently received by the receiving Party from a Third Party who is not known by the receiving Party to be under an obligation of confidentiality to the disclosing Party under any agreement between such Third Party and the disclosing Party; or

(iv) is independently developed by or for the receiving Party without reference to, or use or disclosure of, the disclosing Party's Confidential Information (as evidenced by the receiving Party's or such Affiliate's written records or other competent evidence);

provided, further, that clauses (ii) through (iv) above will not apply to the terms and conditions of this Agreement.

Section I.31. "Confidentiality Agreement" means that certain mutual nondisclosure agreement by and between BioNova and Sutro, effective as of February 11, 2021.

Section I.32. "Contract Manufacturing Organization" or "CMO" means any Third Party contract manufacturing organization.

Section I.33. "Contract Research Organization" or "CRO" means any Third Party contract research organization.

Section I.34. "Contract Sales Organization" or "CSO" means any Third Party contract sales organization.

Section I.35.“Control” or “Controlled” means, with respect to any Know-How, Patent Right, Regulatory Filing, Regulatory Approval or other property right, the legal authority or right (whether by ownership, license (other than a license granted pursuant to this Agreement) or otherwise) of a Party or its Affiliate, to grant access, a license or a sublicense of or under such Know-How, Patent Right, Regulatory Filing, Regulatory Approval or other property right, without breaching the terms of any agreement with a Third Party.

Section I.36.“Cover,” “Covering” or “Covered” means, when referring to the Licensed Product: (a) with respect to an issued Patent Right, that, in the absence of a license granted to a Person under an issued claim included in such Patent Right, the manufacture, use, sale, offer for sale or import by such Person, or the conduct of any other specified activity by such Person, with respect to such Licensed Product would infringe such claim, or (b) with respect to an application for Patent Rights, that, in the absence of a license granted to a Person under a claim included in such application, the manufacture, use, sale, offer for sale or import by such Person, or the conduct of any other specified activity by such Person, with respect to such Licensed Product would infringe such claim if such patent application were to issue as a patent.

Section I.37.“Defect” has the meaning set forth in Section 5.1(g).

Section I.38.“Development,” “Developing” or “Develop” means non-clinical, pre-clinical and clinical drug research and development activities, whether before or after Regulatory Approval, including drug metabolism and pharmacokinetics, translational research, toxicology, pharmacology, test method development and stability testing, process and packaging development and improvement, process validation, formulation development, delivery system development, quality assurance and quality control development, statistical analysis, conduct of Clinical Studies, regulatory affairs, the preparation and submission of Regulatory Filings, performance of Clinical Study regulatory activities, and any other activities directed towards obtaining or maintaining Regulatory Approval of any Licensed Product. Development includes use and importation of the relevant compound (including the Licensed Compound) or product (including the Licensed Product) to conduct such Development activities. Development will not include Commercialization activities or Manufacturing.

Section I.39.“Development Milestone Event” has the meaning set forth in Section 8.2.

Section I.40.“Development Milestone Payment” has the meaning set forth in Section 8.2.

Section I.41.“Development Plans” has the meaning set forth in Section 4.2.

Section I.42.“Disclosure Process” means, with respect to the disclosure of any information relating to Expression Technology, provision of such information (a) via a right of reference to a drug master file (or DMF) (or its equivalent in the applicable country or region in the Territory) filed by Sutro in the applicable country or region in the Territory or (b) directly to a Regulatory Authority by Sutro or a Third Party CRO mutually agreed by the Parties, in each case without disclosure to, or access by, BioNova or any of its Affiliates of any such information.

Section I.43.“Dollars” or “US\$” means United States dollars.

Section I.44.“Effective Date” has the meaning set forth in the Preamble.

Section I.45.“Expression Technology” means [\*]

Section I.46.“FDA” means the United States Food and Drug Administration or any successor agency thereto.

Section I.47.“Field” means [\*]

Section I.48.“First Commercial Sale” means with respect to the Licensed Product in any Region in the Territory, the first sale for monetary value for use or consumption by the end user of such Licensed Product in such Region after the Marketing Authorization for such Licensed Product has been obtained in such Region.

Section I.49.“Force Majeure Event” has the meaning set forth in Section 16.9.

Section I.50.“Fully Burdened Manufacturing Cost” means the cost of Manufacturing the Licensed Product. Fully Burdened Manufacturing Costs will be a “standard cost” per unit (calculated annually), comprised of the following elements calculated in accordance with the applicable Accounting Standards, as consistently applied across Sutro’s or BioNova’s organization (as applicable) and with respect to Sutro’s or BioNova’s other products (as applicable): (a) [\*] (b) [\*], (c) [\*] (d) [\*], (e) [\*] (f) [\*] and (g) [\*]. To the extent that Licensed Products are sourced by Sutro from one or more CMOs engaged by Sutro, Sutro’s Fully Burdened Manufacturing Costs will be [\*], and to the extent any Licensed Products are sourced by a Selling Party from another Person, such Selling Party’s Fully Burdened Manufacturing Costs of such Licensed Products will be [\*]. For clarity, [\*]

Section I.51.“GCP” or “Good Clinical Practice” means all applicable then-current standards for the design, conduct, performance, monitoring, auditing, recording, analyses and reporting of Clinical Studies, including, as applicable, (a) as set forth in the International Conference on Harmonization of Technical Requirements for Registration of Pharmaceuticals for Human Use Harmonized Tripartite Guideline for Good Clinical Practice (CPMP/ICH/135/95) and any other guidelines for good clinical practice for trials on medicinal products, (b) the Declaration of Helsinki (2013) as last amended at the 64th World Medical Association in October 2013 and any further amendments or clarifications thereto, (c) as set forth in the PRC Good Clinical Practice for Pharmaceuticals effective as of July 1, 2020 and its subsequent amendments, (d) U.S. Code of Federal Regulations Title 21, Parts 50 (Protection of Human Subjects), 56 (Institutional Review Boards) and 312 (Investigational New Drug Application), and (e) the equivalent applicable Laws in any relevant Region, each as may be amended and applicable from time to time and in each case, that provide for, among other things, assurance that the clinical data and reported results are credible and accurate and protect the rights, integrity, and confidentiality of trial subjects.

Section I.52.“Global Development Plan” has the meaning set forth in Section 4.2.

Section I.53.“GLP” or “Good Laboratory Practice” means all applicable then-current standards for laboratory activities for pharmaceuticals, as set forth in the FDA’s Good Laboratory Practice regulations as defined in 21 C.F.R. Part 58, the PRC Good Laboratory Practice effective as of September 1, 2017, or the Good Laboratory Practice principles of the Organization for Economic Co-Operation and

Development (OECD), and such standards of good laboratory practice as are required by the equivalent applicable Laws in the relevant Region and other organizations and governmental agencies in countries in which the Licensed Product is intended to be sold by the Party that is subject to such standards.

Section I.54.“GMP” or “Good Manufacturing Practice” means all applicable then-current standards for Manufacturing, including, as applicable, (a) the principles detailed in the U.S. Current Good Manufacturing Practices, 21 C.F.R. §§ 201, 211, 600 and 610 and all applicable FDA guidelines and requirements, (b) European Directive 2003/94/EC for medicines and investigational medicines for human use and the applicable guidelines stated in the Eudralex guidelines, (c) Pharmaceutical Good Manufacturing Practice of the PRC effective as of March 1, 2011 and its appendices, and all relevant NMPA guidelines and regulations, (d) the principles detailed in the applicable ICH guidelines, (e) the conduct of an inspection by a Qualified Person (as defined therein) and the execution by such Qualified Person of an appropriate certification of inspection and (f) the equivalent applicable Laws in any relevant Region, each as may be amended and applicable from time to time. For clarity, applicable GMP will include the GMP in the Region where Licensed Products are intended to be used or sold.

Section I.55.“Governmental Authority” means any multinational, federal, national, state, provincial, local or other entity, office, commission, bureau, agency, political subdivision, instrumentality, branch, department, authority, board, court, arbitral or other tribunal, official or officer, exercising executive, judicial, legislative, police, regulatory, administrative or taxing authority or functions of any nature pertaining to government.

Section I.56.“Gross Profit” means, for specific units of Licensed Product sold during a particular time period, (a) the Net Sales arising from such Licensed Product sales *minus* (b) the Selling Party’s Fully Burdened Manufacturing Costs and Other Costs of such Licensed Product, in all instances solely to the extent actually paid or incurred by BioNova, its Affiliate, or its Sublicensee (as appropriate) and not otherwise reimbursed or deducted more than once (i.e. not ‘double counted’).

Section I.57.“ICH” means the International Conference on Harmonization of Technical Requirements for Registration of Pharmaceuticals for Human Use.

Section I.58.“IND” means any (a) Investigational New Drug application filed with the FDA pursuant to Part 312 of Title 21 of the U.S. Code of Federal Regulations, or (b) any comparable filings outside the U.S. required to commence human clinical trials in such country or Region (such as an application for clinical trial authorization or clinical trial approval in the Territory), and all supplements or amendments that may be filed with respect to the foregoing.

Section I.59.“IND-Enabling Studies” means the non-clinical pharmacokinetic and toxicology studies required to meet the requirements for filing an IND.

Section I.60.“Indemnified Party” means a Person entitled to indemnification under ARTICLE XII.

Section I.61.“Indemnifying Party” means a Party from whom indemnification is sought under ARTICLE XII.

Section I.62.“Indication” means, with respect to a particular compound or product, the use of such compound or product for treatment of: (a) [\*]; or (b) [\*]. For clarity, (i) [\*]; (ii) [\*]; and (iii) [\*]

Section I.63.“Initial Clinical Supply” has the meaning set forth in Section 5.1(a).

Section I.64.“Infringement” has the meaning set forth in Section 9.3(a).

Section I.65.“Infringement Action” has the meaning set forth in Section 9.3(b).

Section I.66.“Infringement Claim” has the meaning set forth in Section 9.4.

Section I.67.“Invention” means any process, method, composition of matter, article of manufacture, discovery or finding, patentable or otherwise, that is invented as a result of a Party (or the Parties jointly) exercising its (their) rights or carrying out its obligations under this Agreement, including all rights, title and interest in and to the intellectual property rights therein.

Section I.68.“Joint Global Study” has the meaning set forth in Section 4.5.

Section I.69.“Joint Patents” has the meaning set forth in Section 9.1(b).

Section I.70.“Joint Inventions” has the meaning set forth in Section 9.1(b).

Section I.71.“JSC” has the meaning set forth in Section 7.1.

Section I.72.“Know-How” means all proprietary chemical and biological materials and other tangible materials, inventions, practices, methods, protocols, formulae, knowledge, know-how, trade secrets, processes, procedures, assays, skills, experience, techniques, information (including scientific, technical or regulatory information), data, documentation, processes, methods, techniques, materials, technology, results, analyses, laboratory, pre-clinical, clinical, and other data, clinical dossiers, or other know-how, including pharmacology, toxicology, drug stability, manufacturing and formulation methodologies and techniques, clinical and non-clinical safety and efficacy studies, marketing studies, absorption, distribution, metabolism and excretion studies, whether patentable or otherwise.

Section I.73.“Law” or “Laws” means all laws, statutes, rules, codes, regulations, orders, decrees, judgments or ordinances of any Governmental Authority, or any license, permit or similar right granted under any of the foregoing, or any similar provision having the force or effect of law.

Section I.74.“Licensed Compound” means (a) STRO-001, an ADC the chemical structure of which is described in Exhibit A, (b) [\*], and (c) [\*]

Section I.75.“Licensed Know-How” means any and all Know-How that is Controlled by Sutro or any of its Affiliates as of the Effective Date or at any time during the Term (including any Regulatory Filings, all information and data contained in Regulatory Filings, CMC Data, and interest in any Joint Inventions) that is necessary or reasonably useful to Develop, Manufacture, Commercialize, or otherwise to research, make, have made, use, offer for sale, sell, have sold, and import the Licensed Compound or Licensed Products; provided that with respect to all Licensed Know-How comprising Expression

Technology that is not publicly available, access provided by Sutro to BioNova thereto shall be limited to the Disclosure Process. For the avoidance of doubt, Licensed Know-How includes the dossier of the Licensed Products and all documents and materials.

Section I.76.“Licensed Mark(s)” means any Trademark(s) that Sutro or its Affiliates registers with a Governmental Authority in any Region in the Territory is used or intended to be used in connection with the Commercialization of a Licensed Product. Licensed Marks as of the Effective Date are set forth in Exhibit B.

Section I.77.“License Option” has the meaning set forth in Section 2.1.

Section I.78.“License Option Payment” has the meaning set forth in Section 2.2.

Section I.79.“License Option Exercise Notice” has the meaning set forth in Section 2.5.

Section I.80.“License Option Exercise Payment” has the meaning set forth in Section 8.1.

Section I.81.“License Option Exercise Period” has the meaning set forth in Section 2.5.

Section I.82.“Licensed Patents” means any and all Patent Rights that are Controlled by Sutro or any of its Affiliates as of the Effective Date or at any time during the Term (including any interest in any Joint Patents) that (a) are set forth in Exhibit C, (b) are necessary or reasonably useful to Develop, Manufacture, Commercialize, or otherwise to research, make, have made, use, offer for sale, sell, have sold, and import the Licensed Compound or Licensed Products, or (c) Cover any Licensed Know-How; provided that with respect to all Licensed Patents comprising Expression Technology that is not publicly available, access provided by Sutro to BioNova thereto shall be limited to the Disclosure Process. Licensed Patents as of the Effective Date are set forth in Exhibit C.

Section I.83.“Licensed Product” means any product containing a Licensed Compound (whether alone as the sole Active Ingredient or as a monotherapy or as part of a Combination), in any form, presentation, formulation or dosage form.

Section I.84.“Licensed Technology” means collectively Licensed Patents and Licensed Know-How.

Section I.85.“Losses” means damages, losses, liabilities, costs (including costs of investigation, defense), fines, penalties, taxes, expenses, or amounts paid in settlement (in each case, including reasonable attorneys’ and experts’ fees and expenses), in each case resulting from an Action.

Section I.86.“Manufacture,” “Manufactured” or “Manufacturing” means all activities related to the manufacture or production of the Licensed Compound or Licensed Product, including the production of any of the following to the extent used in the Licensed Product: any drug substance produced in bulk form for use as an Active Ingredient, drug product, compounded or finished final packaged and labeled form, and in intermediate states, including the following activities: reference standard preparation, purification, formulation, scale-up, packaging, quality assurance oversight, quality control testing (including in-process release and stability testing), validation activities directly related to all of the

foregoing, and data management and recordkeeping related to all of the foregoing. References to a Person engaging in Manufacturing activities will include having any or all of the foregoing activities performed by a Third Party.

Section I.87. "Manufacturing License" has the meaning set forth in Section 5.6.

Section I.88. "Manufacturing Requirements" has the meaning set forth in Section 5.1(e).

Section I.89. "Marketing Authorization" means the grant of all necessary final or conditional permits, registrations, authorizations, licenses and approvals (or waivers) required for the Commercialization of the Licensed Product for use in the Field and in the Territory, including any Regulatory Approval for sale or marketing, and, where required, Pricing and Reimbursement Approvals.

Section I.90. "NDA" means a new drug application or similar application or submission filed with or submitted to any Regulatory Authority to obtain permission to commence marketing and sales of a pharmaceutical product in any particular jurisdiction.

Section I.91. "Net Sales" means all amounts invoiced on sales by BioNova or any of its Affiliates or its or their Sublicensees (for the purpose of this definition, "Sublicensees" will not include any distributors or wholesalers) (the "Selling Party") for any Licensed Product sold to Third Parties other than Sublicensees less the following deductions in each case solely to the extent reasonable, customary, allocable and actually taken or applied:

(a) discounts (including trade, cash and quantity discounts), cash and non-cash coupons, charge back payments and rebates granted to managed health care organizations, hospitals, pharmacies, or group purchasing organizations, or to federal, state and local governments, their agencies, and purchasers and reimbursors or to customers or required by applicable Law (including governmental medical assistance programs);

(b) credits, allowances, repayments, discounts to and chargebacks for claims, spoiled, damaged, or outdated goods, rejections or returns of the Licensed Products, including Licensed Products returned in connection with recalls or withdrawals;

(c) any sales, value added or similar taxes, insurance, custom duties, excise or other similar governmental charges levied directly on the production, sale, transportation, delivery or use of a Licensed Product that are paid by or on behalf of the Selling Party, but not including any tax levied with respect to income;

(d) actual freight and insurance costs and other expenses incurred in distributing, warehousing, importing, handling and transporting the Licensed Product to distributors or customers;

(e) wholesaler's stocking, inventory management or distribution fees; and



(f) amounts that are written off as uncollectible; provided that if any such written-off amounts are subsequently collected, such collected amounts will be included in Net Sales in the Calendar Quarter in which they are subsequently collected.

In the event that a Licensed Product is sold as a Combination, Net Sales, for the purposes of determining royalty payments on the Combination, will mean the gross amount collected for the Combination less the deductions set forth in clauses (a) - (f) above, multiplied by a proration factor that is determined as follows:

(i) If all active pharmaceutical components of the Combination were sold separately, the proration factor will be determined by the formula [\*];

(ii) If the Licensed Product components containing only the Licensed Compound as their Active Ingredient are sold separately from the other component(s), but the other Active Ingredient components in such Combination are not sold separately, then the proration factor will be determined by the formula [\*];

(iii) If the Licensed Product components containing only the Licensed Compound as their Active Ingredient are not sold separately from the other component(s), but the other Active Ingredient components in such Combination are sold separately, then the proration factor will be determined by the formula [\*] or

(iv) If all Active Ingredient(s) of the Combination were not sold or provided separately, the proration factor will be determined by the Parties in good faith negotiations based on the relative value contributed by each component.

With respect to the calculation of Net Sales:

(A) Net Sales only include the value charged or invoiced on the first arm's length sale to a Third Party. The transfer of a Licensed Product to an Affiliate, Sublicensee, or other Third Party (w) in connection with the Development or testing of a Licensed Product (including the conduct of Clinical Studies), (x) for purposes of distribution as promotional samples, (y) for indigent or similar public support or compassionate use programs, or (z) by and between BioNova and its Affiliates or its or their Sublicensees will not, in any case, be considered a Net Sale of a Licensed Product under this Agreement;

(B) Net Sales (including deductions taken in accordance with subsections (a)-(f) above) shall be determined in accordance with the Accounting Standards or in the case of Sublicensees, such similar accounting principles, consistently applied; and

(C) Notwithstanding anything to the contrary in this Agreement, in no event (after accounting for deductions taken in accordance with subsections (a)-(f) above) shall Net Sales for a Licensed Product be lower than 'net sales' of such Licensed Product as reported in BioNova's (or the applicable Affiliate's or Sublicensee's) publicly available financial statements or reports.

Section I.92."NMPA" means the National Medical Products Administration of the PRC (formerly known as the China Food and Drug Administration), or its successor.

Section I.93. “Non-Breaching Party” has the meaning set forth in Section 14.3(a).

Section I.94. “Non-Conforming Product” has the meaning set forth in Section 5.1(g).

Section I.95. “Other Costs” means freight, import/export fees, taxes, and other charges associated with the supply or acquisition of a given order or quantity of Licensed Product calculated in accordance with the applicable Accounting Standards, as consistently applied across Sutro’s or BioNova’s organization (as applicable) and with respect to Sutro’s or BioNova’s other products (as applicable), and which charges are not included or otherwise accounted for in the costs, expenses and other charges tabulated in determining the Fully Burdened Manufacturing Cost for the same given order or quantity of Licensed Product.

Section I.96. “Part 2 – STRO-001-BCM1 Phase 1 Study” means the Part 2 dose expansion of the STRO-001-BCM1 Phase 1 Study, as illustrated in the study design described in Exhibit D.

Section I.97. “Party” means either Sutro or BioNova; “Parties” means Sutro and BioNova, collectively.

Section I.98. “Patent Challenge” has the meaning set forth in Section 14.3(d).

Section I.99. “Patent Rights” means the rights and interests in and to (a) all patents and patent applications (including provisional applications), including all divisionals, continuations, substitutions, continuations-in-part, re-examinations, re-issues, additions, renewals, extensions, confirmations, registrations, any other pre- or post-grant forms of any of the foregoing, (b) any confirmation patent or registration patent or patent of addition, utility models, patent term extensions, and supplemental protection certificates or requests for continued examinations, foreign counterparts, and the like of any of the foregoing, and (c) any and all patents that have issued or in the future issue from the foregoing patent applications, including author certificates, utility models, petty patents, innovation patents and design patents and certificates of invention.

Section I.100. “Periodic Updates” has the meaning set forth in Section 2.3.

Section I.101. “Person” means any natural person, corporation, general partnership, limited partnership, joint venture, proprietorship or other business organization or a Governmental Authority.

Section I.102. “Pharmacovigilance Agreement” has the meaning set forth in Section 4.10.

Section I.103. “Phase 1 Study” means a Clinical Study of an investigational product in subjects with the primary objective of characterizing its safety, tolerability, and pharmacokinetics and identifying a recommended dose and regimen for future studies as described in 21 C.F.R. 312.21(a), or a comparable Clinical Study prescribed by the relevant Regulatory Authority in the Territory.

Section I.104. “Phase 1/2 Study” means a Clinical Study of the Licensed Product conducted by or on behalf of BioNova or its Affiliates in the Territory, as illustrated in the study design and development plan described in Exhibit E.

Section I.105. “Phase 2 Study” means a Clinical Study of an investigational product in subjects with the primary objective of characterizing its activity in a specific disease state as well as generating more detailed safety, tolerability, pharmacokinetics, pharmacodynamics, and dose finding information as described in 21 C.F.R. 312.21(b), or a comparable Clinical Study prescribed by the relevant Regulatory Authority in the Territory.

Section I.106. “Phase 3 Study” means a Clinical Study of an investigational product in subjects that incorporates accepted endpoints for confirmation of statistical significance of efficacy and safety with the aim to generate data and results that can be submitted to obtain Regulatory Approval as described in 21 C.F.R. 312.21(c), or a comparable Clinical Study prescribed by the relevant Regulatory Authority in the Territory.

Section I.107. “Pivotal Study” means any (a) Phase 3 Study, or (b) other Clinical Study (or any arm thereof) in humans of a pharmaceutical or biologic product, the results of which, together with prior data and information concerning such product, are intended to be or otherwise are sufficient, without any additional clinical trial to meet the evidentiary standard for demonstrating the safety, purity, efficacy, and potency of such active substance of such product established by a Regulatory Authority in any particular jurisdiction and that is intended to support, or otherwise supports, the filing of an Marketing Authorization application in such jurisdiction (including any bridging study).

Section I.108. “PRC” means the People’s Republic of China, [\*].

Section I.109. “Pricing and Reimbursement Approval” means, with respect to the Licensed Product, the governmental approval, agreement, determination or decision establishing the price or level of reimbursement for such Licensed Product in a given Region in the Territory in such jurisdiction in the Field in the Territory.

Section I.110. “Purchase Order” has the meaning set forth in Section 5.1(c).

Section I.111. “Quality Agreement” has the meaning set forth in Section 5.1(j).

Section I.7. “Region” means each of the PRC, Hong Kong Special Administrative Region, Macau Special Administrative Region, and Taiwan.

Section I.8. “Regulatory Approval” means the final or conditional approval of the applicable Regulatory Authority necessary for the marketing and sale of a Licensed Product in the Field in a country(ies) or Region(s), excluding separate Pricing and Reimbursement Approval that may be required.

Section I.9. “Regulatory Approval Application” means an application to seek regular or expedited Regulatory Approval of the Licensed Product for sale or marketing in any country(ies) or Region(s) in the Territory, as defined in the applicable Laws and filed with the Regulatory Authority of such country(ies) or Region(s).

Section I.10. “Regulatory Authority” means any multinational, federal, national, state, provincial or local regulatory agency, department, bureau or other Governmental Authority with authority over the clinical development, Manufacture, marketing or sale of the Licensed Product in a Region,

including the National Medical Products Administration (formerly the China Food and Drug Administration) in the PRC.

Section I.11. "Regulatory Data Exclusivity" means with respect to a Licensed Product in a Region, the period of time during which (a) a Party or its Affiliate or Sublicensee has been granted the exclusive legal right by a Regulatory Authority in such Region to market and sell the Licensed Product; and (b) the data and information submitted by a Party or its Affiliate or Sublicensee to the relevant Regulatory Authority in such Region for purposes of obtaining Regulatory Approval may not be disclosed, referenced, or relied upon in any way by a Third Party or such Regulatory Authority (including by relying upon the Regulatory Authority's previous findings regarding the safety or effectiveness of the Licensed Product) to support the Regulatory Approval of any product by a Third Party in such Region.

Section I.12. "Regulatory Filing" means any documentation comprising or relating to or supporting any filing or application with any Regulatory Authority with respect to the Licensed Product, including any documents submitted to any Regulatory Authority, including INDs, Regulatory Approval Applications and all correspondence with any Regulatory Authority with respect to any Licensed Product (including minutes of any meetings, telephone conferences or discussions with any Regulatory Authority).

Section I.13. "Regulatory Standards" means all laws, ordinances, rules and regulations applicable to the Manufacturing of Licensed Product or any aspect thereof, including (a) all applicable Laws; (b) GMP, and (c) the applicable rules and regulations promulgated under or by the NMPA or any other applicable Regulatory Authority, in each of the above cases, as may be amended from time to time.

Section I.14. "Required Manufacturing Changes" has the meaning set forth in Section 5.1(f).

Section I.15. "Royalty Term" has the meaning set forth in Section 8.4(b).

Section I.16. "Safety Data" means any Adverse Event information from Clinical Studies and all results from non-clinical safety studies, including toxicology and carcinogenicity data (if any), with respect to the Licensed Product required by one or more Regulatory Authorities to be collected or to be reported to such Regulatory Authorities under applicable Laws, but excluding any information related to the efficacy of the Licensed Product.

Section I.17. "Sales Milestone Event" has the meaning set forth in Section 8.3.

Section I.18. "Sales Milestone Payment" has the meaning set forth in Section 8.3.

Section I.19. "Sell-Off Period" has the meaning set forth in Section 14.4(f)(i).

Section I.20. "Senior Officers" means, (a) with respect to BioNova, [\*] and (b) with respect to Sutro, [\*]. If the position of any of the Senior Officers identified in this definition no longer exists due to a corporate reorganization, corporate restructuring or the like that results in the elimination of the identified position, the applicable title of the Senior Officer set forth herein will be replaced with the title of another executive officer with responsibilities and seniority comparable to the eliminated Senior Officer, and the relevant Party will promptly provide notice of such replacement title to the other Party.

Section I.21. "SIAC" has the meaning set forth in Section 15.2.

Section I.22. "SIAC Rules" has the meaning set forth in Section 15.2.

Section I.23. "Specifications" means the specifications for the Licensed Product set forth in the Quality Agreement.

Section I.24. "Sole Inventions" has the meaning set forth in Section 9.1(b).

Section I.25. "STRO-001-BCM1 Phase 1 Study" means the STRO-001-BCM1 Phase 1 Study (ClinicalTrials.gov Identifier: NCT03424603) being conducted by Sutro in the US, as illustrated in the study design set forth in Exhibit D.

Section I.26. "Subcontract" has the meaning set forth in Section 3.2(b).

Section I.27. "Subcontractor" has the meaning set forth in Section 3.2(b).

Section I.112. "Sublicense" means a grant of rights from BioNova to a Sublicensee under any of the rights licensed to BioNova by Sutro under Section 3.1 and Section 3.4.

Section I.113. "Sublicensee" means, with respect to a Party, a Third Party sublicensee of rights granted to such Party under this Agreement or a Third Party licensee of rights with respect to the Licensed Product, which rights are retained by such Party under this Agreement with respect to such Licensed Product, or any further sublicensee of such rights (regardless of the number of tiers, layers or levels of sublicenses of such rights).

Section I.114. "Sutro" has the meaning set forth in the Preamble.

Section I.115. "Sutro Indemnified Party" has the meaning set forth in Section 12.2.

Section I.116. "Tax Withholdings" has the meaning set forth in Section 8.8.

Section I.117. "Term" has the meaning set forth in Section 14.1.

Section I.118. "Territory" means one or more or all of the following Regions: PRC, Macau, Hong Kong, and Taiwan, in each case as the context may require.

Section I.119. "Territory-Specific Development Plan" has the meaning set forth in Section 4.2.

Section I.120. "Third Party" means any Person other than a Party or any of its Affiliates.

Section I.121. "Third Party Blocking IP" has the meaning set forth in Section 8.6(a).

Section I.122. "Third Party Claim" has the meaning set forth in Section 12.3(a).

Section I.123. "Third Party Losses" means Losses resulting from an Action by a Third Party.

Section I.124. “Trademark” means all registered and unregistered trademarks, service marks, trade dress, trade names, logos, insignias, domain names, symbols, designs, and combinations thereof.

Section I.125. “United States” or “U.S.” or “US” means the United States and its territories, possessions and commonwealths.

Section I.126. “Upstream Licenses” means any and all agreements between Sutro or any of its Affiliates, on the one hand, and any Third Party, on the other hand, pursuant to which Sutro has (a) in-licensed any Patent Rights or Know-How owned or Controlled by such Third Party that are included as part of the Licensed Patents or Licensed Know-How or (b) agreed to provisions that would require BioNova to make any payments (including royalties) to any Third Party or to undertake or observe any restrictions or obligations with respect to the Development or Commercialization of Licensed Products in the Field in the Territory.

Section I.127. “Upstream Licensor” means a Third Party that is party to an Upstream License.

Section I.128. “Valid Claim” means either: (a) a claim Covering the composition of matter or the method of use of the Licensed Compound or Licensed Product included within an issued and unexpired patent included in the Licensed Patents that (i) has not been irrevocably or unappealably disclaimed or abandoned, or been irrevocably or unappealably held unenforceable, unpatentable or invalid by a decision of a court or other Governmental Authority of competent jurisdiction; and (ii) has not been admitted to be invalid or unenforceable through reissue, disclaimer, or otherwise, or (b) a claim Covering the composition of matter of the Licensed Compound or Licensed Product [\*] included within the Licensed Patents, in each case, that has neither been irretrievably cancelled, withdrawn or abandoned without the possibility of appeal or refile; provided, however, that Valid Claim will exclude any such pending claim in a patent application that has not been granted within [\*] years following the earliest priority filing date for such application.

## **ARTICLE II LICENSE OPTION**

Section I.28. Grant of License Option. Sutro hereby grants to BioNova or its designated Affiliate an exclusive option as described in this ARTICLE II to obtain the license grant set forth in Section 3.1 below and other related rights under this Agreement (the “License Option”).

Section I.29. License Option Payment. In consideration of the License Option granted by Sutro to BioNova hereunder, within [\*] immediately following the Effective Date and BioNova’s receipt of an invoice from Sutro, BioNova will pay to Sutro Four Million Dollars (US\$4,000,000) (the “License Option Payment”). The License Option Payment will be non-creditable and non-refundable [\*]

Section I.30. Periodic Updates. On a periodic basis and on an ad-hoc basis, as frequently as the Parties reasonably determine would be helpful in BioNova’s decision regarding the License Option, but in any event no less frequently than [\*], Sutro will disclose and provide updates to BioNova of the available clinical data from the STRO-001 BCM1 Phase 1 Study (the “Periodic Updates”) and the Parties will discuss in good faith such updates and the progress of the STRO-001 BCM1 Phase 1 Study.

Section I.31. Phase 1/2 Study.

(A) Responsibility. BioNova will use Commercially Reasonable Efforts to conduct the Phase 1/2 Study in the PRC.

(B) Phase 1/2 Study Milestone. BioNova (directly, or through its Affiliates, or its or their contractors) will use Commercially Reasonable Efforts to [\*]; provided (i) [\*] (ii) [\*] and (iii) [\*]

(C) License. Subject to the terms and conditions of this Agreement, Sutro hereby grants to BioNova and its Affiliates an exclusive (even with respect to Sutro and its Affiliates), sublicensable (to Affiliates only, subject to Section 3.2(a)), non-transferable (except as provided in Section 16.1), royalty-free license under the Licensed Technology to Develop and otherwise use, distribute, and import the Licensed Products in the Field in the Territory solely to conduct the Phase 1/2 Study in the Territory.

(D) Right of Reference. Sutro, on behalf of itself and its Affiliates and its and their Sublicensees, hereby grants to BioNova and its Affiliates, a right of reference to use, and will provide BioNova and its Affiliates with access to, any and all Regulatory Filings and Regulatory Approvals (including all data therein) owned or otherwise Controlled by Sutro, its Affiliates, and its and their Sublicensees that are necessary or reasonably useful to conduct the Phase 1/2 Study in the Territory, provided however that BioNova's access to any Expression Technology will be provided through the Disclosure Process, with which BioNova will provide its assistance upon Sutro's request.

(E) Subcontracting. Section 3.2 and Section 3.3 will apply to BioNova's engagement of Subcontractors in connection with the conduct of the Phase 1/2 Study.

(F) Transfer of Licensed Know-How. Within [\*] and as promptly as reasonably practicable after the Effective Date, Sutro will disclose and make available to BioNova the Licensed Know-How and Regulatory Filings Controlled by Sutro or its Affiliates that exist as of the Effective Date and are reasonably necessary for BioNova to prepare the Regulatory Filings required by the NMPA and conduct the Phase 1/2 Study in the Territory. Sutro may make such Licensed Know-How and Regulatory Filings available in such reasonable form as is maintained by Sutro or its Affiliates or Sublicensees and reasonably acceptable for use in certain Development activities in the Territory as contemplated by this Section 2.4. Sutro will provide BioNova with reasonable access to Sutro's or its Affiliates' personnel involved in the Development or Manufacture of such Licensed Compound and Licensed Product, either in-person at Sutro's or its Affiliates' facilities or by teleconference, at no cost and expense to BioNova, as reasonably necessary for use of such Licensed Know-How and Regulatory Filings as contemplated under this Section 2.4. BioNova acknowledges and agrees that any Know-How relating to the Manufacture of the Licensed Product beyond what is reasonably required for the Regulatory Filings (portions of which relate to the Expression Technology will be provided through the Disclosure Process), will be provided only after BioNova has exercised the License Option and only pursuant to the terms and conditions of the Commercial Supply Agreement.

(G) Clinical Supply. Section 5.1 will apply to the Clinical Supply of the Licensed Product by Sutro to BioNova for the conduct of the Phase 1/2 Study. Except in the event BioNova exercises the License Option, BioNova will not use such Clinical Supply for any other purpose.

Section I.32. Exercise of License Option. BioNova or its designated Affiliate will have the right to exercise or not exercise, for any or no reason in its sole discretion, the License Option. BioNova or its designated Affiliate may exercise the License Option by (a) providing to Sutro written notice of its exercise of the License Option (such notice, the “License Option Exercise Notice”) at any time during the period commencing on the Effective Date until the earlier to occur of the following: (i) [\*] following BioNova’s completion [\*] in the dose expansion portion, and (ii) [\*](such period, the “License Option Exercise Period”), and (b) paying in full to Sutro the License Option Exercise Payment pursuant to Section 8.1. In the event that BioNova or its designated Affiliate has not provided Sutro with a License Option Exercise Notice and paid the License Option Exercise Payment prior to the expiration of the License Option Exercise Period, then the License Option and this Agreement will automatically expire without any further action of the Parties and Sutro will thereafter retain the exclusive right to Develop, Manufacture and Commercialize and otherwise make, have made, use, offer for sale, sell, have sold, and import the Licensed Compounds and Licensed Products, in all fields including in and outside of the Field, and throughout the world including in and outside of the Territory, whether on its own or in collaboration with a Third Party, and Sutro will have no further obligation or liability to BioNova whatsoever in respect of the License Option or otherwise under this Agreement.

Section I.33. Effect of License Option Exercise. Except for this ARTICLE II, ARTICLE VIII (solely with respect to the License Option Payment), ARTICLE X, ARTICLE XI, ARTICLE XIII, ARTICLE XV, ARTICLE XVI, Section 3.8, Section 5.1 (as necessary to effectuate Section 2.4(g)), Section 5.3 (as necessary to effectuate Section 2.4(g)), Section 5.4 (as necessary to effectuate Section 2.4(g)), Section 14.3(b)(i), and the provisions of ARTICLE I and the other provisions of this Agreement necessary to give effect to such provisions, which will be effective as of the Effective Date and will continue in full force until the earlier of BioNova’s exercise of the License Option (in which case, Section 14.1 will apply to all the provisions of this Agreement) or the expiration of the License Option, the provisions of this Agreement will not be effective unless and until BioNova exercises the License Option in accordance with the terms and conditions of this ARTICLE II. In the event, during the License Option Exercise Period, BioNova or its designated Affiliate provides to Sutro the License Option Exercise Notice stating that BioNova wishes to exercise the License Option, (a) BioNova will pay Sutro the License Option Exercise Payment pursuant to Section 8.1 and (b) as of the date of such License Option Exercise Notice, the license grant set forth in Section 3.1 and the remaining provisions of this Agreement that are not then-currently in effect will be automatically effective without any further action of the Parties.

Section I.34. Sutro Obligations in Support of Option. During the License Option Exercise Period, Sutro will not, and will cause its Affiliates not to, license, assign, transfer, sell, encumber or otherwise grant to any Third Party any rights under the Licensed Technology or to Develop or Commercialize the Licensed Compound or Licensed Product in any manner that would conflict with, restrict, or limit BioNova’s rights under the License Option, right to conduct the Phase 1/2 Study under this ARTICLE II, and the right to obtain the licenses and rights under Sutro’s rights in the Licensed Technology with respect to Licensed Compounds and Licensed Products as contemplated under the License Option as set forth in this ARTICLE II. As of the Effective Date, Sutro intends to [\*] In the event (a) \* or (b) [\*]



**ARTICLE III**  
**LICENSE GRANTS**

Section I.35. License Grant to BioNova. Subject to the terms and conditions of this Agreement, Sutro hereby grants to BioNova and its Affiliates an exclusive (even with respect to Sutro and its Affiliates), sublicensable (subject to Section 3.2(a)), non-transferable (except as provided in Section 16.1), royalty-bearing license under the Licensed Technology to Develop (subject to this Section 3.1), Commercialize and otherwise use, offer for sale, sell, have sold, and import the Licensed Compounds and Licensed Products in the Field in the Territory. Notwithstanding the foregoing sentence, Sutro shall have the right to conduct Development in the Territory with respect to the Licensed Compounds and Licensed Products provided that during the Term, Sutro will first furnish to BioNova a written outline of its intended Development activities in the Territory and provide BioNova a reasonable opportunity to participate in such proposed activities. If no understanding is reached after a reasonable period of discussion with BioNova, Sutro will be entitled, notwithstanding the exclusive license grant above, to proceed with Development activities in the Territory if such Development activities would not, or would not reasonably be expected to, materially negatively impact BioNova's Development or Commercialization of the Licensed Compounds and Licensed Products in the Field in the Territory, and in such event, Sutro will keep BioNova reasonably informed of the Development activities occurring in the Territory. The Parties agree the technology transfer and license agreement referenced in Section 5.5 will (a) [\*], and (b) [\*]

Section I.36. Sublicensing and Subcontracting.

(A) BioNova Right to Sublicense. Subject to the terms and conditions of this Agreement, BioNova may grant Sublicenses of (i) any and all rights granted to BioNova by Sutro under this Agreement, including pursuant to Section 3.1 and Section 3.4, to its Affiliates (through multiple tiers) with prior notice to Sutro but without Sutro's prior written approval or consent, (ii) any and all rights granted to BioNova by Sutro under this Agreement, including pursuant to Section 3.1 and Section 3.4, with respect to Hong Kong, Macau, and Taiwan, to any Third Party with prior notice to Sutro but without Sutro's prior written approval or consent, and (iii) any and all rights granted to BioNova by Sutro under this Agreement, including pursuant to Section 3.1 and Section 3.4, with respect to the PRC, to any Third Party with Sutro's prior written approval (not to be unreasonably withheld, delayed or conditioned). All such Sublicenses granted to BioNova's Affiliates will be subject to any and all rights of Sutro under this Agreement and will subsist only for so long as such Sublicensee remains an Affiliate of BioNova.

(B) BioNova Right to Sublicense Subcontractors. Subject to the terms and conditions of this Agreement, BioNova may engage Third Party subcontractors engaged to provide contract research services (i.e. a CRO), contract manufacturing services (i.e. a CMO), or contract sales services (i.e. a CSO) in connection with this Agreement to Develop, Manufacture and/or Commercialize the Licensed Compound and Licensed Product (each, a "Subcontract"), and the Person so engaged, a "Subcontractor"), without prior notice to Sutro and without Sutro's prior written approval or consent.

(C) Sublicense and Subcontract Requirements. Each Sublicense and Subcontract shall be consistent with the terms and conditions of this Agreement and shall contain the following additional terms and conditions:

(i)requiring each Sublicensee and Subcontractor to protect and keep confidential any Confidential Information of the Parties in accordance with ARTICLE X of this Agreement;

(ii)requiring each Sublicensee and Subcontractor to provide BioNova with Control of all Patent Rights and rights in Know-How and other intellectual property rights in any and all Inventions developed by such Sublicensee or Subcontractor so that BioNova is fully enabled to fulfill its obligations under Section 3.5 and Section 9.1;

(iii)restricting each Sublicensee from granting a further sublicense of any Licensed Technology (except as expressly provided in the case of sublicenses to BioNova's Affiliates pursuant to Section 3.2(a)(i) or with Sutro's prior written consent); and

(iv)not imposing any obligation or liability upon Sutro.

(D)BioNova Responsible and Liable. BioNova shall remain directly responsible and liable for all of its obligations under this Agreement that have been delegated or sublicensed to any Sublicensee or Subcontractor. Any conduct by a Sublicensee or Subcontractor that would have constituted a breach of this Agreement if such conduct had been by BioNova shall be imputed to BioNova and be deemed a breach of this Agreement. BioNova must not grant a Sublicense or Subcontract to any Third Party Sublicensee or Subcontractor who has been debarred or disqualified by a Regulatory Authority (as more fully detailed in Section 11.4).

(E)Copies of Sublicense Agreements. Within [\*] after the grant of each Sublicense that is not related to the engagement of a CRO, CMO, CSO, or other Subcontractor, BioNova shall provide to Sutro a copy of the Sublicense agreement, which agreement may be redacted with respect to sensitive financial terms, provided that the extent of such redactions are consistent with the United States Securities and Exchanges Commission's requirements and guidelines governing redaction of information from material contracts.

(F)Sublicense Survival. Upon the termination of this Agreement, at the written request of any Third Party Sublicensee of BioNova that is granted a Sublicense to Commercialize in the Territory or any Region thereof and which Sublicensee is not then in breach of its Sublicense agreement, Sutro agrees to consider in good faith entering into a direct license agreement with such Sublicensee under substantially the same terms and conditions of this Agreement (except for ARTICLE II), *mutatis mutandis*, such substitute Sublicense agreement, subject to agreement by Sutro and such Sublicensee, to be effective from and after the date of such written request so as to avoid a gap in the Sublicensee's rights.

Section I.37.Performance by Independent Contractors. BioNova may contract or delegate any portion of its obligations hereunder to a contractor (including a Subcontractor) subject to the terms and condition of the applicable provisions of Section 3.2 and Section 16.8.

Section I.38.Right of Reference. Each Party, on behalf of itself and its Affiliates and its and their Sublicensees, hereby grants to the other Party, its Affiliates, and its and their Sublicensees, a right of reference to use, and will provide the other Party, its Affiliates, and its and their Sublicensees with access to, any and all Regulatory Filings and Regulatory Approvals (including all data therein) owned or

otherwise Controlled by the first Party, its Affiliates, and its and their Sublicensees that are necessary or reasonably useful for the Development, Manufacture, Commercialization or other exploitation of the Licensed Compound or Licensed Products in the Field in the other Party's territory, provided however that BioNova's access to any Expression Technology for such Regulatory Filings will be provided through the Disclosure Process, with which BioNova will provide its assistance upon Sutro's request.

Section I.39. License Grant to Sutro. During the Term, BioNova hereby grants to Sutro a non-exclusive, fully paid-up, royalty-free, sublicensable (through multiple tiers), transferable license under the BioNova Technology to Develop, Manufacture and Commercialize the Licensed Compound and Licensed Products in the Field and in and outside the Territory, subject to the rights of BioNova under the licenses granted to it during the Term.

Section I.40. Reservation of Rights. No rights, other than those expressly set forth in this Agreement, are granted to either Party under this Agreement, and no additional rights will be deemed granted to either Party by implication, estoppel or otherwise, with respect to any intellectual property rights. All rights not expressly granted by either Party, or its Affiliates to the other Party under this Agreement are hereby reserved. Notwithstanding anything to the contrary set forth in this Agreement, Sutro retains the right (on behalf of itself, its Affiliates and its licensees (other than BioNova), and its and their Sublicensees) under the Licensed Technology, with the right to grant licenses and sublicenses through multiple tiers, to Manufacture and have Manufactured the Licensed Compounds and Licensed Products anywhere in the world, including in the Territory, (a) for supply to and use by BioNova as contemplated under this Agreement or the Commercial Supply Agreement, or (b) for any and all uses outside the Territory including by Sutro, its Affiliates and its licensees (other than BioNova) and its and their Sublicensees). Neither Party nor any of its Affiliates will use or practice any Know-How or Patent Rights licensed or provided to such Party or any of its Affiliates outside the scope of or otherwise not in compliance with the rights and licenses granted to such Party and its Affiliates under this Agreement.

Section I.41. No Inconsistent Third Party Agreements. During the Term, each Party will not, and will cause its Affiliates and its and their Sublicensees not to, sell, license or engage in any other transaction or action relating to any (a) intellectual property or (b) any Regulatory Filing, Regulatory Approval, Marketing Authorization and all corresponding documentation, in each case ((a) and (b)), in any way that would contravene, adversely affect or be inconsistent or in conflict with the rights of the other Party or the obligations of the other Party under this Agreement, or agree to do any of the foregoing.

Section I.42. Transfer of Licensed Know-How.

(G) Initial Technology Transfer. As promptly as reasonably practicable after the Effective Date, but no later than [\*] thereafter, Sutro will disclose and make available to BioNova the Licensed Know-How and Regulatory Filings Controlled by Sutro or its Affiliates that exist as of the Effective Date and are reasonably necessary for BioNova to prepare the Regulatory Filings required by the NMPA and execute the Territory-Specific Development Plan. Sutro may make such Licensed Know-How and Regulatory Filings available in such reasonable form as maintained by Sutro or its Affiliates or Sublicensees and reasonably acceptable to BioNova. Sutro will provide BioNova with reasonable access to Sutro's or its Affiliates' personnel involved in the Development or Manufacture of such Licensed Compound and Licensed Product, either in-person at Sutro's or its Affiliates' facilities or by

teleconference, [\*] as reasonably necessary for BioNova to understand and use such Licensed Know-How and Regulatory Filings as contemplated under this Agreement. BioNova acknowledges and agrees that any Know-How relating to the Manufacture of the Licensed Product beyond what is reasonably required for the Regulatory Filings (portions of which relate to the Expression Technology will be provided through the Disclosure Process), will be provided only after BioNova has exercised the License Option and only pursuant to the terms and conditions of the Manufacturing License.

(H)Updates. In addition, Sutro will provide updates throughout the Term to BioNova of any Know-How and Regulatory Filings that Sutro or its Affiliates comes to Control that constitutes Licensed Know-How (such updates to be made reasonably promptly after any Calendar Quarter in which such Know-How and Regulatory Filings comes into Control of Sutro or its Affiliates), and Sutro will (i) [\*], make reasonably available to BioNova all such Licensed Know-How and Regulatory Filings Controlled by Sutro or its Affiliates and not previously provided to BioNova hereunder, and (ii) provide BioNova with reasonable access to Sutro's or its Affiliates' personnel involved in the Development or Manufacture of such Licensed Compound and Licensed Product, either in-person at Sutro's or its Affiliates' facilities or by teleconference, [\*] as reasonably necessary for BioNova to understand and use such Licensed Know-How and Regulatory Filings as contemplated under this Agreement and reasonably necessary for BioNova to prepare the Regulatory Filings required by the NMPA and execute the Territory-Specific Development Plan.

Section I.43. Exclusivity.

(I)Obligations on Sutro. During the Term of this Agreement and subject to the terms and conditions of this Agreement, [\*] anywhere in the Territory nor collaborate with, enable or otherwise authorize, license or grant any right to any Third Party to Develop, Manufacture or Commercialize [\*] anywhere in the Territory.

(J)Obligations on BioNova. During the Term of this Agreement and subject to the terms and conditions of this Agreement, neither BioNova nor any of its Affiliates nor Sublicensees will, directly or indirectly, Develop, Manufacture or Commercialize any Competitive Product anywhere in the Territory nor collaborate with, enable or otherwise authorize, license or grant any right to any Third Party to Develop, Manufacture or Commercialize any Competitive Product anywhere in the Territory.

(K)Change of Control Exception. Notwithstanding the provisions of the foregoing Section 3.9(a) and Section 3.9(b), if either Party undergoes a Change of Control with a Third Party who owns or has rights to a Competitive Product that is in ongoing clinical development or being marketed by such Third Party as of the date of the Change of Control that would cause such Party to be in breach of the foregoing Section 3.9(a) or Section 3.9(b) (as applicable) (each, an "Acquired Competing Product"), then such Party shall be deemed not to be in breach of the foregoing Section 3.9(a) or Section 3.9(b) (as applicable) as a result of the continued Development or Commercialization of any such Acquired Competing Product during the Term; provided that (i) such continued activities are conducted independently of the activities under this Agreement (including maintaining separate lab notebooks), (ii) no Know-How or Confidential Information of the other Party is provided to or shared with any personnel working on the Acquired Competing Product, and (iii) the Party undergoing such Change of Control

implements firewalls, clean room procedures and other protections reasonably acceptable to the other Party that are designed to reasonably facilitate compliance with the foregoing clauses (i) and (ii).

## **ARTICLE IV DEVELOPMENT**

### Section I.44. Development Responsibilities in General.

(A)Development Diligence. Sutro (directly, or through its respective Affiliates or its or their Sublicensees and contractors) will [\*]. BioNova will not be deemed to be in breach of its obligations under this Section 4.1(a) to the extent it is prevented from or delayed in using Commercially Reasonable Efforts to perform an activity assigned to it in the Territory-Specific Development Plan as a result of the [\*] or Sutro's breach of any of its obligations under this Agreement or [\*] under the Development Plans.

(B)Development Responsibilities. Subject to the terms and conditions of this Agreement, including this ARTICLE IV, BioNova will have sole authority and discretion to, at its own expense, Develop the Licensed Product for the purpose of obtaining Regulatory Approval in the Field in the Territory. BioNova will be responsible for the day-to-day implementation of any Development activities for which it (or any of its Affiliates) is assigned responsibility under this Agreement (including the Territory-Specific Development Plan) and will keep Sutro reasonably informed as to the progress of such activities.

Section I.45. Development Plans. BioNova has sole discretion to decide, finalize, and update from time to time, the development plan for Development in the Field in the Territory (the "Territory-Specific Development Plan"), and Sutro or its licensee outside the Territory has sole discretion to decide, finalize, and update from time to time, the development plan for Development outside of the Territory (the "Global Development Plan"), and together with the Territory-Specific Development Plan, the "Development Plans"). Notwithstanding the foregoing sentence, the Parties agree to coordinate and cooperate with each other on the preparation and updating of the Territory-Specific Development Plan through the JSC, and in particular, the Parties will discuss the Territory-Specific Development Plan, consider the other Party's comments in good faith, and will use good faith efforts to make the Development Plans consistent in and outside the Territory, including in respect of requirements previously encountered by Sutro in its Development efforts outside of the Territory. To facilitate such coordination, each Party will provide a copy of the Development Plan for such Party's territory to the other Party [\*]

### Section I.46. Development Records and Reporting.

(C)Records. BioNova will maintain complete and accurate records of all work conducted by BioNova in furtherance of seeking Regulatory Approval for the Licensed Product in the Field in the Territory including details of all Development activities planned, commenced and completed together with the associated data and results. [\*]

(D)Reporting. BioNova will provide to Sutro a written report [\*], in English, describing in reasonable detail BioNova's activities and progress related to the Development of, and

pursuit of Regulatory Approval for, the Licensed Product in the Field in the Territory. BioNova will respond to Sutro's [\*]

Section I.47. Development Costs. Except as otherwise provided in this Agreement, BioNova will be [\*] including all [\*] incurred by BioNova and its Affiliates.

Section I.48. Global Development Plan and Joint Global Study. The Parties agree to consider the optimal regulatory pathway to achieve Marketing Authorization in the PRC, including the utility and appropriateness of conducting joint global Clinical Studies to which BioNova would contribute subjects; provided, however, any final decision to conduct clinical development outside of the Territory will remain in Sutro's sole and absolute discretion. In the event that Sutro has decided to proceed with a global Clinical Study, both Parties will collaborate in good faith to assess the clinical development plan for the Territory. Following agreement [\*] no less than the minimum number of subjects required by the applicable Regulatory Authorities in the applicable Region in the Territory, including the NMPA, for BioNova to qualify the Clinical Study for the Licensed Product to be conducted in the applicable Region in the Territory as part of the Joint Global Study (along with any data generated by the Joint Global Study outside the Territory) as a Pivotal Study in the applicable Region in the Territory. [\*] The Global Development Plan will specify a budget for the Development activities. BioNova will be responsible for [\*] as specified in the Global Development Plan. Sutro will be responsible for [\*] as specified in the Global Development Plan.

Section I.49. Regulatory Submissions and Approvals; Communications; Meetings.

(E) Regulatory Filings and Approvals. BioNova, or its relevant Affiliates or Sublicensees, will have the sole and exclusive right to file and hold all INDs and Regulatory Filings, and to apply for and maintain all INDs, Regulatory Filings, Regulatory Approvals, and Pricing and Reimbursement Approvals, in each case, for all Licensed Products in the Field in the Territory at BioNova's cost and expense in the name of BioNova or any of its Affiliates and its or their Sublicensees; provided that (i) the Parties will [\*] cooperate to effectuate this Section 4.6(a), and (ii) in the event that after the Parties' [\*], BioNova or any of its Affiliates, or its or their Sublicensees is unable under applicable Law to hold or become the legal and beneficial owner of the INDs, Regulatory Filings, Regulatory Approvals, and Pricing and Reimbursement Approvals for the Licensed Products in the Field in the Territory in order to exercise its rights and perform its obligations under this Agreement, then, subject to reasonable advance notice and subject to the terms and conditions of this Section 4.6, only for so long as the foregoing legal inability subsists and subject to all reasonably applicable conditions and limitations: (A) Sutro will be the legal and beneficial owner of the INDs, Regulatory Filings, Regulatory Approvals, and Pricing and Reimbursement Approvals for the Licensed Products in the Field in the Territory, (B) Sutro will designate BioNova or its Affiliates or its or their Sublicensees as Sutro's regulatory agent and exclusive general distributor for the Licensed Products in the Field in the Territory, and (C) to the extent later permitted by applicable Laws, Sutro will cooperate with BioNova and its Affiliates and its or their Sublicensees, including transferring and assigning all INDs, Regulatory Filings, Regulatory Approvals, and Pricing and Reimbursement Approvals to BioNova or its Affiliates or its or their Sublicensees, to allow BioNova or its Affiliates or its or their Sublicensees to be the legal and beneficial owner of all INDs, Regulatory Filings, Regulatory Approvals, and Pricing and Reimbursement Approvals for the Licensed Products in the Field in the Territory. Sutro understands and acknowledges

that as of the Effective Date, BioNova intends to Develop and obtain Regulatory Approval of the Licensed Product in the PRC as an imported pharmaceutical product, and accordingly, the applicable Laws and practice of the applicable Regulatory Authority in the PRC as of the Effective Date require Sutro to be the holder of the IND and sponsor of the Clinical Trials of the Licensed Product conducted in the PRC and the holder and legal and beneficial owner of the IND and Regulatory Approvals for the Licensed Products as an imported pharmaceutical product in the PRC. Subject to the terms and conditions of this Agreement, BioNova will be responsible, at its sole cost and expense, for all regulatory activities leading up to and including the submitting and obtaining of INDs, Regulatory Filings, Regulatory Approvals, and Pricing and Reimbursement Approvals, as applicable, for the Licensed Products in the Field in the Territory from Regulatory Authorities or Governmental Authorities in the Territory, provided that, BioNova will conduct such activities (and any and all regulatory activities delegated to BioNova in this Agreement) (1) in its own name, if BioNova is the holder and legal and beneficial owner of the INDs, Regulatory Filings, Regulatory Approvals, and Pricing and Reimbursement Approvals for the Licensed Products in the Field in the Territory, or (2) as the express and authorized regulatory agent of record for Sutro in the Field in the Territory, if Sutro is the legal and beneficial owner of the INDs, Regulatory Filings, Regulatory Approvals, and Pricing and Reimbursement Approvals for the Licensed Products in the Field in the Territory, under which situation such actions will be taken on behalf of Sutro and for the benefit of BioNova in the Field in the Territory.

(F)Regulatory Communications. Subject to applicable Laws and this Section 4.6, BioNova will oversee, monitor and manage all interactions and communications with Regulatory Authorities with respect to the Licensed Products in the Field in the Territory. Subject to the other provisions in this ARTICLE IV, including Section 4.9, BioNova will have final decision-making authority regarding all regulatory activities, including the labeling strategy and the content of Regulatory Filings for Licensed Products in the Field in the Territory, subject to the terms and conditions of this Agreement. BioNova will promptly notify Sutro of all material communications or correspondence with Regulatory Authorities with respect to the Licensed Product in the Field in the Territory that are received by BioNova from any Regulatory Authority or submitted by BioNova to any Regulatory Authority.

(G)Regulatory Meetings. Until such time as BioNova obtains Regulatory Approval for the Licensed Product in the Field in the Territory, to the extent legally permissible and practicable, BioNova will provide Sutro with [\*] of all material meetings with Regulatory Authorities (including advisory committee meetings and any other meeting of experts convened by a Regulatory Authority) regarding the Licensed Product if permitted by applicable Laws or the Regulatory Authority. At BioNova's request, Sutro will cooperate and provide reasonable assistance to BioNova in connection with such meetings with Regulatory Authorities, including attending such meetings with Regulatory Authorities to the extent permitted under applicable Laws and by the Regulatory Authority, and BioNova [\*] incurred by Sutro personnel in connection with any such attendance.

(H)Termination or Suspension of Clinical Studies. Notwithstanding anything to the contrary in this Agreement or the Pharmacovigilance Agreement, the Parties hereby agree that BioNova may terminate or suspend any Clinical Study relating to the Licensed Product in the Field in the Territory, without the approval or consent of the JSC or the other Party, if (i) a Regulatory Authority, institutional review board or safety data review board for such Clinical Study has required or recommended such termination or suspension or (ii) following review and discussion with the JSC, BioNova believes in good

faith that such termination or suspension is warranted because of observed efficacy or safety data or signals in the Clinical Studies. In either case, BioNova will notify Sutro in writing of such termination or suspension prior to public disclosure of such termination or suspension and promptly provide to Sutro a detailed report of the observations and assessments leading to such termination or suspension.

(I)Regulatory Investigation or Inquiry. If any Regulatory Authority (i) contacts BioNova or its Affiliate or its or their Sublicensee with respect to the alleged improper Development, Manufacture, or Commercialization of any Licensed Product, (ii) conducts, or gives notice of its intent to conduct, an inspection at BioNova's or its Affiliate's or its or their Sublicensee's facilities used in the Development of the Licensed Product, or (iii) takes, or gives notice of its intent to take, any other regulatory action with respect to any activity of BioNova or its Affiliate or its or their Sublicensee that could reasonably be expected to adversely affect any Development, Manufacture, or Commercialization activities with respect to the Licensed Product in or outside of the Territory, then BioNova will [\*] Sutro in writing of such contact, inspection or notice with all material details available to BioNova.

Section I.129.Delivery of Documentation. [\*] during the Term, upon a Party's reasonable request, the other Party will promptly provide the requesting Party with copies of all data and information (including communications with Regulatory Authorities, existing Regulatory Filings, and clinical and pre-clinical data and supporting documentation, in each case, in the form such data and information is maintained) relating to Licensed Products that are (i) Controlled by and in the possession of the other Party, its Affiliates or its Sublicensees and (ii) necessary or reasonably useful to support the requesting Party's Development, Manufacture or Commercialization of, or Regulatory Approval or Marketing Authorization for, Licensed Products, in the case that BioNova is the requesting Party, in Field and the Territory, and in the case that Sutro is the requesting Party, outside the Territory.

Section I.130.Development of the Licensed Products Outside the Territory. Subject to Section 4.9, Sutro retains the exclusive right and will be solely responsible and have sole discretion and control over the Development activities (including regulatory activities) of the Licensed Products anywhere in the world other than in the Territory. Sutro will, in its sole discretion, oversee, monitor and manage all interactions and communications with Regulatory Authorities with respect to such Licensed Products outside of the Territory. Sutro will have final decision-making authority regarding all regulatory activities, including the labeling strategy and the content of Regulatory Filings with respect to such Licensed Products outside of the Territory, including in connection with the conduct of a Joint Global Study (with BioNova accepting Sutro's invitation to participate in a global Clinical Study).

Section I.131.No Harmful Actions. Each Party will [\*] the other Party of all material communications or correspondence with any Regulatory Authority with respect to the Licensed Product in such Party's territory that would [\*] the Development, Manufacture or Commercialization of the Licensed Products in the Field anywhere in the world including outside of the Territory. In the event either Party or its Affiliates' or its or their Sublicensees Development activities (including regulatory activities) of the Licensed Product in the Field would reasonable be expected to materially adversely impact the Development, Manufacture or Commercialization of the Licensed Products in or outside the Field anywhere in the world including outside of the Territory, such Party will promptly notify the other Party of any such activities and, prior to undertaking such activities, in good faith consider the other Party's comments. [\*] following such notice, the Parties will discuss at the JSC an action plan to address



such Development activities (including regulatory activities) to minimize the impact on the other Party's Development timeline and other activities of the Licensed Product. In the event the Parties fail to agree on the magnitude or likelihood of the material adverse impact of such proposed activities or an action plan, and such failure to agree persists after escalation to the Senior Officer of each Party, then, [\*]

Section I.132. Pharmacovigilance. Within [\*] after the Effective Date, the Parties will negotiate [\*] with respect to the Licensed Product to protect patients and promote their well-being in a written pharmacovigilance agreement (the "Pharmacovigilance Agreement"). These responsibilities will include [\*] guidelines and procedures for the receipt, investigation, recordation, communication, and exchange (as between the Parties) of Adverse Event reports and any other information concerning the safety of any Licensed Product, including recall and withdrawal responsibilities, processes and procedures. Such guidelines and procedures will be in accordance with, and enable the Parties to fulfill, local and national regulatory reporting obligations under applicable Laws. BioNova will be responsible for reporting quality complaints, Adverse Events and Safety Data related to the Licensed Product in the Field to applicable Regulatory Authorities in the Territory, as well as responding to safety issues and to all requests of Regulatory Authorities relating to Licensed Products in the Field in the Territory. Sutro will be responsible for reporting quality complaints, Adverse Events and Safety Data related to Licensed Product to applicable Regulatory Authorities outside the Territory, as well as responding to safety issues and to all requests of Regulatory Authorities relating to Licensed Product outside the Territory. The Pharmacovigilance Agreement will also provide for a worldwide safety database to be maintained by Sutro, which worldwide safety database may be made accessible by BioNova, its Affiliates, and its or their Sublicensees and contractors to the full extent necessary for BioNova to exercise its rights under this Agreement, comply with its obligations under this Agreement and comply with all applicable Laws subject to a [\*] in the Pharmacovigilance Agreement. Each Party hereby agrees to comply with its respective obligations under such Pharmacovigilance Agreement and to cause its Affiliates and its or their Sublicensees and contractors to comply with such obligations.

**ARTICLE V**  
**MANUFACTURE AND SUPPLY**

Section I.50. Clinical Supply.

(A)General. In accordance with the provisions in this Section 5.1, Sutro will, or cause its designee to, Manufacture and supply BioNova with all of BioNova's, its Affiliates' and its or their Sublicensees' reasonable requirements of Licensed Product to use in connection with the Development in the Field in the Territory (the "Clinical Supply"). BioNova acknowledges that Sutro's responsibility [\*] by Sutro in its Development activities in the United States as of the Effective Date, and with the existing label (it being understood that Sutro makes no claim or statement that the existing label contains the necessary information required for importation in the Territory). The necessary information required for importation of the Licensed Product in the PRC is included in the sample label for the PRC attached hereto as Exhibit G. In the event that the existing label does not contain the necessary information required for importation of the Licensed Product in a Region in the Territory, Sutro will label or relabel the Licensed Product using the sample label for such Region in the Territory provided by BioNova (or in the case of the PRC, using the sample label for the PRC attached hereto as Exhibit G). In addition and in accordance with the provisions in this Section 5.1, Sutro will (i) [\*] (the "Initial Clinical Supply") [\*] following the Effective Date, and (ii) [\*]. With respect to all Clinical Supply, including the Initial Clinical Supply, consistent with the foregoing provisions of this Section 5.1(a), [\*] to ensure that the Clinical Supply is ready for use in clinical trials in the Territory, including the QA/QC (to the extent specifically required for the Territory) and release testing, packaging & labeling (including translation and printing), shipment, export and import, warehousing, insurance and other similar costs and charges associated with such quantities of Licensed Product from the applicable CMO directly to the facilities of BioNova, its Affiliates and its or their Sublicensees in the Territory, which Other Costs is understood to be excluded (notwithstanding any other provision in this Agreement to the contrary) from Sutro's Fully Burdened Manufacturing Cost, and accordingly all such Other Costs will be paid by BioNova upon invoice by Sutro. Unless otherwise agreed by the Parties or provided under this Agreement, the provisions of this Section 5.1 will apply only to Clinical Supply.

(B)Manufacturing by CMOs. BioNova acknowledges and agrees that Sutro's sources the manufacture and supply of Licensed Product from its CMOs. Accordingly, notwithstanding any provision in this Agreement to the contrary, BioNova hereby accepts that Sutro's capacity to provide the Initial Clinical Supply and the Clinical Supply thereafter as specified in this Agreement shall in all events be subject to the manufacturing capacities of each such CMO at the material times and the limitations in Sutro's contracts with its CMOs. In no event will Sutro be considered to be in breach of its obligations to supply quantities of Licensed Products to BioNova under this Agreement in connection with the Initial Clinical Supply and Clinical Supply provisions set forth in this Agreement if any delay or inability to supply is attributable to capacity constraints with Sutro's CMOs or limitations in Sutro's contracts with its CMOs.

(C)Purchase Orders. BioNova will place purchase orders (each, a "Purchase Order") in quantities of the Licensed Product in the form set forth in the attached Exhibit H. Each Purchase Order submitted by BioNova must be placed at least [\*] prior to the requested date of delivery. Subject always to the caveats set forth in this Section 5.1, Sutro will use Commercially Reasonable Efforts to accept any

Purchase Order for reasonable quantities with reasonable lead times submitted by BioNova. If Sutro fails to provide an acceptance or rejection of a Purchase Order within [\*] after receipt by Sutro, such Purchase Order will be deemed accepted. Purchase Orders that are accepted are binding on the Parties and may not be cancelled without the prior written agreement of both Parties (such binding Purchase Orders, "Binding Orders"), provided that in the event of a delay of a Clinical Study arising from circumstances beyond BioNova's reasonable anticipation or control, a Binding Order may be cancelled by BioNova subject to BioNova's payment of (i) all applicable [\*] which cancellation fees are subject to change without notice based on changes in the underlying CMOs or the agreements therewith, and (ii) [\*] to the extent Sutro is not able to utilize the quantities of Licensed Product ordered in such cancelled Binding Order elsewhere, using Commercially Reasonable Efforts. If any term or condition contained in any Purchase Order or any other document exchanged between the Parties under this Agreement is inconsistent with this Agreement, then the terms and conditions provided in this Agreement will control. No additional term or condition set forth in any such document will be binding upon either Party unless agreed to in writing by the Parties.

(D)Delivery; Risk of Loss. Licensed Product will be delivered, transfer of title will occur, and [\*]

(E)Product Warranty. Sutro hereby undertakes to ensure, and represents and warrants, that all Licensed Product delivered to BioNova under this Agreement at the time of delivery (i) conforms with the Specifications, (ii) is Manufactured in accordance with applicable Regulatory Standards and this Agreement and is not adulterated or misbranded under applicable Laws, (iii) is delivered with full title, free and clear of any liens, charges, encumbrances or security interests, and (iv) has at least [\*] drug product shelf-life remaining (collectively (i) through (iv), the "Manufacturing Requirements").

(F)Changes. With respect to any changes to the Specifications of Licensed Products, the Manufacturing process for Licensed Products, or the CMO or facility used to Manufacture Licensed Products, in each case, then being supplied to BioNova as part of the Clinical Supply, which changes are required by a Regulatory Authority or Manufacturing Requirements in a Region ("Required Manufacturing Changes"), Sutro will use good faith efforts to consider implementing such Required Manufacturing Changes but BioNova acknowledges and agrees that Sutro shall have no obligation to implement such changes. BioNova further agrees that Sutro will have no liability to BioNova for not implementing any Required Manufacturing Change and understands that if the Licensed Product as manufactured for Sutro as of the Effective Date does not satisfy requirements for their use in Development in the Territory (other than labeling, which is addressed in accordance with Section 5.1(a) and Section 5.1(h)), BioNova will make alternative arrangements for manufacture and supply of Licensed Products compatible for use in the Territory for which effort Sutro will reasonably assist subject to terms and conditions to be mutually agreed. For the duration of Clinical Supply as contemplated under Section 5.1(a), Sutro will not implement any change to the Specifications or the Manufacturing process for Licensed Product or any change of the CMO or facility used to Manufacture the quantities of Licensed Product to be supplied to BioNova as part of the Clinical Supply without first notifying BioNova in advance of delivery. BioNova will be responsible for the costs and expenses of implementing any changes under this Section 5.1(f) that are (i) requested by BioNova (including any Required Manufacturing Changes) or (ii) specific solely to the Territory, in each case if agreed to be implemented by Sutro, and Sutro will otherwise be responsible for such costs and expenses for all other changes.

(G)Acceptance and Rejection. BioNova will have the right to reject all or part of any shipment of Licensed Product it orders and receives from Sutro based on the grounds that such Licensed Product fails to conform to any of the Manufacturing Requirements (a “Defect,” and any unit with a Defect, a “Non-Conforming Product”). BioNova will deliver written notice to Sutro of any rejection permitted in this Section 5.1(g) for any Non-Conforming Product within [\*] from the date of delivery of the same. If a dispute arises as to whether the Licensed Product is a Non-Conforming Product that is not resolved by good faith negotiations between the Parties within [\*] of the delivery by BioNova of the notice of rejection for non-conformance, then the matter (along with related samples, batch records, and/or other evidence, as appropriate) will be submitted to an independent testing laboratory mutually agreed to by the Parties. The determination of the independent testing laboratory will be binding upon the Parties, save for manifest error. If the Parties agree or the independent laboratory confirms that any Licensed Product is a Non-Conforming Product, [\*] replace the Non-Conforming Product as soon as practicable. The cost and expenses of the laboratory that conducts the testing described above will be borne by the Party deemed to be the cause of such non-conformance, and if the cause cannot be determined, then such costs will be shared equally between the Parties. Any Licensed Product that is determined to be Non-Conforming Product that is in BioNova’s control will, at Sutro’s option, [\*]

(H)Packaging, Product Labels and Inserts, and Artwork. With respect to Sutro’s supply to BioNova of quantities of Licensed Product beyond the Initial Clinical Supply provided for above, by a date mutually agreed upon by the Parties, BioNova will provide Sutro with labeling specifications and draft labels and inserts, including artwork, as required in the Territory and that comply with all applicable Laws. BioNova will additionally provide all materials and information so as to enable Sutro to (i) liaise with its packaging material suppliers and printers, (ii) arrange for printing and preparing such packaging, labels and inserts, and (iii) coordinate delivery of such packaging, labels and inserts to Sutro’s CMO so that the Licensed Product supplied for use in Clinical Studies in the Territory, beyond those quantities supplied as part of the Initial Clinical Supply, will be delivered fully packaged and labeled.

(I)Payment: Invoices. Sutro will promptly invoice BioNova for the Clinical Transfer Price for all applicable quantities of Licensed Product delivered in accordance with this Section 5.1. BioNova acknowledges and agrees that in addition to [\*], any and all Other Costs associated with delivering quantities of Licensed Product to BioNova, its Affiliates and its or their Sublicensees incurred by Sutro, including freight, taxes and other charges paid by Sutro to its CMOs, will be passed on to BioNova and will be BioNova’s responsibility to pay. The undisputed portions of such invoices will be due and payable within [\*] of the invoice date, and any such undisputed amounts not paid when due will accrue interest in accordance with Section 8.10.

(J)Quality Agreement. Within [\*] after the Effective Date, the Parties will negotiate in good faith and finalize a quality agreement with respect to the quality assurance, quality control and technical requirements of the Licensed Product supplied by Sutro as part of the Clinical Supply (the “Quality Agreement”). In the event of any conflict between this Agreement and the Quality Agreement, the terms and conditions of this Agreement will govern and control except with respect to quality assurance requirements which shall be governed and controlled by the Quality Agreement.

Section I.51. Commercial Supply. No later than [\*] prior to the date BioNova anticipates its First Commercial Sale of Licensed Products in the Territory but not prior to Sutro’s receipt of the License

Option Exercise Notice and the applicable License Option Exercise Payment, the Parties will negotiate in good faith and enter into a commercial supply agreement for such supply (the "Commercial Supply Agreement") on such terms as are reasonable and customary for commercial supply of pharmaceutical products and at a supply price not to exceed (a) [\*] of Sutro's Fully Burdened Manufacturing Costs plus Other Costs for the Manufacture and supply of quantities of Licensed Product finished by CMOs engaged by Sutro and intended for commercial sale in the Territory, and (b) [\*] of Sutro's Fully Burdened Manufacturing Costs [\*] of Other Costs for the Manufacture and supply by Sutro of quantities of bacterial extracts, reagents, antibody for use in the further Manufacture of Licensed Products intended for commercial sale in the Territory.

Section I.52. Audit by BioNova. With respect to any Clinical Supply that BioNova is supplied by Sutro pursuant to this Agreement, Sutro will keep reasonably sufficient records, materials and documents necessary to calculate the Fully Burdened Manufacturing Cost for such Clinical Supply and all Other Costs related to supplying such Clinical Supply to BioNova that BioNova is responsible for [\*] thereafter. BioNova will have the right annually to have an independent, certified public accountant, selected by BioNova and reasonably acceptable to Sutro to inspect such records, materials and documents for the sole purpose of determining the accuracy of Sutro's Fully Burdened Manufacturing Cost and such Other Costs for Clinical Supply supplied within the [\*]. Such audit may not be conducted more than [\*] and will take place at the location(s) where such records, materials, documents are maintained by Sutro upon [\*], during regular business hours and with such certified public accountant being bound by written obligations of confidentiality substantially similar to those under this Agreement and reasonably acceptable to Sutro, and subject to the understanding that the results of such accountant's review will state whether there was an overpayment or underpayment and, if known, the source of the error. If it is determined that any amounts were overpaid or underpaid during such period, Sutro will pay BioNova such overpaid amounts, or BioNova will pay Sutro the underpaid amounts within [\*] after the date the independent certified public accountant's written report is received by the paying Party. The fees charged by such independent certified public accountant will be paid by BioNova, unless it is determined that any overpaid amounts exceed [\*] of the total amount payable by BioNova to Sutro for the period then being audited, in which case Sutro will be responsible for the fees charged by such independent certified public accountant. The records covering any specific period of time may be audited no more than once.

Section I.53. Regulatory Audit. During the Term, if BioNova receives any audit notice from any Regulatory Authority in the Territory with respect to the Manufacturing of any Product, then, BioNova will [\*] notify Sutro of such audit notice. For any such audit of Sutro or its Affiliates or Sutro's or its Affiliates' own facilities, Sutro will (a) facilitate any such audit and (b) permit a reasonable number of representative(s) appointed by the applicable Regulatory Authority, or, upon written approval by Sutro, representative(s) of BioNova (at BioNova's sole expense), to be present at any such audit. For any such audit of Sutro's CMO or its facilities, Sutro will use Commercially Reasonable Efforts to discuss with its CMO the conduct of such audit, and if its CMO permits such audit or Sutro otherwise has the right to require its CMO under its agreement with such CMO to facilitate such audit, Sutro will (i) facilitate any such audit of its CMO and (ii) permit a reasonable number of representative(s) appointed by the applicable Regulatory Authority, or, upon written approval by Sutro and its CMO, representative(s) of BioNova (at BioNova's sole expense), to be present at any such audit. All representatives of BioNova participating in any such audits will agree in writing to be bound by confidentiality obligations substantially similar to those under this Agreement or otherwise requested by Sutro's CMO and any such

audit will need to be scheduled and conducted in a manner that is in compliance with and as permitted under Sutro's agreement with such CMO. Any reference samples, manufacturing records and books, or audit results or reports disclosed to BioNova pursuant to this [Section 5.4](#) will be considered as Confidential Information of Sutro for purpose of this Agreement.

[Section I.54. Manufacturing License and Technology Transfer.](#) Upon BioNova's written notice to Sutro, and following payment of the License Option Exercise Payment, Sutro and BioNova shall discuss and agree on the terms and conditions of a technology transfer and license agreement that will permit BioNova to Manufacture (by itself, or through Affiliates or Third Parties) the Licensed Compound and Licensed Product in the Territory. Unless otherwise agreed by the Parties, Sutro will, within [\*] following execution of such technology transfer and license agreement, provide access to and transfer to BioNova, or an Affiliate or a CMO all Know-How Controlled by Sutro or its Affiliates that is necessary or reasonably useful for such entity to Manufacture the Licensed Compound and the Licensed Products in the Territory. Such agreement shall provide that, upon reasonable request from BioNova and at BioNova's cost, Sutro will provide to BioNova all necessary and reasonably requested assistance and services and all reasonable access to Sutro's or its Affiliates' or its or their CMOs' personnel involved in the Manufacture of such Licensed Compound and Licensed Product to enable BioNova or its Affiliates or Sublicensees to Manufacture the Licensed Compound and the Licensed Product in substantially the same manner and quality as Sutro or its Affiliate or its or their CMOs Manufactures the Licensed Compound and the Licensed Product for Sutro or its Affiliates or Sublicensees. Sutro will provide a Manufacturing technology transfer plan to facilitate the foregoing for the Parties' good faith discussion and the Parties will negotiate in good faith and agree to such a plan. No additional financial consideration shall be due in connection with the license permitting BioNova to Manufacture the Licensed Compound and Licensed Product in the Territory.

[Section I.55. \[\\*\].](#) If the Parties after reasonable and good faith effort have failed to agree upon any one or more terms of the technology transfer and license agreement contemplated by [Section 3.1](#) and [Section 5.5](#) (the "[Manufacturing License](#)"), the matter shall be submitted to and finally resolved by [\*] arbitration in accordance with the following provisions. [\*]. Within [\*] of the arbitrator's appointment, each Party shall prepare and deliver to both the arbitrator and other Party its last, best offer for the applicable unresolved term(s) of the Manufacturing License and a memorandum in support thereof. The Parties shall also provide the arbitrator with a copy of the relevant provisions of this Agreement. Each Party may submit to the arbitrator (with a copy furnished to the other Party) a rebuttal to the other Party's support memorandum and will at such time have the opportunity to amend its last such offer based on any new information contained in the other Party's support memorandum. Within [\*] after the arbitrator's appointment, the arbitrator will [\*].

[Section I.56. Direct CMO Engagement.](#) Without limiting [Section 2.6](#), after BioNova has paid to Sutro the License Option Exercise Payment, upon BioNova's written request and at BioNova's election, Sutro will permit BioNova or its Affiliate and Sublicensees to enter into a supply agreement directly with one or more CMOs engaged by Sutro or its Affiliates or Sublicensees for clinical and/or commercial supply of the Licensed Compound and Licensed Product for the Territory. Upon BioNova's request, Sutro will introduce BioNova to such CMOs for BioNova to commence such discussions and provide BioNova and such CMOs with its consent to allow such CMOs to Manufacture and supply Licensed Compound and Licensed Product directly to BioNova and its Affiliates and Sublicensees and for

BioNova and its Affiliates and Sublicensees to directly purchase Licensed Compound and Licensed Product from such CMOs.

## ARTICLE VI COMMERCIALIZATION

Section I.57. Commercialization Diligence. Within [\*] following receipt of the Regulatory Approval by the NMPA for a Licensed Product in the Field in the PRC, BioNova (directly, or through its Affiliates, or its or their Sublicensees or contractors) will effect Commercial launch and achieve First Commercial Sale in the PRC. Additionally, following receipt of Regulatory Approvals from the appropriate Regulatory Authorities for a Licensed Product in the Field in the other three Regions in the Territory, BioNova will use Commercially Reasonable Efforts to Commercialize such Licensed Product in the Field in the other three Regions in the Territory. Subject to the foregoing sentences and other provisions of this Agreement, BioNova will be solely responsible for, at its expense, and will have sole discretion with respect to, Commercializing the Licensed Product in the Field in the Territory.

Section I.58. Notification. BioNova will provide Sutro with written notice of the First Commercial Sale of each Licensed Product in the Field in the Territory within [\*] after such event.

### Section I.59. Trademarks.

(A) BioNova will have the right to brand the Licensed Products in the Field in the Territory using BioNova related Trademarks and any other Trademarks and trade names it determines appropriate for the Licensed Products, which branding may vary by Region or within a Region. BioNova will own all rights in such Trademarks and register and maintain such Trademarks in the countries and regions within the Territory, where and how it determines appropriate, subject to Section 14.4(k).

(B) BioNova will also have the right to brand the Licensed Products in the Field and in the Territory using the Licensed Marks, and BioNova will comply with Sutro's reasonable trademark usage guidelines in effect from time to time as provided by Sutro. Sutro will own and retain all rights to the Licensed Marks (together with all goodwill associated therewith) in the Territory, and will prepare, file, prosecute and maintain all Licensed Marks in the Territory at its own expense; provided, however, Sutro will provide to BioNova copies of all applications, submissions, communications, and correspondence intended to be sent to, sent to or received by Governmental Authorities or Third Parties in connection with such filing, prosecution, and maintenance of the Licensed Marks in the Territory so that BioNova may review and comment thereon (which will be provided with sufficient advanced notice so that BioNova may meaningfully review and comment, to the extent practicable), and will incorporate any reasonable comments provided by BioNova with respect to such applications, submissions, communications, or correspondence. Subject to terms and conditions of this Agreement, Sutro will grant and hereby grants a non-exclusive, sublicensable (subject to Section 3.2), fully paid-up, royalty free, non-transferrable (subject to Section 16.1(a)) license under the Licensed Marks for BioNova to Commercialize the Licensed Products in the Field in the Territory. BioNova will comply with Sutro's guidelines on the use and display of the Licensed Marks and quality control instructions.

Section I.60. Diversion. Subject to applicable Law, each Party hereby covenants and agrees that (A) it and its Affiliates will not, and it will contractually obligate (and use Commercially Reasonable Efforts to enforce such contractual obligation) its licensees, and its or their Sublicensees and contractors not to, directly or indirectly, actively promote, market, distribute, import, sell or have sold any Licensed Product, including via the Internet or mail order, to any Third Party or to any address or Internet Protocol address or the like, in the other Party's territory, and (B) neither Party will engage, nor permit its Affiliates, or its or their Sublicensees or contractors to engage, in any advertising or promotional activities relating to any Licensed Product for use directed primarily to customers or other buyers or users of such product located in any country, Region or jurisdiction in the other Party's territory, or solicit orders from any prospective purchaser located in any country, Region or jurisdiction in the other Party's territory. Notwithstanding the foregoing, nothing in this Section 6.4, will prevent Sutro, its Affiliates and licensees from undertaking, or having undertaken, any of the foregoing activities with respect to any Licensed Product outside of the Field in the Territory.

Section I.61. No Violation. Notwithstanding anything to the contrary contained herein, BioNova (including its Affiliates, its or their Sublicensees and contractors) will not be obligated to undertake or continue any Commercialization activities with respect to Licensed Products if BioNova (or its Affiliates, its or their Sublicensees or contractors, as applicable) reasonably determines that performance of such Commercialization activity would violate applicable Laws or infringe any Third Party Patent Rights.

## **ARTICLE VII GOVERNANCE; JOINT STEERING COMMITTEE**

Section I.62. Formation: Purposes and Principles. As soon as practicable following the Effective Date (but in no event later than [\*] after the Effective Date), Sutro and BioNova will form a joint steering committee (the "JSC") to serve as a forum for discussion and to facilitate information sharing between the Parties with respect to the activities of the Parties under this Agreement.

Section I.63. Specific Responsibilities. In addition to its overall responsibility to provide a forum for discussion and to facilitate information sharing between the Parties with respect to the activities of the Parties under this Agreement, the JSC will:

- (A) coordinate and share information with respect to the Development and Commercialization of the Licensed Product by BioNova in the Territory;
- (B) keep each Party reasonably informed of the other Party's Development and Commercialization activities and interactions with Regulatory Authorities in the other Party's territory, by receiving updates from the Party conducting such activities;
- (C) attempt to discuss in the first instance all matters between the Parties that are in dispute;
- (D) review and discuss the Territory-Specific Development Plan and any proposed amendments thereto;



(E)review and discuss the Global Development Plan, to the extent relevant to the Territory-Specific Development Plan;

(F)review and discuss matters that may have a material adverse impact upon the regulatory status of the Licensed Products pursuant to Section 4.9;

(G)review and discuss any proposed publication of the results of Development or Commercialization carried out on the Licensed Product by BioNova, its Affiliates and its and their respective Sublicensees; and

(H)perform such other functions as are assigned to it in this Agreement or as appropriate to further the purposes of this Agreement to the extent agreed to in writing by the Parties.

Section I.64.Membership. The JSC will be composed of a total of three (3) representatives of each Party, which will be appointed by each of Sutro and BioNova, respectively. Each individual appointed by a Party as a representative to the JSC will be an employee of such Party with sufficient seniority within the applicable Party to provide meaningful input and make decisions arising within the scope of the JSC's responsibilities, and have knowledge and expertise in the Development, Manufacture or Commercialization of compounds and products similar to the Licensed Compound and Licensed Products under this Agreement. Each Party may replace any of its JSC representatives at any time upon written notice to the other Party, which notice may be given by e-mail, sent to the other Party's co-chairperson. The JSC will be co-chaired by one designated representative of each Party. The two co-chairpersons of the JSC, one from each Party, will cast its Party's vote in the JSC and such designee will have the authority to make decisions on behalf of such Party on matters before the JSC. Each co-chairperson will on an alternate basis be responsible for calling and conducting meetings. Each JSC representative will be subject to confidentiality obligations no less stringent than those in ARTICLE X.

Section I.65.Meetings; Reports. The JSC will hold meetings at least once per Calendar Quarter during the Term for so long as the JSC exists, unless the Parties mutually agree in writing to a different frequency. No later than [\*] prior to any meeting of the JSC (or such shorter time period as the Parties may agree), the applicable co-chairperson or Alliance Manager will prepare and circulate an agenda for such meeting. Either Party may also call a special meeting of the JSC by providing at least [\*] prior written notice to the other Party if such Party reasonably believes that a significant matter must be addressed prior to the next scheduled meeting, in which event such Party will work with the applicable co-chairperson of the JSC or Alliance Manager to provide the members of the JSC no later than [\*] prior to the special meeting with an agenda for the meeting and materials reasonably adequate to enable an informed decision on the matters to be considered. The JSC may meet in person or by audio or video conference as its co-chairpersons may mutually agree. Other representatives of the Parties, their Affiliates, or Third Parties involved in the Development, Manufacture, or Commercialization of Licensed Products may be invited by the members of the JSC to attend meetings as non-voting observers; provided, however, that such representatives are subject to confidentiality obligations no less stringent than those set forth in ARTICLE X. No action taken at a meeting will be effective unless at least one representative of each Party (which representative is not such Party's Alliance Manager) is present or participating. Neither Party will unreasonably withhold attendance of at least one representative of such Party at any meeting of the JSC for which reasonable advance notice was provided.

Section I.66. No Decision-Making Authority. The JSC will function as a forum for discussion, to facilitate the exchange of information, and to facilitate coordination of each Party's activities under this Agreement. The JSC will not have any decision-making authority, and the JSC will not have the authority to waive any Party's rights or obligations or amend the terms or conditions of this Agreement.

Section I.67. Alliance Managers.

(I) Appointment. Each Party will appoint a person to oversee interactions between the Parties for all matters related to the Development and Commercialization of Licensed Products between meetings of the JSC (each, an "Alliance Manager"). The Alliance Managers will have the right to attend all meetings of the JSC as non-voting participants and may bring to the attention of the JSC any matters or issues either Alliance Manager reasonably believes should be discussed and will have such other responsibilities as the Parties may mutually agree in writing. Each Party may replace its Alliance Manager at any time or may designate different Alliance Managers with respect to Development and Commercialization matters, respectively, by notice in writing to the other Party.

(J) Responsibility. The Alliance Managers will have the responsibility of creating and maintaining a constructive work environment within the JSC and between the Parties for all matters related to this Agreement. Without limiting the generality of the foregoing, each Alliance Manager will:

(i) provide a single point of communication within the Parties' respective organizations and between the Parties with respect to this Agreement;

(ii) coordinate cooperative efforts, internal communications and external communications between the Parties with respect to this Agreement;

(iii) on an alternate basis be responsible for (1) preparing and circulating an agenda in advance of each JSC meeting; provided, however, that the applicable co-chairperson will include any agenda items proposed by either Party on such agenda, (2) [\*], and (3) [\*] (iii) of this Section 7.6(b) will be deemed approved unless one or more members of the JSC objects to the accuracy of such minutes within [\*] after receipt or there is evidence of an inaccuracy; and the Alliance Managers will work with the co-chairpersons [\*]; and

(iv) take such other steps as may be required to ensure that meetings of the JSC occur as set forth in this Agreement, that procedures are followed with respect to such meetings (including working with the co-chairpersons with respect to the giving of proper notice [\*]) and that relevant action items resulting from such meetings are appropriately carried out or otherwise addressed.

## **ARTICLE VIII FINANCIAL PROVISIONS**

Section I.1. License Option Exercise Payment. In the event BioNova exercises the License Option pursuant to Section 2.5, BioNova will pay to Sutro [\*] (the "License Option Exercise Payment") within [\*] following receipt of an applicable invoice from Sutro. Sutro will provide BioNova with an invoice for the License Option Exercise Payment following BioNova's exercise of the License Option pursuant to Section 2.5.

Section I.68. Development Milestone Payments. During the Term, BioNova will notify Sutro in writing of the achievement by or on behalf of BioNova, its Affiliates or its or their Sublicensees of any milestone event set forth in this Section 8.2 in respect of a Licensed Product (each, a “Development Milestone Event”) promptly and not later than [\*] after the occurrence thereof, and BioNova will pay Sutro each of the milestone payments set forth in the table below (each, a “Development Milestone Payment”) within [\*] of the achievement of such Development Milestone Event by BioNova, its Affiliates or any of its or their Sublicensees and after BioNova receives an invoice therefor from Sutro. Periodically during the Term and at least once quarterly, BioNova will provide to Sutro written summaries updating its progress on Development activities in the Territory including an updated table identifying the Calendar Quarter in which each of the Development Milestone Events is then projected to occur. Each of the Development Milestone Payments set forth in this Section 8.2 is payable only once upon the first achievement of such Development Milestone Payment by the first Licensed Product to achieve such Development Milestone Event, and none of such Development Milestone Payments will be payable more than once regardless of how many times such Development Milestone Event is achieved by the Licensed Products (regardless of the number of such Licensed Products).

Development Milestone Event	Development Milestone Payment
[*]	[*]
[*]	[*]
[*]	[*]
[*]	[*]
[*]	[*]
[*]	[*]
<b>Total:</b>	[*]

Section I.1. Sales Milestone Payments. During the Term, BioNova will notify Sutro in writing of its achievement of each of the sales milestones below within [\*] after the end of the Calendar Year in which the aggregated annual Net Sales of all Licensed Products in the Territory first exceed the indicated Dollar value (each, a “Sales Milestone Event”). On a Licensed Product-by-Licensed Product basis, BioNova will pay to Sutro each of the milestone payments set forth below within [\*] after the end of the Calendar Year in which the Sales Milestone Event occurs and after BioNova receives an invoice therefor from Sutro (each, a “Sales Milestone Payment”). Each of the Sales Milestone Payments for Licensed Products set forth in this Section 8.3 is payable only once upon the first achievement of such Sales Milestone Event with respect to all Licensed Products, in the aggregate, and none of such Sales Milestone Payments will be payable more than once regardless of how many times such Sales Milestone Event is achieved with respect to all Licensed Products, in the aggregate.

Sales Milestone Event	Sales Milestone Payment for Licensed Products
[*]	[*]
[*]	[*]
[*]	[*]
[*]	[*]
<b>Total</b>	[*]

Section I.69. Royalties.

(A) Royalty Rate. Subject to the terms and conditions of this Agreement, during the Royalty Term, BioNova will pay to Sutro a royalty on the Net Sales of all Licensed Products in the Territory that is the product of the aggregate annual Net Sales of all Licensed Products in the Territory and the applicable royalty rate for Licensed Products in the following table, subject to the provisions of Section 8.6.

Portion of the Annual Net Sales of Licensed Products	Royalty Rate for Licensed Products
[*]	[*]
[*]	[*]
[*]	[*]
[*]	[*]

(A) Royalty Term. On a Licensed Product-by-Licensed Product and Region-by-Region basis, royalties will be due under this Section 8.4 with respect to a given Licensed Product in a given Region in the Territory during the period commencing upon the First Commercial Sale of such Licensed Product in such Region in the Territory and ending upon the latest of (i) the expiration of the last-to-expire Valid Claim Covering such Licensed Product in such Region in the Territory, (ii) the expiry of the applicable Regulatory Data Exclusivity for such Licensed Product in such Region, and (iii) [\*] years have elapsed following First Commercial Sale of such Licensed Product in such Region in the Territory (such latest ending period, the “Royalty Term”).

(B) Royalty Payments and Reports.

(i) BioNova will report to Sutro the date of First Commercial Sale of a Licensed Product within [\*] of occurrence in each Region.

(ii) [\*] following the end of each Calendar Quarter, following the First Commercial Sale of a Licensed Product, BioNova will furnish to Sutro a written report for the Calendar

Quarter showing the Net Sales of Licensed Product sold by BioNova, its Affiliates and its or their Sublicensees in the Territory during such Calendar Quarter and the royalties payable under this Agreement for such Calendar Quarter. Such written report will include the number of Licensed Products sold by BioNova, its Affiliates and its or their Sublicensees in each Region, the gross sales of Licensed Product on a Region-by-Region and Licensed Product-by-Licensed Product basis, an itemized calculation of any deductions taken from such gross sales to arrive at Net Sales for the applicable Calendar Quarter, a calculation of any applicable reductions under Section 8.6, and the calculation of the amount of royalty payment due on such Net Sales. Further, each such royalty report shall indicate gross sales and Net Sales in each Region's currency, the applicable royalty rate, the royalties payable for each Region in such Region's currency, the applicable exchange rate to convert from each Region's currency to U.S. Dollars, and the royalties payable in U.S. Dollars.

(iii) After the receipt of each royalty report provided by BioNova under Section 8.4(c)(i) above, Sutro will submit to BioNova an invoice for the amount of royalties payable set forth therein. BioNova will pay to Sutro the royalties for each Calendar Quarter within [\*] after the receipt of the invoice from Sutro.

Section I.70. Upstream License Fees. Notwithstanding anything to the contrary hereunder, Sutro will be solely responsible for any and all payments Sutro owes to the Upstream Licensors under any applicable Upstream Licenses and in no event will BioNova, its Affiliates, its or their Sublicensees or contractors be directly liable for any of such payments, except as otherwise expressly set forth in this Agreement.

Section I.71. Payment Reductions. The following will only apply if royalties or Sales Milestone Payments are being paid pursuant to Section 8.3 and Section 8.4:

(B) Blocking Third Party Intellectual Property. In the event either Party becomes aware of intellectual property rights Controlled by a Third Party that such Party considers necessary to Develop, Manufacture or Commercialize such Licensed Product and its related Licensed Compound in the Field in the Territory ("Third Party Blocking IP"), such Party will notify the other Party, and Sutro will have the first right to obtain a license to such Third Party Blocking IP from such Third Party. In the event Sutro or any of its Affiliates obtains a license to such Third Party Blocking IP such that it Controls such Third Party Blocking IP, such Third Party Blocking IP will be automatically included in the Licensed Know-How and Licensed Patents, as applicable, and subject to Section 8.6(b), Sutro will be the Party providing payments and other consideration payable to such Third Party in respect of such Third Party Blocking IP arising from BioNova, its Affiliates or its or their Sublicensees use of such Third Party Blocking IP in the Development, Manufacture, and Commercialization of the Licensed Compound and Licensed Products in the Field in the Territory under this Agreement. In the event Sutro does not obtain a license to such Third Party Blocking IP such that it Controls such Third Party Blocking IP within [\*] of the date of the foregoing notice, BioNova will have the right to obtain a license to such Third Party Blocking IP from such Third Party, and BioNova may deduct from its royalties to Sutro with respect to a Licensed Product any payments made to such Third Party for a license to such Third Party Blocking IP. BioNova will provide Sutro with reasonable prior written notice before entering into an agreement with such Third Party in respect of such a license, and will provide a copy of such Third Party agreement to Sutro within

[\*] after its execution, provided that, BioNova may redact from such agreement any sensitive information not necessary to determine the royalty deduction in this Section 8.6(a).

(C)Royalty Reductions. If Sutro obtained the license to the Third Party Blocking IP in the above Section 8.6(a), then BioNova will pay the applicable royalty under Section 8.4 to Sutro and Sutro will be (i) [\*], (ii) [\*], and (iii) [\*]

(D)Generic Entry. At any time during the Royalty Term, after a Biosimilar Product of a Licensed Product receives Marketing Authorization in any Region in the Territory and has launched, BioNova's royalty for such Licensed Product in such Region under Section 8.4 for any Calendar Quarter will be calculated by multiplying Net Sales of such Licensed Product during such Calendar Quarter by the applicable royalty rate after applying the royalty rate reduction equal to BioNova's Gross Profit decline for that Calendar Quarter when compared to the average quarterly Gross Profit of such Licensed Product in the [\*] immediately prior to the entry of such Biosimilar Product. For clarity, [\*].

#### Section I.72. Financial Audits.

(E)Record Keeping. BioNova and its Affiliates will, and will cause its or their respective Sublicensees to, keep complete, true and accurate books and records in accordance with its Accounting Standards of the items underlying (i) Net Sales and Gross Profits, and (ii) royalty payments under this Agreement. BioNova and its Affiliates will, and will cause its or their respective Sublicensees to keep, such books and records for at least [\*] following the Calendar Quarter to which they pertain. Sutro will have the right no more than once per Calendar Year, at its own expense, to have an internationally-recognized independent, certified public accountant, selected by Sutro and reasonably acceptable to BioNova (the "Auditor"), review any such records of BioNova in the location(s) where such records are customarily maintained by BioNova upon reasonable prior notice, during regular business hours and under obligations of confidentiality, except to the extent necessary to enforce Sutro's rights under this Agreement or if disclosure is required by applicable Law, for the sole purpose of verifying the basis and accuracy of payments made under this Agreement and the content of the reports described in Section 8.4(c), within the prior [\*] period after receipt of such report. The Auditor will have the right to disclose to Sutro its conclusions regarding any payment owed under this Agreement. The records covering any specific period of time may be audited no more than once except where an audit has found a discrepancy in which case no such restriction will apply.

(F)Audit Report. The report prepared by the Auditor, a copy of which will be sent or otherwise provided to each Party by such Auditor at the same time before such report is considered final, will contain the conclusions of such Auditor regarding the audit and will specify that the amounts paid pursuant thereto were correct or, if incorrect, the amount of any underpayment or overpayment, and the specific details regarding any discrepancies. No other information will be provided to Sutro without the prior consent of BioNova unless disclosure is required by Laws, regulation or judicial order. If such report shows any underpayment, then BioNova will remit to Sutro, within [\*] after receipt of such report, (i) the amount of such underpayment and (ii) if such underpayment [\*] of the total amount owed for the period then being audited, the actual costs incurred by Sutro in conducting such review. For the avoidance of doubt, payment of the underpayment will be considered a late payment, subject to Section 8.10. If such report shows any overpayment, then BioNova will credit the overpaid amount against future payments

owed to Sutro. The Parties mutually agree that all information subject to review under this Section 8.7 is Confidential Information of both Parties and that the receiving Party will retain and cause the Auditor to retain all such information in confidence in accordance with confidentiality and non-use obligations no less stringent than those contained in ARTICLE X.

Section I.73.Tax Withholding. Each Party will be responsible for its own taxes. In the event any withholding or other tax based on income to Sutro ("Tax Withholdings") is required to be withheld and deducted from payments by BioNova (or its Affiliate paying on behalf of BioNova) pursuant to this Agreement under applicable Laws, BioNova (or its Affiliate paying on behalf of BioNova) will make such deduction and withholding and will pay the remainder to Sutro, and any amounts so withheld and deducted will be remitted by BioNova (or its Affiliate paying on behalf of BioNova) on a timely basis to the appropriate Governmental Authority for the account of Sutro and BioNova (or its Affiliate paying on behalf of BioNova) will provide Sutro reasonable evidence of the remittance within [\*] thereof. For the purposes of this Agreement, with respect to amounts so deducted and withheld and remitted to the appropriate Governmental Authority, BioNova will be deemed to have fulfilled all of its payment obligations to Sutro with respect to such payments paid to the such Governmental Authority. Notwithstanding anything in the foregoing to the contrary, to the extent that the amount of any deduction or withholding for Taxes is increased as a result of the assignment or assumption of any of BioNova's rights or obligations hereunder to or by a Person outside of the Territory for tax purposes, BioNova shall increase amount of its payments hereunder so that Sutro receives the same amount (after such taxes) as it would have received if such assignment or assumption had not occurred. BioNova may satisfy its withholding, value added or other tax obligations under this Section 8.8 through its Affiliates. Further, BioNova agrees to use good faith efforts to arrange its business activities and to cooperate and assist Sutro so as to minimize impact of tax withholdings.

Section I.74.Currency of Payments. All amounts payable and calculations under this Agreement will be in Dollars. As applicable, Net Sales and any royalty reductions will be translated into Dollars using the average of the applicable daily foreign exchange rates published in The Wall Street Journal (or any other qualified source that is acceptable to both Parties) for the last day of each month of the Calendar Quarter in which such Net Sales occurred. All payments under this Agreement will be paid in Dollars by wire transfer to an account designated by the receiving Party (which account the receiving Party may update from time to time in writing).

Section I.75.Late Payments. Without limiting any other rights or remedies available to Sutro hereunder, any late payment by BioNova will bear interest, to the extent permitted by Laws, at an annual rate of the prime rate set by The Wall Street Journal (but in no event in excess of the maximum rate permissible under applicable Law) on the date payment was initially due, computed from the date such payment was due until the date BioNova makes the payment. Notwithstanding the foregoing, no such interest will be assessed if the late payments are due to a change in applicable Law or action or inaction of a Governmental Authority related to Regulatory Approvals or foreign currency, which change was not reasonably foreseeable; provided that, BioNova will use Commercially Reasonable Efforts to remit any such payments to Sutro as promptly as possible.

Section I.76.Blocked Currency. If, by applicable Laws in a Region in the Territory, conversion into Dollars or transfer of funds of a convertible currency to the United States becomes materially

restricted, forbidden or substantially delayed, then BioNova will promptly notify Sutro and, thereafter, amounts accrued in such country or region under this Section 8.11 will be paid to Sutro (or its designee) in such country or region in local currency by deposit to an escrow account in a local bank designated by Sutro and to the credit of Sutro, unless the Parties otherwise agree. Any amounts paid by deposit to such escrow account in accordance under this Section 8.11 will be deemed paid as of the date of deposit to such escrow account for purposes of Section 8.10.

Section I.77.Invoices. Any invoice to be submitted to BioNova by Sutro hereunder may be submitted by email or other similar form of electronic communication and need not conform to any particular format provided that such invoice satisfies Sutro's Accounting Standards, except where required by applicable Laws or the banks of BioNova or BioNova's Affiliates to convert local currency to Dollars or to make payments in Dollars directly to Sutro, in which case, Sutro will provide to BioNova such invoice in the form and with information consistent with the pro forma invoice provided to Sutro by BioNova, an example of which is attached hereto as Exhibit F.

## **ARTICLE IX INTELLECTUAL PROPERTY OWNERSHIP, PROTECTION AND RELATED MATTERS**

### Section I.78.Ownership of Inventions.

(C)Background Technology. As between the Parties, subject to Section 9.1(b), Sutro will remain the sole and exclusive owner of all Licensed Technology and BioNova will remain the sole and exclusive owner of all Know-How, Patent Rights, and other intellectual property rights Controlled by BioNova or its Affiliates as of the Effective Date or during the Term.

(D)Ownership of Inventions. Ownership of all Inventions will be determined based on inventorship, as determined in accordance with the rules of inventorship under United States patent Laws. Each Party will own all Inventions that are made solely by its and its Affiliates' employees, agents, and independent contractors during the performance of activities under this Agreement ("Sole Inventions"); provided that for clarity, Sole Inventions Controlled by Sutro or any of its Affiliates will be included in the Licensed Technology and included in the licenses and rights granted to BioNova by Sutro hereunder and provided that for clarity, Sole Inventions Controlled by BioNova or any of its Affiliates or its or their Sublicensees will be deemed included within BioNova Technology and included in the licenses and rights granted to Sutro by BioNova hereunder including under Section 3.5. The Parties will jointly own all Inventions that are made jointly by the employees, agents, and independent contractors of one Party and its Affiliates together with the employees, agents, and independent contractors of the other Party and its Affiliates ("Joint Inventions"). Patents claiming the Joint Inventions will be referred to as "Joint Patents." Each Party will own an undivided half interest in the Joint Inventions, without a duty of accounting or an obligation to seek consent from the other Party for the transfer, assignment, exploitation or license of the Joint Inventions (subject to the licenses granted to the other Party under this Agreement).

(A)Assignment Obligation. Each Party will assign its rights, and cause all employees of such Party who perform activities for such Party under this Agreement to be under an obligation to assign their rights, in any Patent Rights and Know-How resulting therefrom to such Party to effectuate the



terms and conditions set forth in Section 9.1(b). Subject to Section 3.2(c)(ii), with respect to any activities of BioNova or exercise of its rights under this Agreement that are subcontracted to a Person that is not an employee, BioNova will include in the applicable subcontract an assignment to BioNova of all rights in Patent Rights and Know-How related to the Licensed Compound or Licensed Product made by such subcontractor resulting from such activities or exercise of its rights, and in any event where such assignment is precluded, will include in the applicable subcontract a license of such Patent Rights and Know-How to BioNova that is sublicensable (through multiple tiers) to Sutro under this Agreement.

(B)Disclosure of Inventions. Each Party will promptly disclose to the other Party all Inventions related to the Licensed Compound or Licensed Product, including all invention disclosure or other similar documents submitted to such Party by its or its Affiliates' employees, agents, or independent contractors relating to such Inventions, and will also promptly respond to reasonable requests from the other Party for additional information relating to such Inventions.

Section I.79.Prosecution and Maintenance of the Licensed Patents and Joint Patents.

(C)Licensed Patents. As between the Parties, Sutro will have the first right, at its expense, to prepare, file, prosecute, maintain, and defend the Licensed Patents in the Field in all Regions in the Territory, at Sutro's sole cost and expense. Sutro will keep BioNova reasonably informed of all steps with regard to and the status of such preparation, filing, prosecution, maintenance, and defense of such Patent Rights, including by providing BioNova with (i) copies of all correspondence and material communications it sends to or receives from any patent office or agency in the Territory relating to such Patents Rights, (ii) a draft copy of all applications sufficiently in advance of filing to permit reasonable review and comment by BioNova and giving due consideration to such comments, and (iii) a copy of applications as filed, together with notice of its filing date and serial number. Before Sutro submits any material filing, including a new patent application, or response to such patent authorities with respect to any Licensed Patents, Sutro will provide BioNova with a reasonable opportunity to review and comment on such filing or response and will take into account and consider in good faith BioNova's reasonable and timely requests and suggestions regarding the preparation, filing, prosecution, maintenance, and defense of such Licensed Patents under this Section 9.2(a).

(D)Joint Patents. BioNova will have the first right to prepare, file, prosecute, maintain and defend Joint Patents in the Territory, at BioNova's sole cost and expense. Sutro will have the first right to prepare, file, prosecute, maintain and defend the Joint Patents outside the Territory, at Sutro's sole cost and expense. Each Party will keep the other Party reasonably informed of the status of all actions taken, and will consider in good faith the other Party's recommendations and proposals for coordinating the prosecution efforts to optimize protections for both Parties.

(E)Step-In Right. If the Party having the first right in Section 9.2(a) or Section 9.2(b) elects not to prepare, file, prosecute, continue to prosecute or maintain a given Patent Right within the Licensed Patents, Patent Rights in Sole Inventions or Joint Patents ("Abandoning Party"), then the Abandoning Party will give the other Party notice thereof within a reasonable period (but not less than [\*] prior to allowing such Patent Rights to lapse or become abandoned or unenforceable, and the other Party will have the right to prepare, file, prosecute, maintain or defend such Patent Right. The other Party will have the right, but not the obligation, to assume responsibility for the preparation, filing, prosecution, or

continuation of the prosecution of such Patent Rights in such region and paying any required fees to maintain such Patent Rights in such region or defending such Patent Rights, all at such other Party's sole expense, through patent counsel or agents of its choice. A Party will not become an assignee of any such Patent Rights as a result of its assumption of any such responsibility, except as expressly provided herein. Upon transfer of the Abandoning Party's responsibility for preparing, filing, prosecuting, maintaining or defending any of the Patent Rights to the other Party under this Section 9.2(c), the Abandoning Party will promptly deliver to the other Party copies of all necessary files related to the Patent Rights with respect to which responsibility has been transferred and will take all actions and execute all documents reasonably necessary for the other Party to assume such prosecution, maintenance and defense. In the event BioNova assumes the preparation, filing, prosecution, maintenance, and defense of any Licensed Patent, such Patent Right will no longer be considered a Licensed Patent for purposes of determining the Royalty Term pursuant to Section 8.4(b). In the event Sutro assumes the preparation, filing, prosecution, maintenance, and defense of any patent application or patent in respect of a BioNova Sole Invention (which for clarity BioNova has itself elected to protect and had then filed a patent application to seek to protect), at Sutro's option, BioNova agrees to assign, and does hereby assign, to Sutro its entire right, title and interest in and to such Patent Right and thereafter, BioNova shall have a royalty-free, non-exclusive, non-transferrable and non-sublicensable license under such Patent Right for its internal research purposes.

(F)Cooperation. Each Party will, and will cause its Affiliates to, reasonably cooperate, with the other Party with respect to the preparation, filing, prosecution and maintenance of Licensed Patents and Joint Patents pursuant to this Section 9.2, including with respect to obtaining patent term restoration, supplemental protection certificates or their equivalents, and patent term extensions with respect to the Licensed Patents and Joint Patents in any Region where applicable.

#### Section I.80. Third Party Infringement.

(G)Notice. Each Party will promptly notify the other in writing of any (i) apparent, threatened or actual infringement by a Third Party of any Licensed Patent, Patent Right in a Sole Invention or Joint Patent, or (ii) unauthorized use or misappropriation of any Licensed Know-How by a Third Party of which it becomes aware, and, in each case, will provide the other Party with all evidence in such Party's possession or control supporting such infringement or unauthorized use or misappropriation (each, an "Infringement").

(H)BioNova First Right. As between the Parties, BioNova will have the first right, but not the obligation, using counsel of its choosing and at its sole expense, to institute any Action alleging Infringement of the Licensed Patents or Joint Patents (any such Action, an "Infringement Action") in the Territory. Sutro will have the right, at its own expense, to be represented in any such Infringement Action by counsel of its own choice. BioNova will notify Sutro of its decision to commence an Infringement Action and will keep Sutro apprised in writing of any such Infringement Action and will consider Sutro's reasonable interests and requests regarding such Infringement Action.

(I)Step-in Right. If BioNova fails to commence a suit to enforce the Licensed Patents or Joint Patents against such Infringement Action (or to settle or otherwise secure the abatement of such Infringement Action) within (i) [\*] after its receipt or delivery of notice under Section 9.3(a), or (ii) [\*] before the time limit, if any, set forth in applicable Laws for the filing of such actions, whichever comes

first, or ceases to diligently pursue such Infringement Action, Sutro will have the right, but not the obligation, at its own expense to institute such Infringement Action against the applicable Third Party infringer(s).

(J)Cooperation. In any Infringement Action brought under the Licensed Patents or Joint Patents pursuant to Section 9.3(b) and Section 9.3(c), each Party will, and will cause its Affiliates to, reasonably cooperate with each other, in good faith, relative to the other Party's efforts to protect the Licensed Patents and Joint Patents, and will join such suit as a party, if requested by the other Party. Furthermore, the Party initiating any Infringement Action pursuant to Section 9.3(b) or Section 9.3(c) will consider in good faith all reasonable and timely comments from the other Party on any proposed arguments asserted or to be asserted in litigation related to the enforcement or defense of any such Patent Rights. Neither Party will have the right to settle any patent infringement litigation with respect to any Licensed Patent or Joint Patents under this Section 9.3 in a manner that diminishes the rights or interests of the other Party without the consent of such other Party (which will not be unreasonably withheld).

(K)Allocation of Recoveries. Any settlements, damages or monetary awards recovered by either Party pursuant to any Infringement Action with respect to the Licensed Patents or Joint Patents in the Territory will, after reimbursing the Parties for their reasonable out-of-pocket expenses in making such recovery (which amounts will be allocated pro rata if insufficient to cover the totality of such expenses), [\*]

Section I.81 Claimed Infringement. Each Party will promptly notify the other Party if a Third Party brings any Action alleging patent infringement by BioNova or Sutro or any of their respective Affiliates or its or their Sublicensees with respect to the Development, Manufacture or Commercialization of any Licensed Product or Joint Patents (any such Action, an "Infringement Claim") in the Field in the Territory. BioNova will have the right, but not the obligation, to control the defense and response to any such Infringement Claim in the Field and in the Territory with respect to BioNova's activities, at BioNova's sole cost and expense, and Sutro will have the right, at its own expense, to be represented in any such Infringement Claim in the Field and in the Territory by counsel of its own selection. Sutro will have the sole right, but not the obligation, to control the defense and response to any such Infringement Claim with respect to Sutro's activities, including any such Infringement Claim in the Territory or outside of the Territory. Upon the request of the Party controlling the response to the Infringement Claim, the other Party will reasonably cooperate with the controlling Party in the reasonable defense of such Infringement Claim. The other Party will have the right to consult with the controlling Party concerning any Infringement Claim and to participate in and be represented by independent counsel in any associated litigation. If the Infringement Claim is brought against both Parties, then each Party will have the right to defend against the Infringement Claim. The Party defending an Infringement Claim under this Section 9.4 will (a) consult with the other Party as to the strategy for the prosecution of such defense, (b) consider in good faith any comments from the other Party with respect thereto, and (c) keep the other Party reasonably informed of any material steps taken and provide copies of all material documents filed, in connection with such defense. The Party controlling the defense against an Infringement Claim will have the right to settle such Infringement Claim on terms deemed reasonably appropriate by such Party; provided, that, unless any such settlement includes a full and unconditional release from all liability of the other Party and does not adversely affect the rights of the other Party, any such settlement will be subject to the other Party's prior written consent (not to be unreasonably withheld).

Section I.82. Common Interest. All information exchanged between the Parties regarding the preparation, filing, prosecution, maintenance, defense, and enforcement of Licensed Patents and Joint Patents under this ARTICLE IX will be deemed Confidential Information of the disclosing Party. In addition, the Parties acknowledge and agree that, with regard to such activities, the interests of the Parties as collaborators and licensor and licensee are to obtain the strongest patent protection possible, and as such, are aligned and are legal in nature. The Parties agree and acknowledge that they have not waived, and nothing in this Agreement constitutes a waiver of, any legal privilege concerning the Patent Rights under this ARTICLE IX, including privilege under the common interest doctrine and similar or related doctrines. Notwithstanding anything to the contrary contained herein, to the extent a Party has a good faith belief that any information required to be disclosed by such Party to the other Party under this ARTICLE IX is protected by attorney-client privilege or any other applicable legal privilege or immunity, such Party will not be required to disclose such information, and the Parties will in good faith cooperate to agree upon a procedure (including entering into a specific common interest agreement, disclosing such information on a “for counsel eyes only” basis or similar procedure) under which such information may be disclosed without waiving or breaching such privilege or immunity.

## ARTICLE X CONFIDENTIALITY AND PUBLICITY

### Section I.83. Confidential Information.

(A) Confidentiality Obligation. During the Term and for a period of [\*] thereafter, each Party agrees to, and will cause its Affiliates and its or their Sublicensees and contractors to, keep in confidence and not to disclose to any Third Party, or use for any purpose, except to exercise its rights or perform its obligations under this Agreement, any Confidential Information of the other Party, without the prior written consent of such disclosing Party. The existence and terms of this Agreement are the Confidential Information of each Party.

(B) Permitted Disclosures. Each Party agrees that it and its Affiliates will provide or permit access to the other Party’s Confidential Information only to the receiving Party’s employees, consultants, advisors, licensees and Sublicensees, and to the employees, consultants and advisors of the receiving Party’s Affiliates, in each case on a need-to-know basis who are subject to obligations of confidentiality and non-use with respect to such Confidential Information no less stringent than the obligations of confidentiality and non-use of the receiving Party pursuant to this Section 10.1; provided, however, that each Party will remain responsible for any failure by its Affiliates, licensees or Sublicensees, and its and its Affiliates’ respective employees, consultants and advisors, to treat such Confidential Information as required under this Section 10.1 as if such Affiliates, employees, consultants, advisors, licensees and Sublicensees were parties directly bound to the requirements of this Section 10.1.

(C) Confidentiality Limitation. Notwithstanding anything to the contrary herein, each Party may use and disclose the other Party’s Confidential Information as follows: (i) under appropriate written confidentiality and non-use obligations no less stringent than those in this Agreement, to its Affiliates, *bona fide* potential or actual collaborators, licensors, Sublicensees, licensees, or strategic partners and to employees, directors, agents, consultants, and advisers of any other Third Parties, (ii) to its financial advisors, attorneys and accountants, *bona fide* actual or potential acquisition partners, financing

sources or investors and underwriters on a need-to-know basis, in each case under appropriate confidentiality and non-use obligations (which may include professional ethical obligations) no less stringent than those in this Agreement; provided, however, that each Party may disclose the terms of this Agreement (but not any other Confidential Information) to *bona fide* actual or potential acquisition partners, financing sources or investors on a need to know basis, in each case under appropriate confidentiality and non-use obligations (which may include professional ethical obligations) no less stringent than those in this Agreement and of duration customary in confidentiality agreements entered into for a similar purpose; provided, further, that each Party will remain responsible for any failure by any of the foregoing individuals to treat such Confidential Information as required under Section 10.1 as if such individuals were parties directly bound to the requirements of this Section 10.1, or (iii) as required by any court or other governmental body or as otherwise required by applicable Laws (including any such disclosures as are required by a Regulatory Authority in connection with making any Regulatory Filing or seeking Regulatory Approval, Pricing and Reimbursement Approval, import authorization for any Licensed Product in the Territory, or the rules or regulations of the United States Securities and Exchange Commission or similar Regulatory Authority in a country other than the United States or of any stock exchange or listing entity (including in connection with the public sale of securities)); provided, that, notice is promptly given to the other Party and the disclosing Party cooperates with reasonable requests from the other Party to seek a protective order or other appropriate remedy to protect the Confidential Information. Notwithstanding anything to the contrary contained in this ARTICLE X, Confidential Information that is permitted or required to be disclosed will remain otherwise subject to the confidentiality and non-use provisions of Section 10.1(b) and this Section 10.1(c). If either Party concludes that a copy of this Agreement must be filed with the United States Securities and Exchange Commission or similar Regulatory Authority in a country other than the United States, then such Party will, within a reasonable time prior to any such filing, provide the other Party with a copy of such agreement showing any provisions hereof as to which the Party proposes to request confidential treatment, will provide the other Party with an opportunity to comment on any such proposed redactions and to suggest additional redactions, and will take such Party's reasonable comments into consideration before filing such agreement and use Commercially Reasonable Efforts to have terms identified by such other Party afforded confidential treatment by the applicable Regulatory Authority.

Section I.84. Publicity. The Parties acknowledge the importance of supporting each other's efforts to publicly disclose results and significant developments regarding the Licensed Product in the Field in the Territory, and each Party may make such disclosures from time to time, subject to the terms and conditions of this Agreement, including this Section 10.2. Such disclosures may include achievement of milestones, significant events in the Development process with respect to Licensed Products, or Commercialization activities with respect to Licensed Products.

(D) On a date to be mutually agreed by the Parties, the Parties will jointly issue a press release regarding the signing of this Agreement. Except as set forth in the preceding sentence and for disclosures permitted in accordance with Section 10.1(b), whenever either Party elects to make any public disclosure regarding milestones, significant events in the Development or Commercialization of the Licensed Products in the Field in the Territory, it will first notify the other Party of such planned press release or public announcement and provide a draft for review no less than [\*] in advance of issuing such press release or making such public announcement (or, with respect to press releases and public announcements that are required by applicable Laws, with as much advance notice as possible under the

circumstances if it is not possible to provide notice no less than [\*]. Each Party will have the right to review and approve any such planned press release or public announcement proposed by the other Party with respect to Licensed Products in the Field in the Territory, or that includes Confidential Information of the other Party; provided, however, that (A) the reviewing Party will attempt to provide such approval as soon as reasonably possible and will not unreasonably withhold such approval; (B) the reviewing Party will provide explanations of its disapproval of such press release; and (C) a Party desiring to make such public disclosure may issue such press release or public announcement without such prior review by the other Party if (1) the contents of such press release or public announcement have previously been made public other than through a breach of this Agreement by such Party, and (2) such press release or public announcement is consistent with the previously issued press release or other publicly available information; and provided, further, that the other Party will have the right to review, but not approve, any press release or public announcement that the proposing Party determines is required by applicable Laws based on the advice of counsel, which public disclosures are subject to Section 10.2. The Party reviewing a press release provided under this Section 10.2(a) will review and approve or disapprove such press release within [\*] after its receipt thereof.

(E)The principles to be observed in such disclosures will include accuracy, compliance with applicable Laws and regulatory guidance documents, reasonable sensitivity to potential negative reactions of Regulatory Authorities and the need to keep investors informed regarding the business of the Party making such public disclosure.

(F)In the event that either Party proposes to publish or present the results of Development or Commercialization carried out on the Licensed Product in the Territory, including any oral presentation or abstract that contain clinical data or pertain to results of Clinical Studies or other studies conducted in the Territory, such publication or presentation will be subject to the prior review by the JSC for patentability and protection of both Parties' Confidential Information and approval by the other Party (not to be unreasonably withheld). Each Party will provide to the JSC the opportunity to review any proposed abstracts, manuscripts or summaries of presentations that cover the results of Development or Commercialization of Licensed Products in the Territory during the Term. The JSC will review such proposed material at the next meeting of the JSC, and may issue a specific statement of concern, based upon either the need to seek patent protection or concern regarding competitive disadvantage arising from the proposal. In the event that the JSC provides such a statement of concern, the submitting Party will not submit such publication that contains such information until the other Party is given a reasonable period of time to seek patent protection for any material in such publication or presentation that it believes is patentable or to resolve any other issues, and the submitting Party will remove from such proposed publication any Confidential Information of the other Party as requested by the other Party.

## **ARTICLE XI REPRESENTATIONS AND WARRANTIES; CERTAIN COVENANTS**

Section I.85. Mutual Representations and Warranties. Each Party represents and warrants to the other Party that, as of the Effective Date and, with respect to Sutro, as of the date of the License Option Exercise Notice:

(A)Organization. It is a corporation duly organized, validly existing, and in good standing under the Laws of the jurisdiction of its organization, and has all requisite power and authority, corporate or otherwise, to execute, deliver, and perform this Agreement.

(B)Authority. It has full right, power and authority to enter into this Agreement and to perform its respective obligations under this Agreement, it has the right to grant to the other the licenses and sublicenses granted pursuant to this Agreement, and this Agreement and the performance by such Party of this Agreement do not violate such Party's charter documents, bylaws or other organizational documents.

(C)Consents. Except for any Marketing Authorizations, Regulatory Approvals, Regulatory Filings, Pricing and Reimbursement Approvals, Manufacturing approvals or similar approvals necessary for the Development, Manufacture or Commercialization of Licensed Products in the Territory, all necessary consents, approvals and authorizations of all Governmental Authorities and other Persons required to be obtained by it in connection with the execution, delivery and performance of this Agreement have been obtained.

(D)No Conflict. It is not under any obligation, contractual or otherwise, to any Person that would materially affect the diligent and complete fulfillment of obligations under this Agreement and the execution and delivery of this Agreement by such Party, and the performance of such Party's obligations under this Agreement (as contemplated as of the Effective Date) and the licenses and sublicenses to be granted by such Party pursuant to this Agreement (i) do not conflict with or violate any requirement of Laws applicable to such Party, (ii) do not conflict with or violate any order, writ, judgment, injunction, decree, determination, or award of any court or governmental agency presently in effect applicable to such Party, and (iii) do not conflict with, violate, breach or constitute a default under, or give rise to any right of termination, cancellation or acceleration of, any contractual obligations of such Party or any of its Affiliates.

(E)Enforceability. This Agreement is a legal and valid obligation binding upon it and is enforceable against it in accordance with its terms, subject to the general principles of equity and subject to bankruptcy, insolvency, moratorium, judicial principles affecting the availability of specific performance and other similar Laws affecting the enforcement of creditors' rights generally.

(F)Compliance with Laws. The Parties will, and will ensure that their respective Affiliates and Sublicensees will, comply in all material respects with all applicable Laws in exercising their rights and fulfilling their obligations under this Agreement. Without limiting the generality of the foregoing, the Parties will comply with all applicable Laws concerning bribery, money laundering, or corrupt practices or which in any manner prohibit the giving of anything of value to any official, agent, or employee of any government, political party, or public international organization, candidate for public office, health care professional, or to any officer, director, employee, or representative of any other organization specifically including the Anti-Corruption Laws in connection with the activities conducted pursuant to this Agreement. The Parties will require any contractors, subcontractors, Sublicensees, or other Persons that provide services to such Party in connection with this Agreement to comply with such Party's obligations under this Section 11.1(f).

Section I.86. Additional Representations, Warranties and Covenants of Sutro. Sutro represents and warrants as of the Effective Date and as of the date of the License Option Exercise Notice, and covenants to BioNova that:

(G)Licensed Patents. All Licensed Patents as of the Effective Date are listed in Exhibit C. Except as otherwise noted in Exhibit C, Sutro is the sole and exclusive owner of the Licensed Patents, all of which are free and clear of any claims, liens, charges or encumbrances. With respect to Licensed Patents not solely owned by Sutro, Sutro licenses such Licensed Patents in a manner that permits exclusive sublicenses as provided in this Agreement. All Licensed Patents owned by Sutro and, to Sutro's knowledge, all other Licensed Patents, have been filed and prosecuted in good faith in the patent offices in accordance with applicable Laws, and all applicable fees have been paid on or before the due date for payment. To Sutro's knowledge, all issued Licensed Patents are valid and enforceable.

(H)Licensed Know-How. To its knowledge, Sutro owns or Controls the Licensed Know-How, and has the right to grant the licenses under the Licensed Know-How to BioNova on and the terms set forth in this Agreement. To its knowledge, Sutro has the right to use and disclose (in each case, under appropriate circumstances of confidentiality) the Licensed Know-How free and clear of any claims, liens, charges or encumbrances.

(A)Licensed Technology. Sutro has not granted to any Third Party, including any academic organization or agency, any license, option or other rights to research, Develop, Manufacture, use or Commercialize the Licensed Compound or the Licensed Products in the Field in the Territory. No Third Party has any license, option or other rights or interest in or to the Licensed Technology other than the rights that are expressly reserved or contingent under this Agreement. The Licensed Technology constitutes all the Patent Rights and Know-How Controlled by Sutro or any of its Affiliates that are necessary for the Development or Commercialization, but for clarity, and notwithstanding the implication of the foregoing terms "Development" and "Commercialization", in no way related to Manufacturing, of the Licensed Compound and the Licensed Product in the Field in the Territory without infringing Patent Rights or misappropriating any Know-How Controlled by Sutro or any of its Affiliates.

(B)Licensed Marks. All Licensed Marks as of the Effective Date are listed in Exhibit B.

(C)Delivery of Documentation. True, accurate and materially complete copies of: (i) all existing material Regulatory Filings in its possession and control relating to Licensed Products, (ii) all material adverse information with respect to the safety and efficacy of the Licensed Products in Sutro's or its Affiliates' possession and control, and (iii) all material data in Sutro's or its Affiliates' possession and control, in each case ((i), (ii) and (iii)) have been provided or made available to BioNova prior to the Effective Date.

(D)Third Party Challenges. There are no claims, judgments, or settlements against, or amounts with respect thereto, made or, to Sutro's knowledge, threatened by any Person against Sutro or any of its Affiliates relating to the Licensed Patents or the Licensed Know-How. No claim or notice of proceeding has been received by Sutro or its Affiliates or, to Sutro's knowledge, threatened by any Person (i) alleging that the Licensed Patents are invalid or unenforceable, (ii) asserting the misuse of any of the



Licensed Patents, (iii) challenging Sutro's Control of the Licensed Patents (i.e., alleging that a Third Party has a right or interest in or to the Licensed Technology) or (iv) alleging misappropriation of the Know-How of any Third Party used in the Development, Manufacture or Commercialization of the Licensed Compound or Licensed Products by or on behalf of Sutro prior to the Effective Date.

(E)Non-Infringement of Third Party IP. To Sutro's knowledge, the Development, Manufacture or Commercialization of the Licensed Product, as conducted by Sutro, its Affiliates, or its or their Sublicensees prior to the Effective Date did not infringe any Patent Right in the Territory or misappropriate or otherwise violate any Know-How of any Third Party (in the case of pending Patent Rights, evaluating them as if issued). No claim of infringement of the Patent Rights in the Territory or misappropriation of the Know-How of any Third Party has been received by Sutro, or to Sutro's knowledge, threatened, against Sutro, any of its Affiliates or its or their Sublicensees with respect to the Development, Manufacture or Commercialization of Licensed Products in the Territory. To Sutro's knowledge, the Development, Manufacture or Commercialization of the Licensed Compound or Licensed Product would not infringe, if Developed, Manufactured or Commercialized as of the date hereof, any Patent Right in the Territory or misappropriate or otherwise violate any Know-How of any Third Party (in the case of pending Patent Rights, evaluating them as if issued).

(F)Absence of Litigation. There are no judgments or settlements against or owed by Sutro, its Affiliates or its or their Sublicensees, or, to Sutro's knowledge, pending litigation against Sutro, its Affiliates, or its or their Sublicensees, or litigation threatened against Sutro, its Affiliates, or its or their Sublicensees, in each case related to the Licensed Compound or Licensed Products, including any such litigation any relating to any Regulatory Filings, Regulatory Approvals, Pricing and Reimbursement Approvals, or Marketing Authorizations Controlled by Sutro, its Affiliates or its or their Sublicensees as of the Effective Date.

(G)Maintenance of Regulatory Filings, Good Laboratory and Clinical Practices. Sutro, its Affiliates, and its or their Sublicensees have generated, prepared, maintained, and retained all Regulatory Filings, Regulatory Approvals, and Marketing Authorizations in its control that are required to be maintained or retained pursuant to and in material compliance with applicable Laws, and have conducted in material compliance with applicable Laws, including GLP and GCP all Development of Licensed Products in the Field conducted prior to the Effective Date except to the extent that any material non-compliance has not had a material adverse effect, and to Sutro's knowledge of Development and the regulation of pharmaceuticals in the Territory, would not be likely to materially and adversely impact the integrity of the data or the ability of BioNova to use or reference such Regulatory Filings, Regulatory Approvals, and Marketing Authorizations in connection with the Developing, seeking, obtaining, or maintaining Regulatory Approval of, and Commercializing the Licensed Products in the Territory, and to Sutro's knowledge of Development and the regulation of pharmaceuticals in the Territory, would not be likely to cause and require any studies, tests and pre-clinical and Clinical Studies to be repeated in the Territory, in whole or in part.

(H)Confidentiality of Know-How. Sutro has taken and will continue during the Term to take precautions, consistent with its usual business practice, to preserve the confidentiality of the Licensed Know-How.

(I)Assignment of Third Party Rights: Third Party Consents.

(i)Sutro has obtained from each of its employees and agents, and from the employees and agents of its Affiliates, who are performing Development activities for the Licensed Products, rights to any and all Know-How created by such employees and agents in the course of such activities that relates to Licensed Products, such that BioNova will, by virtue of this Agreement, receive from Sutro, without payments beyond those required by ARTICLE VIII, the licenses and other rights granted to BioNova under this Agreement.

(i)Each Person who has or has had any ownership rights in or to any Licensed Patents purported to be owned solely by Sutro, has assigned and has executed an agreement assigning its entire right, title, and interest in and to such Licensed Patents to Sutro, and to Sutro's knowledge, no current officer, employee, agent, or consultant of Sutro or any of its Affiliates is in violation of any term of any assignment or other agreement, in each case, regarding the protection of the Licensed Patents.

(ii)Prior to the Effective Date, Sutro has all rights and licenses, and has obtained all consents from Third Parties with which it has a contractual relationship necessary to grant BioNova the licenses and rights Sutro purports to grant to BioNova under this Agreement other than consents which may be required pursuant to Sutro's Loan and Security Agreement dated February 2020 with Oxford Finance and Silicon Valley Bank which consents Sutro agrees to obtain and provide copies thereof to BioNova as soon as practicable after the Effective Date. In the event Sutro fails to obtain such foregoing consents, BioNova will have the right to terminate this Agreement in its entirety by written notice to Sutro and, upon such termination, Sutro will return to BioNova in full the License Option Payment within [\*] of its receipt of such written notice of termination from BioNova.

(J)Statements to Regulatory Authorities. Neither Sutro nor any of its Affiliates, nor, to Sutro's knowledge, its or their Sublicensees nor any of its or their respective officers, employees, or agents has made or will make an untrue statement of material fact or fraudulent statement to any Regulatory Authority with respect to the Development or Commercialization of Licensed Products, or failed or will fail to disclose a material fact required under applicable Laws to be disclosed to any Regulatory Authority with respect to the Development or Commercialization of Licensed Products.

(K)Compliance with Laws. To Sutro's knowledge, all of the studies, tests and pre-clinical and Clinical Studies of Licensed Products conducted prior to, or being conducted as of, the Effective Date, or that are conducted during the Term by or on behalf of Sutro have been, are being conducted, and will be conducted in all material respects in accordance with applicable Laws.

(I)No Conflict. During the Term, Sutro and its Affiliates will not grant any interest in the Licensed Technology that is inconsistent with the terms and conditions of this Agreement.

(J)No Government Funding. The inventions claimed by the Licensed Patents and any other Patent Rights with respect to the Licensed Compound or Licensed Product were not conceived, reduced to practice, discovered, developed or otherwise made in connection with any research activities funded, in whole or in part, by any grants, funds, or other money received from any Governmental Authority, and no Governmental Authority or academic institution has any right to, ownership of

(including any “step-in” or “march-in” rights with respect to), or right to royalties for, or to impose any restriction on the assignment, transfer, grant of licenses or other disposal of the Licensed Technology, or to impose any requirement or restriction on the use of the Licensed Compound or Licensed Product as contemplated herein, in each case.

Section I.87. Additional Representations, Warranties and Covenants of BioNova. BioNova represents and warrants as of the Effective Date and as of the date of the License Option Exercise Notice, and covenants to Sutro that:

(K) No Claims. There are no claims, judgments, settlements, litigations, suits, actions, disputes, arbitration, judicial, or legal, administrative, or other proceedings or governmental investigations pending or, to BioNova’s knowledge, threatened against BioNova or its Affiliates which would reasonably be expected to adversely affect or restrict the ability of BioNova and its Affiliates to consummate and perform the transactions and activities contemplated under this Agreement.

(L) Maintenance of Regulatory Filings, Good Laboratory and Clinical Practices. BioNova, its Affiliates, and its or their Sublicensees will generate, prepare, maintain, and retain all Regulatory Filings, Regulatory Approvals, and Marketing Authorizations in its Control that are required to be maintained or retained pursuant to and in material compliance with applicable Laws, and will conduct in material compliance with applicable Laws, including GLP and GCP, all Development activities for the Licensed Product in the Territory.

(M) Assignment of Rights. BioNova will obtain from each of its employees and agents, and from the employees and agents of its Affiliates, who will be performing Development activities for the Licensed Products, rights to any and all Know-How created by such employees and agents in the course of such activities that relates to Licensed Products, such that Sutro will, by virtue of this Agreement, receive from BioNova, without any payment or other consideration, the licenses and other rights granted to Sutro under this Agreement.

(N) Compliance with Laws. All of the studies, tests and pre-clinical and Clinical Studies of drug products (other than the Licensed Products) conducted by BioNova prior to, or being conducted as of, the Effective Date, have been conducted, to BioNova’s knowledge, in all material respects in accordance with applicable Laws. All of the studies, tests and pre-clinical and Clinical Studies of Licensed Products to be conducted by BioNova under this Agreement will be conducted in all material respects in accordance with applicable Laws.

(O) No Conflict. During the Term, BioNova and its Affiliates will not grant any interest in the BioNova Technology that is inconsistent with the terms and conditions of this Agreement and the licenses and rights of Sutro hereunder.

(P) Expertise and Experience. BioNova has or will acquire the requisite expertise and experience to perform the Development, obtain Regulatory Approval for, and Commercialize the Licensed Products as contemplated by this Agreement.

Section I.88. No Debarment. Each Party represents and warrants that neither it nor any of its or its Affiliates’ employees or agents performing under this Agreement has ever been, or is currently: (a)

debarred under 21 U.S.C. § 335a or by any Regulatory Authority; (b) excluded, debarred, suspended, or otherwise ineligible to participate in federal health care programs or in federal procurement or non-procurement programs; (c) listed on the FDA's Disqualified and Restricted Lists for clinical investigators; or (d) convicted of a criminal offense that falls within the scope of 42 U.S.C. § 1320a-7(a), but has not yet been excluded, debarred, suspended, or otherwise declared ineligible. Each Party further covenants that if, during the Term of this Agreement, it becomes aware that it or any of its or its Affiliates' employees or agents (including any Third Party subcontractor or Sublicensee of BioNova) performing under this Agreement is the subject of any investigation or proceeding that could lead to that Party becoming a debarred entity or individual, an excluded entity or individual or a convicted entity or individual, such Party will promptly notify the other Party.

Section I.89. Compliance.

(Q) Each Party covenants that: (a) in the performance of its obligations under this Agreement, such Party shall comply and shall cause its and its Affiliates' employees and contractors to comply with all applicable Laws, including all export control, and shall not cause such other Party's indemnitees (as defined in Section 12.1 and Section 12.2) to be in violation of any applicable Laws or otherwise cause any reputational harm to such other Party.

(R) Each Party covenants that in the performance of its obligations under this Agreement, such Party shall comply and shall cause its and its Affiliates' employees and contractors to comply with, all Anti-Corruption Laws. Such Party and its and its Affiliates' employees and contractors shall not, in connection with the performance of their respective obligations under this Agreement, directly or indirectly through Third Parties, pay, promise or offer to pay, or authorize the payment of, any money or give any promise or offer to give, or authorize the giving of anything of value to any Governmental Authority or representative thereof or other person for the purpose of obtaining or retaining business for or with, or directing business to, any person, including either Party, in any manner that would be in breach of any Anti-Corruption Laws.

Section I.90. No Other Warranties. EXCEPT AS EXPRESSLY STATED IN SECTION 11.1, SECTION 11.2, SECTION 11.3, OR SECTION 11.4, NEITHER PARTY MAKES ANY REPRESENTATIONS OR EXTENDS ANY WARRANTIES OF ANY KIND, EITHER EXPRESS OR IMPLIED, STATUTORY OR OTHERWISE, INCLUDING WARRANTIES OF TITLE, NON-INFRINGEMENT OR NON-MISAPPROPRIATION OF THIRD PARTY INTELLECTUAL PROPERTY WITH RESPECT TO THE LICENSED COMPOUND, THE LICENSED PRODUCT, VALIDITY, ENFORCEABILITY, MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE.

**ARTICLE XII**  
**INDEMNIFICATION; DAMAGES**

Section I.91. Indemnification by Sutro. Sutro will defend, indemnify and hold harmless BioNova, its Affiliates and their respective directors, officers, employees and agents (each, a "BioNova Indemnified Party"), from, against and in respect of any and all Third Party Losses incurred or suffered by any BioNova Indemnified Party to the extent resulting from: (a) any breach of any representation or

warranty made by Sutro in this Agreement, or any breach by Sutro of any obligation, covenant or agreement in this Agreement; (b) the gross negligence or intentional misconduct of, or violation of Laws by, Sutro or any of its Affiliates, its or their licensees (other than BioNova) or Sublicensees, or contractors, or any of their respective directors, officers, employees and agents, in performing Sutro's obligations or exercising Sutro's rights under this Agreement; (c) activities conducted by or on behalf of Sutro, its Affiliates or its or their licensees (other than BioNova) or Sublicensees, or contractors related to the Development, Manufacture or Commercialization of Licensed Products anywhere in the world prior to the Effective Date; and (d) the Development, Manufacture or Commercialization of the Licensed Products by or on behalf of Sutro, any of its Affiliates, or its or their licensees (other than BioNova) or Sublicensees, or contractors (i) outside the Territory, (ii) outside the Field in the Territory, or (iii) in the Territory following any termination of this Agreement; provided, however, that Sutro's obligations pursuant to this Section 12.1 will not apply to the extent such Third Party Losses result from Third Party Losses for which BioNova has an obligation to indemnify Sutro pursuant to Section 12.2.

Section I.92. Indemnification by BioNova. BioNova will defend, indemnify and hold harmless Sutro, its Affiliates, and their respective directors, officers, employees and agents (each, a "Sutro Indemnified Party") from, against and in respect of any and all Third Party Losses incurred or suffered by any Sutro Indemnified Party to the extent resulting from: (a) any breach of any representation or warranty made by BioNova in this Agreement, or any breach by BioNova of any covenant or agreement in this Agreement, (b) the gross negligence or intentional misconduct of, or violation of Laws by, BioNova, any of its Affiliates, or its or their Sublicensees or contractors, or any of their respective directors, officers, employees and agents, in performing BioNova's obligations or exercising BioNova's rights under this Agreement, (c) the Development, Manufacture or Commercialization of the Licensed Product by or on behalf of BioNova, its Affiliates, or its or their Sublicensees (other than Sutro) or contractors, or (d) activities of the Parties conducted under Section 4.6 and any consequence howsoever arising therefrom; provided, however, that (i) BioNova's obligations pursuant to subsections (a), (b) and (c) of this Section 12.2 will not apply to the extent such Third Party Losses result from Third Party Losses for which Sutro has an obligation to indemnify BioNova pursuant to Section 12.1, and (ii) BioNova's obligations pursuant to subsection (d) of this Section 12.2 will not apply to the extent such Third Party Losses result from Third Party Losses resulting from the intentional misconduct or gross negligence of any Sutro Indemnified Party.

Section I.93. Claims for Indemnification.

(A) Notice. An Indemnified Party entitled to indemnification under Section 12.1 or Section 12.2 will give prompt written notification to the Indemnifying Party from whom indemnification is sought of the commencement of any Action by a Third Party for which indemnification may be sought (a "Third Party Claim") or, if earlier, upon the assertion of such Third Party Claim by a Third Party; provided, however, that failure by an Indemnified Party to give notice of a Third Party Claim as provided in this Section 12.3(a) will not relieve the Indemnifying Party of its indemnification obligation under this Agreement, except and only to the extent that such Indemnifying Party is materially prejudiced as a result of such failure to give notice.

(B) Defense. Within [\*] after delivery of a notice of any Third Party Claim in accordance with Section 12.3(a), the Indemnifying Party may, upon written notice thereof to the

Indemnified Party, assume control of the defense of such Third Party Claim with counsel reasonably satisfactory to the Indemnified Party. If the Indemnifying Party does not assume control of such defense, the Indemnified Party may control such defense (with counsel reasonably selected by the Indemnified Party and approved by the Indemnifying Party, such approval not to be unreasonably withheld). The Party not controlling such defense may participate therein at its own expense.

(C)Cooperation. The Party controlling the defense of any Third Party Claim will keep the other Party advised of the status and material developments of such Third Party Claim and the defense thereof and will reasonably consider recommendations made by the other Party with respect thereto. The other Party will reasonably cooperate with the Party controlling such defense and its Affiliates and agents in defense of the Third Party Claim, with all out-of-pocket costs of such cooperation to be borne by the Party controlling such defense.

(D)Settlement. The Indemnified Party will not agree to any settlement of such Third Party Claim without the prior written consent of the Indemnifying Party, which consent will not be unreasonably withheld. The Indemnifying Party will not, without the prior written consent of the Indemnified Party, which will not be unreasonably withheld (unless such compromise or settlement involves (i) any admission of legal wrongdoing by the Indemnified Party, (ii) any payment by the Indemnified Party that is not indemnified under this Agreement, or (iii) the imposition of any equitable relief against the Indemnified Party (in which case, (i) through (iii), the Indemnified Party may withhold its consent to such settlement in its sole discretion)), agree to any settlement of such Third Party Claim or consent to any judgment in respect thereof that does not include a complete and unconditional release of the Indemnified Party from all liability with respect thereto or that imposes any liability or obligation on the Indemnified Party (other than a monetary obligation on the Indemnifying Party).

(E)Mitigation of Loss. Each Indemnified Party will take and will procure that its Affiliates and its or their Sublicensees take all such reasonable steps and actions as are necessary or as the Indemnifying Party may reasonably require in order to mitigate any Third Party Claims (or potential losses or damages) under this ARTICLE XII. Nothing in this Agreement will or will be deemed to relieve any Party of any common law or other duty to mitigate any losses incurred by it.

Section I.94.Insurance. Each Party, at its own expense, will maintain liability insurance (or self-insure) with respect to its activities under this Agreement in an amount consistent with industry standards in each Party's respective territory. Each Party will provide a certificate of insurance (or evidence of self-insurance) evidencing such coverage to the other Party upon request. Without limiting the foregoing, during the Term and thereafter for the period of time required below, each Party will maintain on an ongoing basis comprehensive general liability insurance policies inclusive of Products Liability and/or Clinical Trials insurance which are consistent with normal business practices of prudent companies similarly situated in such Party's territory. Not later than [\*] following receipt of written request from a Party, the other Party will provide to the requesting Party a certificate of insurance evidencing such insurance policies. Each Party will maintain such insurance or self-insurance coverage without interruption during the Term and for a period of [\*] thereafter, and, if applicable, will provide certificates or letters evidencing such insurance coverage without interruption as reasonably requested during the period of time for which such coverage must be maintained. Each Party will be provided at least [\*] prior written notice of any cancellation or material decrease in the other Party's insurance coverage limits

described above. Notwithstanding the foregoing, either Party's failure to maintain adequate insurance will not relieve that Party of its obligations set forth in this Agreement.

### **ARTICLE XIII LIMITATION OF LIABILITY**

Section I.95. No Consequential or Punitive Damages. EXCEPT AS SET FORTH IN Section 13.2, NEITHER PARTY NOR ANY OF ITS AFFILIATES OR AFFILIATED ENTITIES WILL BE LIABLE FOR INDIRECT, INCIDENTAL, CONSEQUENTIAL, SPECIAL, EXEMPLARY, OR PUNITIVE DAMAGES ARISING OUT OF THIS AGREEMENT OR THE EXERCISE OF ITS RIGHTS OR THE PERFORMANCE OF ITS OBLIGATIONS HEREUNDER, INCLUDING ANY LOST PROFITS OR LOST OPPORTUNITY ARISING OUT OF THIS AGREEMENT, IN EACH CASE HOWEVER CAUSED AND ON ANY THEORY OF LIABILITY, WHETHER IN CONTRACT, TORT, NEGLIGENCE, BREACH OF STATUTORY DUTY OR OTHERWISE, REGARDLESS OF ANY NOTICE OF SUCH DAMAGES.

Section I.96. EXCLUSION FROM LIABILITY LIMITATION. THE LIMITATIONS AND DISCLAIMER SET FORTH IN Section 13.1 WILL NOT APPLY TO A CLAIM: (A) FOR FRAUD, GROSS NEGLIGENCE OR WILLFUL MISCONDUCT; (B) FOR A BREACH OF ARTICLE X; (C) FOR A BREACH OF Section 3.9; OR (D) FOR INDEMNIFIABLE LOSSES PURSUANT TO Section 12.1 OR Section 12.2. AS APPLICABLE.

### **ARTICLE XIV TERM AND TERMINATION**

Section I.97. Term. Subject to Section 2.5 and Section 2.6, unless terminated earlier in accordance with this ARTICLE XIV, this Agreement will become effective as of the Effective Date and will continue in full force on a Region-by-Region basis until the expiry of the Royalty Term in each Region in the Territory for all Licensed Products (the "Term").

Section I.98. Paid-Up License Upon End of Royalty Term. On a Licensed Product-by-Licensed Product and Region-by-Region basis, upon the expiration of the Royalty Term for a given Licensed Product in a given Region in the Territory, the licenses and rights of reference granted to BioNova pursuant to Section 3.1 and Section 3.4 will become perpetual, irrevocable, exclusive, sublicensable, transferrable, fully paid-up, and royalty free with respect to such Licensed Product in such Region. Upon the expiration of the Royalty Term of the last Licensed Product in the last Region in the Territory, the licenses granted to Sutro pursuant to Section 3.5 will become perpetual and irrevocable in and outside the Territory.

Section I.99. Early Termination.

(A) Termination for Material Breach. Upon (i) any material breach of this Agreement by Sutro or (ii) any material breach of this Agreement by BioNova (the Party so allegedly breaching being the "Breaching Party"), the other Party (the "Non-Breaching Party") will have the right, but not the obligation, to terminate this Agreement in its entirety by [\*] written notice to the Breaching Party, and if such breach is curable, such breach has not been cured by the Breaching Party within [\*] of such notice.

The notice will, in each case (A) expressly reference this Section 14.3(a), (B) reasonably describe the alleged breach which is the basis of such termination, and (C) clearly state the Non-Breaching Party's intent to terminate this Agreement if the alleged breach is not cured within the applicable cure period. Notwithstanding the foregoing, (1) if such material breach, by its nature, is curable, but is not reasonably curable within the applicable cure period, then such cure period will be extended if the Breaching Party provides a written plan for curing such breach to the Non-Breaching Party and uses Commercially Reasonable Efforts to cure such breach in accordance with such written plan; and (2) if the Breaching Party disputes (x) whether it has materially breached this Agreement, (y) whether such material breach is reasonably curable within the applicable cure period, or (z) whether it has cured such material breach within the applicable cure period, the dispute will be resolved pursuant to Section 14.4(k), and this Agreement may not be terminated during the pendency of such dispute resolution procedure. The termination will become effective at the end of the notice period unless the Breaching Party cures such breach during such notice period.

(B)Termination by BioNova for Convenience. BioNova may,

(i)during the License Option Period, upon thirty (30) days' prior written notice to Sutro, terminate this Agreement in its entirety for convenience without cause; and

(ii)after exercising the License Option, upon ninety (90) days' prior written notice to Sutro, terminate this Agreement in its entirety or on a Licensed Product-by-Licensed Product or Region-by-Region basis for convenience without cause.

(C)Termination for Bankruptcy. This Agreement may be terminated, to the extent permitted by applicable Laws, by either Party upon the filing or institution of bankruptcy, reorganization, liquidation or receivership proceedings, or upon an assignment of a substantial portion of the assets for the benefit of creditors by the other Party; provided, however, that in the case of any involuntary bankruptcy, reorganization, liquidation or receivership proceeding such right to terminate will only become effective if the Party subject to such proceeding consents to the involuntary bankruptcy or such proceeding is not dismissed within [\*] after the filing thereof.

(D)Termination for Patent Challenge. If BioNova or its Affiliates or its or their Sublicensees, individually or in association with any other Person, commences a legal action challenging the validity, enforceability or scope of any Patent Rights within the Licensed Technology (a "Patent Challenge"), then Sutro shall be entitled to terminate this Agreement in its entirety by providing written notice to BioNova, which termination shall take effect on the date of such notice; provided that this Section 14.3(d) will not apply to such action that (i) is first made by BioNova or its Affiliates or its or their Sublicensees in defense of a claim of patent infringement brought by Sutro under the applicable Patent Rights or any Patent Challenge, (ii) was brought by an acquirer of BioNova or its Affiliates or its or their Sublicensees prior to the effective date of a Change of Control involving such Person, or (iii) is brought by any non-Affiliate Sublicensee if BioNova or its Affiliate (A) causes such Patent Challenge to be terminated or dismissed (or in the case of ex-parte proceedings, multi-party proceedings, or other Patent Challenges in which the challenging party does not have the power to unilaterally cause the Patent Challenge to be withdrawn, causes such Sublicensee to withdraw as a party from such Patent Challenge and to cease actively assisting any other party to such Patent Challenge), or (B) terminates such



Sublicensee's sublicense to the Patent Rights being challenged by the Sublicensee, in each case, within [\*] after Sutro's notice to BioNova under this [Section 14.3\(d\)](#).

(E)[Termination for Breach of Anti-Bribery Laws](#). Subject to the provisions of this [Section 14.3\(e\)](#), if a Party (the "[Investigating Party](#)") believes in good faith, based on advice of counsel, that the other party (the "[Investigated Party](#)") is in material breach of the anti-bribery or anti-corruption provisions of [Section 11.1\(f\)](#) or [Section 11.5](#) and that such material breach would reasonably be expected to result in the Investigating Party or any of its Affiliates incurring material Third Party Losses, then the Investigating Party may provide written notice to the Investigated Party specifically referencing such concerns and this [Section 14.3\(e\)](#) (an "[ABAC Notice](#)"). Upon receipt of such ABAC Notice, the Investigated Party will immediately and fully cooperate with the Investigating Party and its Affiliates in the investigation of the alleged breach (the "[Investigation](#)"), including by providing the Investigating Party and its Affiliates access to (i) any and all employees, agents or representatives of the Investigated Party or its Affiliates that are relevant to the Investigation, and (ii) all documents and other materials requested by the Investigating Party or any of its Affiliates, in each case ((i) and (ii)), to the extent reasonably necessary for the Investigating Party to conduct such Investigation. The Investigating Party and the Investigated Party will use Commercially Reasonable Efforts to conclude such Investigation as promptly as possible, but in no event later than [\*] following the Investigated Party's receipt of the applicable ABAC Notice (or such longer period as the Parties may mutually agree in writing) (the "[Investigation Period](#)"). During the Investigation Period, the Investigating Party may also request that the Investigated Party perform reasonable curative actions in respect of such alleged material breach. If by the end of such Investigation Period, the Investigating Party concludes that such material breach would reasonably be expected to result in the Investigating Party incurring material Third Party Losses and such breach has not been cured by the Investigated Party by the end of such Investigation Period, then the Investigating Party may terminate this Agreement with immediate effect upon written notice to the Investigated Party, with respect to the country or region to which such material breach relates. If prior to the end of the Investigation Period the Investigated Party has cured such material breach (subject to the remainder of this [Section 14.3\(e\)](#) with respect to any dispute related thereto), then the Investigated Party shall no longer have the right to terminate this Agreement for such material breach. For purposes of this [Section 14.3\(e\)](#), the Investigated Party will be deemed to have cured such material breach if the Investigated Party has otherwise identified and terminated its relationship with the individual or individuals responsible for such material breach.

#### Section I.100. [Effects of Termination](#).

(F)[Effects of Termination Generally](#). Upon termination of this Agreement in its entirety pursuant to [Section 14.3](#), the JSC will cease to exist, the Parties' rights, licenses and obligations under this Agreement will terminate and neither Party will have any further rights or obligations under this Agreement from and after the effective date of termination, except as set forth in this [Section 14.4](#); [provided, however](#), that, if this Agreement is terminated with respect to a particular Licensed Product or Region only, then such rights and obligations will terminate only to the extent they relate solely to the terminated Licensed Product or Region and the JSC will continue with respect to non-terminated Licensed Products and Regions.

(G)License Grant to Sutro. Except in the case BioNova terminates this Agreement pursuant to Section 14.3(a) or Section 14.3(c), in which case, the licenses granted to Sutro under Section 3.5 will terminate upon the effectiveness of such termination, in case of any other termination or expiration of this Agreement, the licenses granted to Sutro under Section 3.5 will continue following the effective date of termination and for clarity only, is hereby confirmed to be perpetual and irrevocable in all cases and eventualities.

(H)Accrued Obligations. Expiration or termination of this Agreement for any reason will not release either Party from any obligation or liability which, on the effective date of such expiration or termination, has already accrued to the other Party or which is attributable to a period prior to such expiration or termination.

(I)Survival. This Section 14.4, the provisions set forth in the following Sections, as well as, to the extent applicable, any other Sections or defined terms referred to in such Sections or Articles or necessary to give them effect, will survive any expiration or termination of this Agreement in its entirety: Section 3.2(f), Section 5.3 (for the [\*] period specified therein), Section 9.1, Section 9.2 (with respect to Joint Patents), Section 9.3 (with respect to Joint Patents), Section 9.4 (solely with respect to claimed infringement prior to the date of termination), Section 11.2(k)(iii), Section 11.6, Section 14.2 (only upon the expiration but not earlier termination of this Agreement) and ARTICLE X (for the [\*] period specified therein), ARTICLE VIII (with respect to payments payable and Net Sales realized prior to the termination effective date of this Agreement), ARTICLE XII (for Section 12.4, for the [\*] period specified therein), ARTICLE XIII, ARTICLE XV and ARTICLE XVI. Furthermore, any other provisions required to interpret the Parties' rights and obligations under this Agreement, including applicable definitions in ARTICLE I, will survive to the extent required. Except as otherwise expressly provided in this Agreement (including this Section 14.4), any licenses granted under this Agreement, will terminate upon expiration or termination of this Agreement in its entirety or solely with respect to the terminated Region, as the case may be, for any reason.

(J)Ongoing Clinical Study. If at the time of such termination, any Clinical Studies for the Licensed Products are being conducted by or on behalf of BioNova, then, at Sutro's election on a Clinical Study-by-Clinical Study basis: (i) BioNova will, and will cause its Affiliates and its or their Sublicensees to, (A) continue to conduct such Clinical Study for another period of time as determined by Sutro after the effective date of such termination at Sutro's cost, and (B) after such period, to (y) fully cooperate with Sutro to transfer the conduct of all such Clinical Study to Sutro or its designee or (z) continue to conduct such Clinical Studies, at Sutro's cost, for so long as necessary to enable such transfer to be completed without interruption of any such Clinical Studies, and (C) Sutro will assume any and all liability and costs for such Clinical Studies after the effective date of such termination, and (ii) BioNova will, and will cause its Affiliates and its or their Sublicensees to, at Sutro's cost (unless such termination is by Sutro pursuant to Section 14.3(a)), orderly wind down the conduct of any such Clinical Study which is not assumed by Sutro under clause (i).

(K)Inventory.

(i)Sell-Off Period. BioNova will have the right, for a period of [\*] following termination of this Agreement in any Region, to sell or otherwise dispose of any Licensed Products in any

terminated Regions, as applicable, on hand at the time of such termination or in the process of Manufacturing (the “Sell-Off Period”).

(ii)Sutro Buy-Back. Upon expiration of any Sell-Off Period in any Region, Sutro will have the right to purchase all of BioNova’s and its Affiliates’ remaining inventory of Licensed Products held as of the effective date of expiration of such Sell-Off Period at a price equal to (A) BioNova’s actual invoiced cost of such Licensed Product supplied by Sutro; or (B) one hundred and five percent (105%) of BioNova’s actual invoiced cost of such Licensed Product from its CMO or supplier (other than Sutro).

(L)Transfer of Regulatory Filings and Regulatory Approvals. Following the effectiveness of any termination of this Agreement pursuant to Section 14.3, as promptly as practicable after Sutro’s written request, BioNova will, to the extent permitted under applicable Laws and not commercially infeasible, and at Sutro’s sole cost and expense (unless the applicable termination giving rise to Sutro’s rights under this Section 14.4(g) was for BioNova’s material breach pursuant to Section 14.3(a), in which case such transfer will be at BioNova’s sole cost and expense), assign and transfer to Sutro all Regulatory Filings, Regulatory Approvals, Pricing and Reimbursement Approvals and Marketing Authorizations for Licensed Products that are held by or owned by BioNova or its Affiliates or its or their Sublicensees as of the effective date of termination, with respect to the terminated Region, as the case may be, and will take such actions and execute such other instruments, assignments and documents as may be necessary to effect the transfer of rights under such Regulatory Filings, Regulatory Approvals, Pricing and Reimbursement Approvals and Marketing Authorizations to Sutro. If applicable Laws or relevant Regulatory Authorities prevent or delay the transfer of ownership of any such Regulatory Filing, Regulatory Approvals, Pricing and Reimbursement Approvals and Marketing Authorizations to Sutro or if it is commercially infeasible for BioNova to do so, then BioNova will grant, and hereby does grant, to Sutro, its Affiliates, Sublicensees and licensees (other than BioNova) an exclusive and irrevocable right of access and right of reference to such Regulatory Filing, Regulatory Approvals, Pricing and Reimbursement Approvals and Marketing Authorizations for Licensed Products in the Field in the Territory or the terminated Region, as the case may be, and will reasonably cooperate with Sutro, at Sutro’s expense (unless the applicable termination giving rise to Sutro’s rights under this Section 14.4(g) was for BioNova’s material breach pursuant to Section 14.3(a), in which case such transfer will be at BioNova’s sole cost and expense), to make the benefits of such Regulatory Filings, Regulatory Approvals, Pricing and Reimbursement Approvals and Marketing Authorizations available to Sutro or its designee(s).

(M)Return of Confidential Information. Within [\*] after the effective date of termination (but not expiration) of this Agreement in its entirety, each Party will, and will cause its Affiliates to, (i) destroy all tangible items solely comprising, bearing or containing any Confidential Information of the other Party that are in such first Party’s or its Affiliates’ possession or Control, and provide written certification of such destruction, or (ii) prepare such tangible items of the other Party’s Confidential Information for shipment to such other Party, as such other Party may direct, at the first Party’s expense; provided, however, that, in any event, (A) each Party may retain copies of the Confidential Information of the other Party to the extent necessary to perform its obligations or exercise its rights that survive expiration or termination of this Agreement; and (B) each Party may retain one copy of the Confidential Information of the other Party for its legal archives.

(N)Rights in Bankruptcy. The Parties acknowledge that this Agreement constitutes an executory contract under Section 365 of the Code for the license of “intellectual property” as defined under Section 101 of the Code and constitutes a license of “intellectual property” for purposes of any similar laws in any other country. The Parties further acknowledge that BioNova, as licensee of such rights under this Agreement, will retain and may fully exercise all of its protections, rights and elections under the Code, including, but not limited to, Section 365(n) of the Code, and any similar laws in any other country. In the event of the commencement of a bankruptcy proceeding by or against Sutro under the Code and any similar laws in any other country, BioNova will be entitled to a complete duplicate of (or complete access to, as appropriate) any such intellectual property and all embodiments of such intellectual property, and the same, if not already in its possession, will be promptly delivered to it (a) upon any such commencement of a bankruptcy proceeding upon its written request therefor, unless Sutro elects to continue to perform all of its obligations under this Agreement, or (b) if not delivered under (a) above, following the rejection of this Agreement by or on behalf of Sutro upon written request therefor by BioNova. All rights, powers and remedies of BioNova provided for in this Section 14.4(i) are in addition to and not in substitution for any and all other rights, powers and remedies now or hereafter existing at law or in equity (including, without limitation, under the Code and any similar laws in any other country).

(O)Cooperation. Each Party will cause its Affiliates, and its or their licensees or Sublicensees (for Sutro, other than BioNova) and contractors to comply with the obligations in this Section 14.4.

(P)Trademark(s) in Territory. BioNova shall assign and transfer to Sutro all of its rights, including trademark rights and goodwill, in and to each of the Trademark(s) used in association with the marketing of the Licensed Product in the Territory.

## **ARTICLE XV DISPUTE RESOLUTION**

Section I.101. Dispute Resolution; Escalation. The Parties recognize that disputes as to certain matters arising out of or in connection with this Agreement may arise from time to time. It is the objective of the Parties to establish procedures to facilitate the resolution of disputes arising out of or in connection with this Agreement in an expedited manner by mutual cooperation. To accomplish this objective, any and all disputes between the Parties arising out of or in connection with this Agreement will first be referred to the JSC for discussion. Should the Parties, following discussion of the matter at a duly called meeting of the JSC, within [\*] after the date on which the matter is referred to the JSC for discussion, are still unable to resolve such matter, then either Party may refer such matter to the Senior Officers for resolution and the Senior Officers will attempt to resolve the matter in good faith. If the Senior Officers fail to resolve such matter within [\*] after the date on which the matter is referred to the Senior Officers (unless a longer period is agreed to by the Parties), then, either Party may submit the dispute for final resolution by binding arbitration in accordance with Section 15.2.

Section I.102. Arbitration. Except as set forth in this Section 15.2, any dispute, difference, controversy or claim arising in connection with or related or incidental to, or question occurring under, this Agreement or the subject matter hereof that cannot be resolved pursuant to Section 15.1, will be referred to and finally resolved by arbitration in accordance with this Section 15.2. A Party may submit

such dispute to arbitration at Singapore International Arbitration Centre (“SIAC”) by notifying the other Party, in writing, of such dispute. Within [\*] after receipt of such notice, the Parties will each designate in writing an arbitrator to resolve the dispute. Both of the designated arbitrators will elect a third arbitrator; provided, however, that if the designated arbitrators cannot agree on a third arbitrator within [\*] after both arbitrators have been designated, the third arbitrator will be selected by the SIAC. The arbitrators will be a lawyer with biotechnology and/or pharmaceutical industry legal experience, and will not be an Affiliate, employee, consultant, officer, director or stockholder of any Party. The arbitration will be conducted in Singapore in accordance with the Arbitration Rules of the Singapore International Arbitration Centre (“SIAC Rules”) for the time being in force, which rules are deemed to be incorporated by reference in this clause, except to the extent such rules are inconsistent with this Section 15.2, in which case this Section 15.2 will control. All arbitration proceedings will be conducted in the English language. The arbitrators will consider grants of equitable relief and orders for specific performance as co-equal remedies along with awards of monetary damages. The arbitrators will have no authority to award punitive damages. The allocation of expenses of the arbitration, including reasonable attorney’s fees, will be determined by the arbitrators, or, in the absence of such determination, each Party will pay its own expenses. The Parties hereby agree that the arbitrators have authority to issue rulings and orders regarding all procedural and evidentiary matters that the arbitrators deem reasonable and necessary with or without petition therefore by the Parties as well as the final ruling and judgment. All rulings by the arbitrators will be final. Notwithstanding any contrary provision of this Agreement, any Party may seek equitable measures of protection in the form of attachment of assets or injunctive relief (including specific performance and injunctive relief) in any matter relating to the proprietary rights and interests of either Party from any court of competent jurisdiction, pending a decision by the arbitral tribunal in accordance with this Section 15.2. The Parties hereby exclude any right of appeal to any court on the merits of such matter. The provisions of this Section 15.2 may be enforced and judgment on the award (including equitable remedies) granted in any arbitration hereunder may be entered in any court having jurisdiction over the award or any of the Parties or any of their respective assets. Except to the extent necessary to confirm an award or as may be required by Laws, neither a Party nor an arbitrator may disclose the existence, content, or results of an arbitration without the prior written consent of both Parties. The Parties agree that, in the event of a dispute over the nature or quality of performance under this Agreement or a matter under Section 14.3(e), neither Party may terminate this Agreement until final resolution of the dispute through arbitration or other judicial determination. Nothing in this Section 15.2 will preclude either Party from seeking interim or provisional relief from a court of competent jurisdiction, including a temporary restraining order, preliminary injunction or other interim equitable relief, concerning a dispute either prior to or during any arbitration if necessary to protect the interests of such Party or to preserve the status quo pending the arbitration proceeding. Notwithstanding the Parties’ agreement to arbitrate, unless the Parties agree in writing in any particular case, claims and disputes between the Parties relating to or arising out of, or for which resolution depends in whole or in part on a determination of the interpretation, scope, validity, enforceability or infringement of, Patent Rights or of any Trademark rights relating to any Licensed Products, or misappropriation of any Know-How, will not be subject to arbitration under this Agreement, and the Parties may pursue whatever rights and remedies may be available to them under law or equity, including litigation in a court of competent jurisdiction, with respect to such claims and disputes.

Section I.103. Jury Waiver. EACH PARTY, TO THE EXTENT PERMITTED BY LAW, KNOWINGLY, VOLUNTARILY, AND INTENTIONALLY WAIVES ITS RIGHT TO A TRIAL BY JURY IN ANY ACTION OR OTHER LEGAL PROCEEDING ARISING OUT OF OR RELATING TO THIS AGREEMENT AND THE TRANSACTIONS IT CONTEMPLATES TO ARBITRATE AS SET FORTH IN Section 15.2. THIS WAIVER APPLIES TO ANY ACTION OR LEGAL PROCEEDING, WHETHER SOUNDING IN CONTRACT, TORT OR OTHERWISE.

## ARTICLE XVI MISCELLANEOUS

### Section I.104. Assignment; Successors.

(A) Assignment. This Agreement and the rights and obligations of each Party under this Agreement will not be assignable, delegable, transferable, pledged or otherwise disposed of by either Party without the prior written consent of the other Party; provided, however, that either Party may assign or transfer this Agreement together with all of its rights and obligations hereunder, without such consent (but with written notice to the other Party), (i) to an Affiliate or (ii) to a successor in interest in connection with the transfer or sale of all or substantially all of its business or assets to which this Agreement relates, or in the event of its merger or consolidation, reorganization or similar transaction, subject to the assignee agreeing in writing to be bound by the terms and conditions of this Agreement. Any assignment in violation of this Section 16.1(a) will be null and void.

(B) Successors. Any permitted assignment of the rights and obligations of a Party under this Agreement will be binding on, and inure to the benefit of and be enforceable by and against, the successors and permitted assigns of the assigning Party. The permitted assignee or transferee will assume all obligations of its assignor or transferor under this Agreement. Any assignment or attempted assignment by either Party in violation of the terms of this Section 16.1(b) will be null, void and of no legal effect.

Section I.105. Choice of Laws. This Agreement will be governed by and interpreted under the Laws of the State of New York, without regard to the conflicts of law principles thereof. Any dispute, controversy, claim or difference of any kind whatsoever arising out of or in connection with this Agreement will be resolved exclusively in accordance with Section 15.2; provided, however, that all questions concerning (a) inventorship of Patent Rights under this Agreement will be determined in accordance with Section 9.1 and (b) the construction or effect of Patent Rights will be determined in accordance with the Laws of the country, Region or other jurisdiction in which the particular patent within such Patent Rights has been filed or granted, as the case may be. Any communication or proceedings resulting from disputes under this Agreement will be in the English language. The Parties agree to exclude the application to this Agreement of the United Nations Conventions on Contracts for the International Sale of Goods (1980).

Section I.106. Notices. Any notice or report required or permitted to be given or made under this Agreement by one Party to the other will be in writing and will be deemed to have been delivered (a) upon personal delivery (upon written confirmation of receipt), (b) when received by the addressee, if sent by a reputable internationally recognized overnight courier that maintains records of delivery, or

registered or certified mail, postage prepaid, return receipt requested, provided in each case (a) and (b), the Party giving the notice accompanies such notice by an email of the same content to the other Party. This Section 16.3 is not intended to govern the day-to-day business communications necessary between the Parties in performing their obligations under the terms of this Agreement.

If to Sutro:

SUTRO Biopharma, Inc.  
111 Oyster Point Boulevard  
South San Francisco, CA 94080  
Attention: General Counsel  
Email: [\*]

If to BioNova:

BioNova Pharmaceuticals Ltd.  
2889 Jinke Road, Chamime Plaza  
Building B, 9F, Suite 905  
Shanghai 201203, China  
Attention: Chief Executive Officer  
Email: [\*]

Section I.107. Severability. In the event that one or more provisions of this Agreement is held invalid, illegal or unenforceable in any respect, then such provision will not render any other provision of this Agreement invalid or unenforceable, and all other provisions will remain in full force and effect and will be enforceable, unless the provisions that have been found to be invalid or unenforceable will substantially affect the remaining rights or obligations granted or undertaken by either Party. The Parties agree to attempt to substitute for any invalid or unenforceable provision a provision which achieves to the greatest extent possible the economic objectives of the invalid or unenforceable provision.

Section I.108. Integration. This Agreement, together with all schedules and exhibits attached hereto, constitutes the entire agreement between the Parties with respect to the subject matter of this Agreement and supersedes all previous arrangements between the Parties with respect to the subject matter hereof, whether written or oral, including, effective as of the Effective Date, the Confidentiality Agreement; provided that all information disclosed or exchanged under such agreement will be treated as Confidential Information hereunder. In the event of a conflict between a Development Plan or any schedules or attachments to this Agreement, on the one hand, and this Agreement, on the other hand, the terms of this Agreement will govern. Each Party confirms that it is not relying on any representations or warranties of the other Party except as specifically set forth in this Agreement.

Section I.109. Waivers and Amendments. The failure of any Party to assert a right under this Agreement or to insist upon compliance with any term or condition of this Agreement will not constitute a waiver of that right or excuse a similar subsequent failure to perform any such term or condition by the other Party. The exercise by any Party of any right or election under the terms or covenants herein will not preclude or prejudice any Party from exercising the same or any other right it may have under this Agreement, irrespective of any previous action or proceeding taken by the Parties hereunder. Notwithstanding any authority granted to the JSC under this Agreement, (a) no waiver will be effective unless it has been given in writing and signed by the Party giving such waiver, and (b) no provision of

this Agreement may be amended or modified other than by a written document signed by authorized representatives of each Party.

Section I.110. Independent Contractors; No Agency. Neither Party will have any responsibility for the hiring, firing or compensation of the other Party's or such other Party's Affiliates' employees or for any employee benefits with respect thereto. No employee or representative of a Party or its Affiliates will have any authority to bind or obligate the other Party for any sum or in any manner whatsoever, or to create or impose any contractual or other liability on such other Party, without such other Party's written approval. For all purposes, and notwithstanding any other provision of this Agreement to the contrary, each Party's legal relationship under this Agreement to the other Party will be that of independent contractor, and the relationship between the two Parties will not constitute a partnership, joint venture, or agency, including for all tax purposes, except as otherwise required by applicable Law.

Section I.111. Affiliates, Sublicensees, and Contractors. To the extent that this Agreement imposes obligations on Affiliates, Sublicensees or contractors of a Party, such Party will cause its Affiliates and its or their Sublicensees and contractors to perform such obligations, as applicable. Either Party may use one or more of its Affiliates, Sublicensees or contractors to perform its obligations and duties or exercise its rights under this Agreement, solely to the extent permitted and as specified in this Agreement; provided, however, that (a) each such Affiliate, Sublicensees or contractor will perform any such obligations delegated to it in compliance with the applicable terms and conditions of this Agreement as if such Affiliate, Sublicensees or contractor were a party hereto, (b) the performance of any obligations of a Party by its Affiliates, Sublicensees or contractors will not diminish, reduce or eliminate any obligation of such Party under this Agreement, and (c) subject to such Party's assignment to an Affiliate pursuant to Section 16.1, such Party will remain liable under this Agreement for the prompt payment and performance of all of its obligations under this Agreement. Subject to this Section 16.8, if a Party exercises its rights and performs its obligations under this Agreement through one or more of its Affiliates, "Sutro" will be interpreted to mean "Sutro or its Affiliates" and "BioNova" will be interpreted to mean "BioNova or its Affiliates" where necessary to give each Party's Affiliates the benefit of the rights provided to such Party in this Agreement and the ability to perform its obligations under this Agreement.

Section I.112. Force Majeure. Neither Party will be held liable to the other Party nor be deemed to have defaulted under or breached this Agreement for failure or delay performing any obligation under this Agreement to the extent that such failure or delay is caused by or results from acts of God, embargoes, war, acts of war (whether war be declared or not), terrorism, insurrections, riots, civil commotions, strikes, lockouts, or other labor disturbances (other than strikes, lockouts, or labor disturbances involving a Party's own employees), government actions, fire, earthquakes, floods, epidemics, pandemics or quarantines (a "Force Majeure Event") and for so long as such failure or delay continues to be caused by or result from such Force Majeure Event. The Parties agree the effects of the COVID-19 pandemic that is ongoing as of the Effective Date may be invoked as a Force Majeure Event for the purposes of this Agreement even though the pandemic is ongoing to the extent those effects are not reasonably foreseeable by the Parties as of the Effective Date. Notwithstanding the foregoing, a Party will not be excused from making payments owed hereunder due to any such Force Majeure Event affecting such Party. The affected Party will notify the other Party in writing of any Force Majeure Event that may affect its performance under this Agreement as soon as reasonably practical, will provide a good faith estimate of



the period for which its failure or delay in performance under this Agreement is expected to continue based on currently available information, and will undertake reasonable efforts necessary to mitigate and overcome such Force Majeure Event and resume normal performance of its obligations hereunder as soon as reasonably practicable under the circumstances. If the Force Majeure Event continues, then the affected Party will update such notice to the other Party on a weekly basis to provide updated summaries of its mitigation efforts and its estimates of when normal performance under this Agreement will be able to resume.

Section I.113. No Third Party Beneficiary Rights. The representations, warranties, covenants and agreements set forth in this Agreement are for the sole benefit of the Parties and their successors and permitted assigns, and they will not be construed as conferring any rights on any other Third Party. This Agreement is not intended to and will not be construed to give any Third Party any interest or rights (including any Third Party beneficiary rights) with respect to or in connection with any agreement or provision contained herein or contemplated hereby, other than, to the extent provided in ARTICLE XII, the Indemnified Parties.

Section I.114. Non-exclusive Remedy. Except as expressly provided herein, the rights and remedies provided herein are cumulative and each Party retains all remedies at law or in equity, including the Parties' ability to receive legal damages or equitable relief, with respect to any breach of this Agreement. Neither Party will be required (but, for clarity, will have the right as specified in this Agreement) to terminate this Agreement due to a breach of this Agreement by the other Party.

Section I.115. Interpretation. The Article and Section headings used herein are for reference and convenience only, and will not enter into the interpretation of this Agreement. Except as otherwise explicitly specified to the contrary, (a) references to an Article, Section or Exhibit means an Article or Section of, or a Schedule or Exhibit to this Agreement and all subsections thereof, unless another agreement is specified; (b) references in any Section to any clause are references to such clause of such Section; (c) references to any agreement, instrument, or other document in this Agreement refer to such agreement, instrument, or other document as originally executed or, if subsequently amended, replaced, or supplemented from time to time, as so amended, replaced, or supplemented and in effect at the relevant time of reference thereto; (d) references to a particular Laws mean such Laws as in effect as of the relevant time, including all rules and regulations thereunder and any successor Laws in effect as of the relevant time, and including the then-current amendments thereto; (e) words in the singular or plural form include the plural and singular form, respectively; (f) unless the context requires a different interpretation, the word "or" has the inclusive meaning that is typically associated with the phrase "and/or"; (g) the terms "including," "include(s)," "such as," "e.g." and "for example" mean including the generality of any description preceding such term and will be deemed to be followed by "without limitation"; (h) whenever this Agreement refers to a number of days, such number will refer to calendar days unless Business Days are specified, and if a period of time is specified and dates from a given day or Business Day, or the day or Business Day of an act or event, it is to be calculated exclusive of that day or Business Day; (i) "monthly" means on a calendar month basis, (j) "quarter" or "quarterly" means on a Calendar Quarter basis; (k) "annual" or "annually" means on a Calendar Year basis; (l) "year" means a 365-day period unless Calendar Year is specified; (m) references to a particular Person include such Person's successors and assigns to the extent not prohibited by this Agreement; (n) the use of any gender herein will be deemed to encompass references to either or both genders, and the use of the singular will be deemed to

include the plural (and vice versa); (o) a capitalized term not defined herein but reflecting a different part of speech than a capitalized term which is defined herein will be interpreted in a correlative manner; (p) any definition of or reference to any agreement, instrument or other document herein will be construed as referring to such agreement, instrument or other document as from time to time amended, supplemented or otherwise modified (subject to any restrictions on such amendments, supplements or modifications set forth herein); (q) the words “hereof,” “herein,” “hereby” and derivative or similar words refer to this Agreement (including any Exhibits or Schedules); (r) neither Party or its Affiliates will be deemed to be acting “on behalf of” the other Party under this Agreement, except to the extent expressly otherwise provided; (s) provisions that require that a Party, or the JSC hereunder “agree,” “consent” or “approve” or the like will be deemed to require that such agreement, consent or approval be specific and in writing in a written agreement, letter or approved minutes, but, except as expressly provided herein, excluding e-mail and instant messaging; and (t) the word “will” will be construed to have the same meaning and effect as the word “shall” when used to indicate a Party’s obligation or duty.

Section I.116. Further Assurances. Each Party will duly execute and deliver, or cause to be duly executed and delivered, such further instruments and do and cause to be done such further acts and things, including the filing of such assignments, agreements, documents, and instruments, as may be necessary or as the other Party may reasonably request in connection with this Agreement or to carry out more effectively the provisions and purposes hereof, or to better assure and confirm unto such other Party its rights and remedies under this Agreement (including working collaboratively to correct and clerical, typographical, or other similar errors in this Agreement).

Section I.117. Ambiguities; No Presumption. Each of the Parties acknowledges and agrees that this Agreement has been diligently reviewed by and negotiated by and between them, that in such negotiations each of them has been represented by competent counsel and that the final agreement contained herein, including the language whereby it has been expressed, represents the joint efforts of the Parties hereto and their counsel. Accordingly, in interpreting this Agreement or any provision hereof, no presumption will apply against any Party as being responsible for the wording or drafting of this Agreement or any such provision, and ambiguities, if any, in this Agreement will not be construed against any Party under the rule of construction, irrespective of which Party may be deemed to have authored the ambiguous provision.

Section I.118. Execution in Counterparts; Facsimile Signatures. This Agreement may be executed in counterparts, each of which counterparts, when so executed and delivered, will be deemed to be an original, and all of which counterparts, taken together, will constitute one and the same instrument even if both Parties have not executed the same counterpart. Signatures provided by facsimile transmission or in Adobe™ Portable Document Format (PDF) sent by electronic mail will be deemed to be original signatures.

Section I.119. Export Control. This Agreement is made subject to any restrictions required by applicable Laws concerning the export of products or technical information from a country which may be imposed upon or related to the Parties from time to time. Each Party agrees that it will not export, directly or indirectly, any technology licensed to it or other technical information acquired from the other Party under this Agreement or any products using such technical information to a location or in a manner that at

the time of export requires an export license or other governmental approval, except in compliance with applicable export Laws and regulations.

*[Remainder of this page intentionally blank.]*

IN WITNESS WHEREOF, each Party has caused this Agreement to be duly executed by its authorized representative, in duplicate on the Effective Date.

**SUTRO BIOPHARMA, INC.**

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Name: William J. Newell  
Title: Chief Executive Officer

**BIONOVA PHARMACEUTICALS LIMITED**

---

Name: Ye Hua  
Title: Director

*[Signature Page to Option and License Agreement]*

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**Exhibit A**

**LICENSED COMPOUND**

[\*]

*[Signature Page to Option and License Agreement]*

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**Exhibit B**

**LICENSED MARKS**

[\*]

*[Signature Page to Option and License Agreement]*

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**Exhibit C**

**LICENSED PATENTS**

[\*]

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**Exhibit D**

[\*]

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**Exhibit E**

**BIONOVA DEVELOPMENT PLAN FOR THE TERRITORY (TERRITORY-SPECIFIC DEVELOPMENT PLAN)**

[\*]

**Exhibit F**

**SAMPLE SUTRO INVOICE**

[\*]

**Exhibit G**

**PRC SAMPLE LABEL FOR PRODUCT IMPORTATION**

[\*]

**Exhibit H**

**CLINICAL SUPPLY AND BIONOVA ORDER**

[§]

**Exhibit I**

[\*]



**CERTAIN CONFIDENTIAL INFORMATION CONTAINED IN THIS DOCUMENT, MARKED BY [\*], HAS BEEN OMITTED BECAUSE IT IS NOT MATERIAL AND WOULD LIKELY CAUSE COMPETITIVE HARM TO SUTRO BIOPHARMA, INC. IF PUBLICLY DISCLOSED.**

**LICENSE AGREEMENT**

**BY AND BETWEEN**

**SUTRO BIOPHARMA, INC.**

**AND**

**TASLY BIOPHARMACEUTICALS CO., LTD.**

**December 20, 2021**

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## LICENSE AGREEMENT

This License Agreement (the “**Agreement**”) is entered into as of December 20, 2021 (the “**Effective Date**”) by and between Sutro Biopharma, Inc., a Delaware corporation with a place of business at, 111 Oyster Point Boulevard, South San Francisco, CA 94080, U.S.A. (“**Sutro**”) and Tasly Biopharmaceuticals Co., Ltd., a Chinese corporation with a place of business at 280 JuLi Road, China (Shanghai) Pilot Free Trade Zone, P.C.201203 (“**Licensee**”). Sutro and Licensee are sometimes referred to herein individually as a “**Party**” and collectively as the “**Parties**”.

### RECITALS

**WHEREAS**, Licensee wishes to obtain from Sutro and Sutro wishes to grant to Licensee certain rights and licenses under intellectual property Controlled by Sutro to Develop, Manufacture and Commercialize the Product in the Field in the Territory (each as defined below), subject to the terms and conditions set forth herein.

**NOW, THEREFORE**, in consideration of the foregoing and the mutual agreements set forth below, and other good and valuable consideration, the receipt and sufficiency of which are hereby acknowledged, the Parties agree as follows:

### ARTICLE 1 DEFINITIONS AND CONSTRUCTION

The following terms shall have the following meanings as used in this Agreement:

**Section 1.01 “Active Ingredient”** means an active material that provides pharmacological activity in a pharmaceutical or biologic product (excluding formulation components such as coatings, stabilizers, excipients or solvents, adjuvants or controlled release technologies). Drug delivery vehicles, adjuvants and excipients will not be deemed to be Active Ingredients.

**Section 1.02 “ADC”** means any antibody drug conjugate whereby [\*].

**Section 1.03 “Affiliate”** means, with respect to either Party, any Person controlling, controlled by or under common control with such Party, for so long as such control exists. For purposes of this definition of Affiliate, “control” (and, with correlative meanings, the terms “controlled by” and “under common control with”) means (a) direct or indirect ownership of fifty percent (50%) or more of the stock or shares having the right to vote for the election of directors of a Person or (b) the possession, directly or indirectly, of the power to direct, or cause the direction of, the management or policies of a Person, whether through the ownership of voting securities, by contract or otherwise.

**Section 1.04 “Alliance Manager”** shall have the meaning assigned in Section 3.01.

**Section 1.05 “Annual Net Sales”** means the Net Sales made during any given Calendar Year.

**Section 1.06“Anti-Corruption Laws”** means the U.S. Foreign Corrupt Practices Act, as amended, and any other applicable anti-corruption laws and laws for the prevention of fraud, bribery, racketeering, money laundering or terrorism in the Territory.

**Section 1.07“Applicable Laws”** means all applicable statutes, ordinances, codes, executive or governmental orders, laws, rules and regulations, including without limitation, any rules, regulations, guidelines or other requirements of Regulatory Health Authorities that may be in effect from time to time.

**Section 1.08 “Bankruptcy Code”** means Title 11, United States Code, as amended, or analogous provisions of Applicable Laws outside the United States.

**Section 1.09 “Biosimilar”** means, with respect to the Product, any pharmaceutical product that: (a) [\*]; (b) [\*]; (c) [\*]; (d) [\*]; and (e) [\*].

**Section 1.10“BLA”** means (a) in the US, a Biologics License Application, as defined in the BPCI Act, and applicable regulations promulgated thereunder by the FDA, or any equivalent application that replaces such application, (b) in the Territory, the relevant equivalent to the foregoing.

**Section 1.11“BPCI Act”** means the Biologics Price Competition and Innovation Act of 2009 within the Patient Protection and Affordable Care Act, as set forth in Section 351(k) of the United States Public Health Services Act (42 U.S.C. 262), which was signed into law in the United States in March 2010, as may be subsequently amended.

**Section 1.12“Breaching Party”** shall have the meaning assigned in Section 11.02(a).

**Section 1.13“Business Day”** means any day other than (a) a Saturday or a Sunday or (b) a day on which commercial banking institutions are authorized or required by Applicable Laws to be closed in New York City, New York, the U.S., or in Shanghai, People’s Republic of China.

**Section 1.14“Calendar Quarter”** means each successive period of three (3) consecutive calendar months commencing on 1st January, 1st April, 1st July and 1st October.

**Section 1.15“Calendar Year”** means each successive period of twelve (12) consecutive calendar months commencing on 1st January; provided, however, that: (a) the first Calendar Year shall commence on the Effective Date and end on December 31, 2021; and (b) the last Calendar Year shall commence on January 1 of the Calendar Year in which this Agreement terminates or expires and end on the date of termination or expiration of this Agreement.

**Section 1.16“CDx”** means a [\*].

**Section 1.17 “Change of Control”** means, with respect to a Party, (a) a merger or consolidation of such Party with a Third Party that results in the voting securities of such Party outstanding immediately prior thereto, or any securities into which such voting securities have been converted or exchanged, ceasing to represent more than fifty percent (50%) of the combined voting power of the surviving entity or the parent of the surviving entity immediately after such merger or consolidation, (b) a transaction or series of related transactions in which a Third Party,



together with its Affiliates, becomes the beneficial owner of more than fifty percent (50%) of the combined voting power of the outstanding securities of such Party, or (c) the sale or other transfer to a Third Party of all or substantially all of such Party's business to which the subject matter of this Agreement relates.

**Section 1.18** "CMO" means a contract manufacturing organization.

**Section 1.19** "Co-Chair" shall have the meaning assigned in Section 3.04.

**Section 1.20** "Combination Product" means a pharmaceutical product that includes the Product and at least [\*] additional Active Ingredient that [\*].

**Section 1.21** "Commercialization" means all activities undertaken relating to the marketing and sale of Product, including, advertising, detailing, education, planning, marketing, promotion, distribution, storage, transportation, importation, exportation, market and product support, any post-approval clinical studies commenced after the First Commercial Sale of the Product in the Territory and post-approval regulatory activities, including those necessary to maintain Regulatory Approvals. "Commercialize" shall have a corresponding meaning.

**Section 1.22** "Commercialization Plan" shall have the meaning assigned in Section 4.09.

**Section 1.23** "Commercially Reasonable Efforts" shall mean, with respect to a Party's obligations under this Agreement, the efforts and resources typically used by pharmaceutical companies similar in size and scope to perform the obligations at issue in good faith, which efforts shall not be less than those efforts made by the performing Party with respect to other products at a similar stage of development or in a similar market and commercial potential, taking into account the competitiveness of the market place, the proprietary position of the products, the regulatory structure involved and the profitability of the applicable products. Without limiting the foregoing, Commercially Reasonable Efforts requires, with respect to such obligations, that the Party apply efforts sufficient to carry out the given obligation in a diligent and sustained manner without undue interruption, pause, or delay. It is anticipated that the level of effort may change over time, reflecting changes in the status of the Product and the market involved.

**Section 1.24** "Competitive Product" [\*].

**Section 1.25** "Confidential Information" means, subject to the exceptions listed at Section 7.02, any and all non-public or proprietary information, whether oral or in writing or in any other form, disclosed before, on or after the date of this Agreement by one Party to the other Party under this Agreement, including Information, Materials and the terms of this Agreement.

**Section 1.26** "Control" means, with respect to an item of Information, Know-How, Patent or other Intellectual Property Rights, the ability and authority of a Party or its Affiliates, whether arising by ownership, or pursuant to a license or sublicense, to grant licenses, sublicenses, or other rights (including the right to reference) to the other Party under or to such item of Information, Know-How, Patent or Intellectual Property Rights as provided for in this Agreement without breaching the terms of any agreement between such Party and any Third Party, and (with respect to Intellectual Property Rights that Sutro acquires Control of after the Effective Date) without creating or increasing any payment obligation to a Third Party. Notwithstanding anything in this

Agreement to the contrary, a Party and its Affiliates will be deemed to not Control any Information, Know-How, Patents or other Intellectual Property Right that are owned or controlled by a Third Party described in the definition of "Change of Control," or such Third Party's Affiliates (other than an Affiliate of such Party prior to the Change of Control), (a) prior to the closing of such Change of Control, or (b) after such Change of Control to the extent that such Know-How, Patents or other Intellectual Property Rights are created, conceived, discovered or generated by such Third Party or its Affiliates (other than such Party or its pre-existing Affiliates) after such Change of Control without using such Party's or its pre-existing Affiliate's Know-How or Patents or other Intellectual Property Rights.

**Section 1.27**"**Cost of Goods**" or "**COGs**", means the fully burdened manufacturing costs applicable to the supply of the Product (a) supplied by an unaffiliated Third Party, or (b) manufactured directly by Sutro, which manufacturing costs: (x) shall include [\*], (y) shall be calculated in accordance with U.S. GAAP and Sutro's policies and procedures for its other products, in each case consistently applied (and such plant operations and support services costs shall be allocated consistent with U.S. GAAP and the other Sutro products in that facility), and (z), shall exclude [\*].

**Section 1.28**"**Cover**," "**Covered**" or "**Covering**" means, with respect to a product, technology, process or method, that, in the absence of possession of the right (by ownership, license or otherwise) under a Valid Claim, the practice or exploitation of such product, technology, process or method would infringe such Valid Claim (or, in the case of a Valid Claim that has not yet issued, would infringe such Valid Claim if it were to issue).

**Section 1.29**"**CRO**" means a contract research organization, as defined in 21 C.F.R. 312 or in any Applicable Laws, that assumes, as an independent contractor with the sponsor of a clinical trial, one or more of the obligations of a sponsor, e.g., design of a protocol, selection or monitoring of investigations, evaluation or reports, and preparation of materials to be submitted to the applicable Regulatory Authority.

**Section 1.30**"**Development**" means all activities relating to obtaining Regulatory Approval of the Product and Indications therefor, but excluding activities related to the Manufacture of Product. Development activities include (a) the conduct of all preclinical and clinical testing required for Regulatory Approval of the Product, (b) the conduct of all regulatory activities directed to obtaining and maintaining Regulatory Approval of the Product. "**Develop**" and "**Developing**" shall have a corresponding meaning.

**Section 1.31**"**Development Data**" means the Sutro Development Data or the Tasly Development Data, as the case may be.

**Section 1.32**"**Drug Approval Application**" means an application for Regulatory Approval required for the commercial sale or use of the Product as a drug in a regulatory jurisdiction.

**Section 1.33** "**Effective Date**" shall have the meaning assigned in the first paragraph of this Agreement.

**Section 1.34“Exploit”** means to import, use, sell or offer for sale, including to Develop and Commercialize, the Product in the Territory (excluding for clarity Manufacturing). **“Exploitation”** shall have a corresponding meaning.

**Section 1.35“Export Controls and Economic Sanctions Laws”** means all law regulating the export, reexport, transfer, disclosure or provision of products, software, services and technology to, and other export and international trade control activities involving, non-U.S. countries or non-U.S. Persons, and includes the Export Control Reform Act of 2018, the Export Administration Regulations, the International Emergency Economic Powers Act, the Arms Export Control Act, the International Traffic in Arms Regulations, the Chemical Weapons Convention Regulations, and any other export controls and sanctions laws and regulations administered by an agency of the U.S. government; export and import laws and regulations administered by the Bureau of Alcohol, Tobacco, Firearms and Explosives; the Foreign Trade Regulations, Executive Orders of the President regarding restrictions on trade with designated countries, governments and Persons, regulations, orders and restrictions administered by the U.S. Department of the Treasury, Office of Foreign Assets Control and any other economic sanctions or retaliatory sanctions laws and regulations administered by an agency of the U.S. government; the antiboycott regulations administered by the United States Department of Commerce; the antiboycott provisions administered by the United States Department of the Treasury; legislation and regulations implementing the North American Free Trade Agreement or the Chemical Weapons Convention, and restrictions on holding foreign currency and repatriating funds.

**Section 1.36“Expression Technology”** means the Know-How and Patents Controlled by Sutro and/or its Affiliates as of the Effective Date and during the Term that relates to [\*].

**Section 1.37“Extract Supply Agreement”** shall have the meaning assigned in Section 5.02.

**Section 1.38“FDA”** means the United States Food and Drug Administration or any successor thereto.

**Section 1.39“FFDCA”** means the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. §§ 301, et seq., as amended from time to time.

**Section 1.40“Field”** means the use of the Product for the treatment of all human diseases.

**Section 1.41“Filing”** means, with respect to a submission to a Regulatory Health Authority, the date that such submission is confirmed to have been received by the relevant Regulatory Health Authority.

**Section 1.42“First Commercial Sale”** means, with respect to the Product, the first arm’s length sale for monetary value by Licensee, its Affiliates, or its Sublicensees to a Third Party for end use or consumption by the general public of the Product in the Territory for any Indication after all needed Regulatory Approvals (excluding reimbursement approvals) have been obtained in the Territory with respect to such Indication. Sales at nominal cost for test marketing, sampling and promotional uses, clinical trial purposes, or similar use shall not be construed as a First Commercial Sale.

**Section 1.43**“Force Majeure” and “Force Majeure Party” shall have the meaning assigned in Section 14.02.

**Section 1.44** “GCP” or “Good Clinical Practices” means the current standards for clinical trials for pharmaceuticals as are required by applicable Regulatory Authorities or Applicable Laws in the relevant jurisdiction, such as set forth in the Good Clinical Practice for Drugs (i.e. 药物临床试验质量管理规范 ) promulgated by NMPA effective as of July 1, 2020, as well as in the United States Code of Federal Regulations, ICH guidelines and applicable regulations, laws or rules as promulgated thereunder, as amended from time to time.

**Section 1.45**“GLP” or “Good Laboratory Practices” means good laboratory practices required under Applicable Laws, such as the regulations set forth in 21 C.F.R. Part 58 and the requirements thereunder imposed by the FDA, and the equivalent thereof in any applicable jurisdiction, as the same may be amended from time to time.

**Section 1.46** “Government Official” means any Person employed by or acting on behalf of a Regulatory Authority.

**Section 1.47** “ICH” means the International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use.

**Section 1.48**“IND” means an Investigational New Drug application or the equivalent filed with or submitted to the relevant Regulatory Health Authority, including, for example, the FDA and the NMPA, for authorization to commence human clinical trials.

**Section 1.49**“Indication” means [\*].

**Section 1.50**“Indirect Taxes” means value added taxes, sales taxes, consumption taxes and other similar taxes.

**Section 1.51**“Information” means (a) techniques, information and data necessary or useful for the Development or Commercialization of the Product, including without limitation, Know-How, marketing, pricing, distribution, cost, sales and (b) any information or data relating to Materials.

**Section 1.52**“Intellectual Property Rights” or “IPR” means Patents, rights to Know-How, Trademarks, registered designs, design rights, copyrights (including rights in computer software), domain names, database rights and any rights or property similar to any of the foregoing in any part of the world, whether registered or not, together with the right to apply for the registration of any such rights.

**Section 1.53**“Know-How” means all inventions, discoveries, data, information (including scientific, technical or regulatory information), Trade Secrets, processes, means, methods, practices, formulae, instructions, procedures, techniques, materials, technology, results, analyses, designs, drawings, computer programs, apparatuses, specifications, technical assistance, laboratory, pre-clinical and clinical data (including laboratory notes and notebooks), and other material or know-how, in written, electronic or any other form, whether or not confidential, proprietary or patentable, including without limitation: development technology; biology,

chemistry, pharmacology, toxicology, drug stability, manufacturing and formulation, test procedures, synthesis, purification and isolation techniques, quality control data and information, methodologies and techniques; information regarding clinical and non-clinical safety and efficacy studies, including study designs and protocols, marketing studies, absorption, distribution, metabolism and excretion studies; assays and biological methodology.

**Section 1.54“Knowledge”** means the good faith understanding of the officers of the Party associated with the applicable representation.

**Section 1.55“Licensed Compound”** means STRO-002, an ADC, the chemical structure of which is described in Exhibit B.

**Section 1.56“Licensee Technology”** means all Patents and Know-How (i) Controlled by Licensee as of the Effective Date and during the Term, or (ii) that thereafter comes into Licensee’s Control independent of this Agreement. For clarity, Licensee Technology may include inventions that are broadly applicable to the Development, Manufacture or Commercialization of pharmaceutical products generally.

**Section 1.57“Licensee Triggered Termination”** shall have the meaning assigned in Section 11.03.

**Section 1.58“Losses”** means any and all direct and indirect liabilities, claims, actions, damages, losses or expenses, including interest, penalties, and reasonable lawyers’ fees and disbursements. In calculating Losses, the legal duty to mitigate on the part of the Party suffering the Loss shall be taken into account.

**Section 1.59“Manufacture”** or **“Manufacturing”** means activities in connection with the manufacture, processing, formulating, testing (including, without limitation quality control, quality assurance and lot release testing), bulk packaging or storage and delivery of the Product.

**Section 1.60“Manufacturer”** means Sutro or such other Person as may be appointed to supply Product to Licensee pursuant to the Supply Agreement.

**Section 1.61“Materials”** means information, data or assays necessary or useful for the Development or Commercialization of Product in the Territory. Materials excludes any materials associated with Sutro Manufacturing Information.

**Section 1.62“Material Adverse Impact”** shall have the meaning assigned in Section 4.07(c).

**Section 1.63“Net Sales”** means the gross amount invoiced by Licensee, its Affiliates, and/or its Sublicensees for sales of the Product to Third Parties, less the following deductions and offsets that are actually incurred, allowed, accrued and/or taken and are specifically allocated with respect to such sale, but solely to the extent that such deductions or offsets are not otherwise recovered by or reimbursed to Licensee, its Affiliates and/or its Sublicensees:

(i) rebates, chargebacks, quantity, trade and similar discounts, credits and allowances and other price reductions granted, allowed, incurred or paid in so far as they are applied to sales of the Product;

(ii) discounts (including cash discounts and quantity discounts), coupons, retroactive price reductions, charge back payments and rebates granted to managed care organizations or to federal, state and local governments, or to their agencies, in each case, as applied to sales of Product and actually given to customers;

(iii) credits and allowances taken upon rejection, return or recall of the Product;

(iv) freight and insurance costs incurred with respect to the shipment of the Product to customers, but only to the extent charged separately and invoiced to the customer;

(v) customs duties, surcharges and other similar governmental charges (including charges for product testing required for importation) incurred in connection with the exportation or importation of the Product to the extent included in the gross amount invoiced;

(vi) subject to Section 6.07, taxes imposed on the production, sale, delivery or use of the Product (including sales, use, excise or value added taxes but excluding income taxes), or other governmental charges levied on or measured by the billing amount when included in billing, as adjusted for rebates and refunds;

(vii) reasonable discounts due to factoring of receivables that are incurred; and

(viii) bad debts written off which are attributable to sales of Products, provided that the aggregated allowable deductions pursuant to this sub-clause (viii) shall not exceed [\*] of the gross amount invoiced.

The methodology for calculating (i)–(viii) shall conform to P.R.C. GAAP consistently applied. No amount for which deduction is permitted pursuant to this Section shall be deducted more than once.

For the avoidance of doubt, sales between or among Licensee and its Affiliates or Sublicensees will be excluded from the computation of Net Sales, but the subsequent final sales to a Third Party by such Affiliate or Sublicensee will be included in the computation of Net Sales. For the further avoidance of doubt, gross amounts invoiced shall exclude value added taxes payable by Licensee as per Applicable Laws.

Net Sales for a Combination Product in the Territory will mean the gross amount attributable to the Combination Product less the deductions set forth in clauses (i) – (viii) above, to the extent applicable and subject to the limitations set forth above, multiplied by a proration factor that is determined as follows:

(a) If all active pharmaceutical components of the Combination Product were sold separately, the proration factor will be determined by the formula [\*];

(b) If the Product components containing only the Licensed Compound as their Active Ingredient are sold separately from the other component(s), but the other Active Ingredient components in such Combination Product are not sold separately, then the proration factor will be determined by the formula [\*];

(c) If the Product components containing only the Licensed Compound as their Active Ingredient are not sold separately from the other component(s), but the other Active Ingredient components in such Combination Product are sold separately, then the proration factor will be determined by the formula [\*]; or

(d) If all Active Ingredient(s) of the Combination Product were not sold or provided separately, the proration factor will be determined by the Parties in good faith negotiations based on the relative value contributed by each component.

**Section 1.64 “NMPA”** means the National Medical Products Administration under the People’s Republic of China’s State Administration for Market Regulation, or any successor thereto. For the avoidance of doubt, the NMPA shall refer to the agency formerly known as the People’s Republic of China’s Food and Drug Administration (CFDA).

**Section 1.65 “Non-Breaching Party”** shall have the meaning assigned in Section 11.02(a).

**Section 1.66 “Patent”** means (a) any national, regional and international patents and/or patent applications, including provisional patent applications, (b) all patent applications filed either from such patents, patent applications or provisional applications or from an application claiming priority from any of these, including divisionals, continuations, continuations-in-part, provisionals, converted provisionals, and continued prosecution applications, (c) any and all patents that have issued or in the future issue from the foregoing patent applications ((a) and (b)), including utility models, petty patents and design patents and certificates of invention, (d) any and all extensions or restorations by existing or future extension or restoration mechanisms, including revalidations, reissues, re-examinations and extensions (including any supplementary protection certificates and the like) of the foregoing patents or patent applications ((a), (b) and (c)), and (e) any similar rights, including so-called pipeline protection, or any importation, revalidation, confirmation or introduction patent or registration patent or patent of additions to any such foregoing patent applications and patents.

**Section 1.67 “Payments”** shall have the meaning assigned in Section 6.07(a).

**Section 1.68 “Person”** means any individual, sole proprietorship, corporation, partnership, association, joint-stock company, trust, unincorporated organization, joint venture or other similar entity or organization, including a government or political subdivision, department or agency of a government.

**Section 1.69 “Pharmacovigilance Agreement”** shall have the meaning assigned in Section 4.07(a).

**Section 1.70 “Pivotal Study”** means a human clinical trial, or the relevant portion of such trial, in any country that is conducted in accordance with GCPs and the results of which are

intended to be used as a pivotal study to establish both safety and efficacy of a Product as a basis for a BLA submitted to the FDA, the NMPA or the appropriate Regulatory Authority of such other country or Region, or that would otherwise satisfy the requirements of 21 C.F.R. § 312.21(c), or any successor regulation thereto or foreign equivalents. For the avoidance of doubt (subject to the footnote underneath the table set forth in Section 6.02 (under “Ovarian Cancer”, milestone event number 3)), a clinical trial that meets the foregoing criteria shall be deemed a Pivotal Study regardless of whether it is characterized as a “Phase III” clinical trial or otherwise (e.g., “Phase 2b,” or “Phase 2b/3”).

**Section 1.71“People’s Republic China” or “PRC”** means the mainland of the People’s Republic of China, excluding Hong Kong Special Administrative Region, Macao Special Administrative Region, and Taiwan region.

**Section 1.72“PRC GAAP”** means Generally Accepted Accounting Principles of the People’s Republic of China, consistently applied.

**Section 1.73“Product”** means any pharmaceutical product containing the Licensed Compound, whether alone (as the sole Active Ingredient), or as part of a Combination Product. **“The Product”** as used in this Agreement means any and all products that satisfy this definition.

**Section 1.74“Product-related IPR”** means all Intellectual Property Rights that are discovered, invented, generated, collected, or obtained by Licensee, its Affiliates, or Sublicensees in the performance of activities conducted pursuant to this Agreement and related to the Product.

**Section 1.75“Regulatory Approval”** means, with respect to the Product in any Region any approval by the applicable Regulatory Health Authority to market and sell the Product in such Region, including, where applicable, pricing or reimbursement approval in such Region.

**Section 1.76“Regulatory Authority”** means any court or government body, whether national, supra- national, federal, state, local, foreign or provincial, including any political subdivision thereof, including any department, commission, board, bureau, agency, or other regulatory or administrative governmental authority or instrumentality, and further including any quasi-governmental Person or entity exercising the functions of any of these.

**Section 1.77“Regulatory Documentation”** means all applications, registrations, licenses, authorizations and approvals, all correspondence submitted to or received from Regulatory Health Authorities (including minutes and official contact reports relating to any communications with any Regulatory Health Authority) and all supporting documents, including documentation arising in the course of all clinical studies and tests, in each case relating to the Product, including all INDs, BLAs, Regulatory Approvals, regulatory drug lists, advertising and promotion documents, adverse event files and complaint files.

**Section 1.78“Regulatory Health Authority” or “Regulatory Health Authorities”** means any applicable national (for example, FDA or NMPA), supranational, regional, state, provincial or local regulatory health authority, department, bureau, commission, council, or other government entity regulating or otherwise exercising authority with respect to the Exploitation of Product in the Territory, including any such entity involved in the granting of Regulatory Approval for pharmaceutical products.



**Section 1.79**“**Remedial Action**” shall have the meaning assigned in Section 4.07(b).

**Section 1.80**“**Review Period**” shall have the meaning assigned in Section 7.07.

**Section 1.81**“**Safety/Efficacy Issue**” means, with respect to any Product, that (a) the risk/benefit profile (based on the observation of an adverse event or otherwise) of such Product is so unfavorable that it would pose an unacceptable risk of harm in humans to Develop or Commercialize such Product, or (b) the efficacy of such Product is so minimal that it would not be commercially reasonable to continue to Develop such Product, in each case to the extent attributable to the Licensed Compound and not any other component contained in such Product or any Manufacturing-related issues.

**Section 1.82**“**Senior Executives**” means (a) the Chief Executive Officer of Sutro and (b) the Chief Executive Officer of Licensee. A Party shall be entitled, effective upon written notice thereof to the other Party, to designate one of its other representatives having equivalent seniority and experience to replace such foregoing representative as that Party’s Senior Executive for the purpose of this Agreement.

**Section 1.83** “**Shortage**” shall have the meaning assigned in Section 5.02.

**Section 1.84**“**Sublicensee(s)**” shall have the meaning assigned in Section 2.02.

**Section 1.85**“**Supply Agreement**” means Clinical Supply Agreement or Commercial Supply Agreement, as applicable.

**Section 1.86**“**Sutro**” shall have the meaning set forth in the preamble.

**Section 1.87**“**Sutro Corporate Trademarks**” shall have the meaning set forth in Section 1.94.

**Section 1.88**“**Sutro Development Data**” means any [\*] which data is Controlled by Sutro or its Affiliates.

**Section 1.89**“**Sutro Know-How**” means any and all Know How relating to the Product and which is necessary or useful for Licensee to obtain Regulatory Approval of the Product in the Territory, or otherwise import, Develop, or Commercialize the Product in the Territory, which exists as of the Effective Date and during the Term and is Controlled by Sutro. Notwithstanding anything to the contrary, Sutro Know-How specifically excludes all Know-How comprising Expression Technology.

**Section 1.90**“**Sutro Manufacturing Information**” means any and all confidential documents and information relating to the Manufacture of the Product Controlled by Sutro and/or its Affiliates.

**Section 1.91**“**Sutro Patents**” means any and all Patents that are (a) Controlled by Sutro or any of its Affiliates as of the Effective Date or at any time during the Term, and (b) necessary or reasonably useful for Licensee to import, Develop and Commercialize the Product in accordance with this Agreement, including without limitation the following: (a) patent applications and patents

set forth in Exhibit A; (b) divisions, continuations, continuations-in-part, renewals, and substitute applications of any patent applications described in (a); (c) patents that may issue from any patent applications described in (a) or (b); (d) reissues, reexaminations, and extensions or restorations of patents described in (a) or (c) by existing or future extension or restoration mechanisms, including without limitation, patent restoration and supplementary protection certificates or the equivalent thereof; and € any other form of government-issued right in the Territory substantially similar to any of the foregoing. Notwithstanding anything to the contrary, Sutro Patents specifically exclude any patent applications or patents claiming or covering any processes for manufacture of Product or Expression Technology.

**Section 1.92“Sutro Product Trademarks”** shall have the meaning set forth in Section 1.94.

**Section 1.93“Sutro Technology”** shall mean, for purposes of this Agreement, the Sutro Know-How, Sutro Manufacturing Information, Sutro Patents, and Sutro Trademarks.

**Section 1.94“Sutro Trademarks”** means the Trademarks to the extent Controlled by Sutro or its Affiliates in the Territory as of the Effective Date or during the Term and that are (a) specific to and only used with Product (the **“Sutro Product Trademarks”**) or (b) used in connection with, but are not specific to or used exclusively with, the Product (the **“Sutro Corporate Trademarks”**), each of (a) and (b) solely to the extent set forth in Exhibit E.

**Section 1.95“Target Indication”** means a [\*], for which a separate Regulatory Approval is required. For the avoidance of doubt, a different line of therapy or combination therapy will not be deemed a separate and distinct neoplasm.

**Section 1.96“Tasly Development Data”** means any [\*], which data is Controlled by Tasly or its Affiliates.

**Section 1.97“Tax”** means any form of tax or taxation, levy, duty, charge, social security charge, contribution or withholding of whatever nature (including any related fine, penalty, surcharge or interest) imposed by, or payable to, a Tax Authority.

**Section 1.98“Tax Authority”** means any government, state or municipality, or any local, state, federal or other fiscal, revenue, customs, or excise authority, body or official anywhere in the world, authorized to levy Tax.

**Section 1.99“Term”** shall have the meaning assigned in Section 11.01.

**Section 1.100“Territory”** means the People’s Republic of China, Hong Kong Special Administrative Region, Macao Special Administrative Region, and Taiwan region (each of which for purposes of this Agreement shall each be deemed a **“Region”**).

**Section 1.101“Third Party”** means any Person other than Sutro, Licensee, or their respective Affiliates.

**Section 1.102“Third Party Claims”** shall have the meaning assigned in Section 12.01(a).

**Section 1.103** "Third Party Compensation" shall have the meaning assigned in Section 6.04(d).

**Section 1.104** "Trademark" means any trademark, applications to register trademarks, trade name, service mark, service name, brand, domain name, trade dress, logo, slogan or other indicia of origin or ownership, including the goodwill and activities associated with each of the foregoing.

**Section 1.105** "Trademark License Agreement" shall have the meaning assigned in Section 2.06(b).

**Section 1.106** "Trade Secret" means information, including but not limited to formulae, techniques, conditions, reagents, processes, or methods, that (i) derives independent economic value, actual or potential, from not being generally known to, and not being readily ascertainable by proper means by, other persons who can obtain economic value from its disclosure or use; and (ii) is the subject of efforts that are reasonable under the circumstances to maintain its secrecy.

**Section 1.107** "Upstream Agreement" means that certain license agreement by and between Sutro and The Board Of Trustees of the Leland Stanford Junior University, dated October 3, 2007, as may be amended from time to time.

**Section 1.108** "U.S. GAAP" means United States Generally Accepted Accounting Principles, consistently applied.

**Section 1.109** "Valid Claim" means (a) a claim of an issued and unexpired Patent within the Sutro Patents that has not been held unpatentable, invalid, or unenforceable by a court or other government agency of competent jurisdiction in an unappealable decision or has not been admitted to be invalid or unenforceable through disclaimer, or otherwise or (b) a claim of a pending patent application within the Sutro Patents that (i) has not been abandoned, finally rejected or expired without the possibility of appeal or re-filing and (ii) [\*].

**Section 1.110** "Withholding Income Tax" shall mean the aggregate withholding of income tax required and levied by applicable Tax Authorities in the Territory.

**Section 1.111** "Written Disclosure" shall have the meaning assigned in Section 10.02.

**Section 1.112 Construction.** Except where the context requires otherwise, whenever used in this Agreement, the singular includes the plural, the plural includes the singular, the use of any gender is applicable to all genders and the word "or" has the inclusive meaning represented by the phrase "and/or". Whenever this Agreement refers to a number of days, unless otherwise specified, such number refers to calendar days. The term "including" or "includes" as used in this Agreement means including, without limiting the generality of any description preceding such term. The article, section, and subsection headings contained in this Agreement are for the purposes of convenience only and are not intended to define or limit the contents of such articles, sections, and subsections. The wording of this Agreement shall be deemed to be the wording mutually chosen by the Parties and no rule of strict construction shall be applied against any Party.

**ARTICLE 2**  
**GRANT OF RIGHTS AND LICENSES; EXCLUSIVITY**

**Section 2.01 License to Licensee.**

(a) Subject to the terms, conditions and limitations set forth in this Agreement, including without limitation the provisions in Section 2.03 below, Sutro hereby grants to Licensee: (i) an exclusive (including with regard to Sutro and its Affiliates), royalty-bearing license during the Term to import, sell, offer for sale, Develop, and Commercialize, including without limitation repackaging and have repackaged Products in the Field in the Territory, with the right to grant sublicenses solely in accordance with Section 2.02 below, under Sutro Know-How and Sutro Patents (but specifically excluding Sutro Manufacturing Information and any aspects of the Sutro Patents related thereto). For the avoidance of doubt, the license granted in this Section 2.01 does not include the right to (i)[\*] (ii)[\*], or (iii)[\*].

(b) Subject to the terms, conditions and limitations set forth in this Agreement, Licensee shall have the right to engage and appoint service providers, at its own discretion for the sole purpose of conducting clinical development, obtaining Regulatory Approval or import authorization, importing, and/or transportation services (but excluding any distribution and promotional activities) in relation to the Product on behalf of Licensee in the Territory in accordance with this Agreement. For avoidance of doubt, the Affiliates and the Sublicensee (as defined in Section 2.02) of Licensee shall also have the right to engage and appoint service providers at its own discretion for the aforementioned purposes. These service providers shall be bound by obligations of confidentiality that are no less restrictive than those contained in this Agreement and provisions sufficient to ensure that any Product-Related IPR developed by such service providers within the scope of their engagement will be fully assigned to Licensee. Licensee shall remain liable for any action or failure to act by any service provider if such action or failure to act by the service provider would have constituted a breach of this Agreement if such action or failure were committed by Licensee.

**Section 2.02 Sublicenses.** Licensee shall have the right to grant sublicenses under the license granted to Licensee under Section 2.01 in each case only upon prior written consent (such consent not to be unreasonably withheld, conditioned or delayed) of Sutro and subject to the remainder of Section 2.02, provided that Licensee may grant sublicenses to its Affiliates without prior written notice to Sutro so long as such Affiliate remains an Affiliate of Licensee. Where Licensee or its Affiliates grants such sublicense to a Person that is not an Affiliate of Licensee, such Person shall be a “**Sublicensee**” for the purposes of this Agreement, and any Person to which a Sublicensee grants a further sublicense shall also be a Sublicensee; provided, however, that any Person that is engaged and appointed by Licensee, its Affiliates and/or Sublicensees as a service provider pursuant to Section 2.01(b) solely to enable such Person to provide such services shall not be a “**Sublicensee**” for purposes of this Agreement. Licensee, its Affiliates and its Sublicensees shall ensure that all Persons to which they grant sublicenses (a) comply with all terms and conditions of this Agreement, and, without limiting the foregoing (b) are bound by obligations of confidentiality that are no less restrictive than those contained in this Agreement and provisions sufficient to ensure that any Product-Related IPR developed by them will be fully assigned to Licensee, (c) agree to comply with 4.06(c) to the same extent Licensee is obligated thereunder, and (d) do not have the right to grant further sublicenses. Within [\*] days after the execution of

each sublicense agreement, Licensee shall provide to Sutro a copy of such each agreement (which may be redacted to remove any sensitive information not necessary for Sutro to verify its compliance with the terms of this Agreement). Licensee shall remain liable for any action or failure to act by any Sublicensee under the licenses granted in Section 2.01 by Licensee, its Affiliates or its Sublicensees, if such action or failure to act by the Sublicensee would have constituted a breach of this Agreement if such action or failure were committed by Licensee. In the event of early termination of this Agreement, all sublicenses granted to Sublicensees in accordance with the terms hereof shall automatically be revoked without any further action on the part of Sutro.

**Section 2.03 Rights Retained by Sutro.** Notwithstanding the foregoing, Sutro hereby expressly retains (on behalf of itself and its Affiliates) (a) all rights to any Sutro Know-How and Intellectual Property Rights, including the Sutro Manufacturing Information, related to the Manufacture of the Product (which rights are excluded from the license grant in Section 2.01), (b) the right under the Sutro Technology to conduct global studies with respect to the Product in accordance with this Agreement, and (c) all exclusive rights under the Sutro Technology to Develop, Manufacture, Commercialize and otherwise exploit the Product outside of the Territory, whether within or outside of the Field. For clarity, this Section 2.03 shall not be construed to limit Licensee's rights under Section 5.02(b).

**Section 2.04 No Implied Rights; Negative Covenant.** This Agreement confers no right, license, or interest by implication, estoppel, or otherwise under any Patents, Know-How, or other Intellectual Property Rights of either Party except as expressly set forth in this Agreement. Each Party hereby expressly retains and reserves all rights and interests with respect to Patents, Know-How, or other Intellectual Property Rights not expressly granted to the other Party hereunder. Without limiting the generality of the foregoing, no license or other rights are granted to Licensee under this Agreement to any pharmaceutical compositions claimed or disclosed in any Sutro Patents other than the Product. Licensee shall not, and shall not permit any of its Affiliates or Sublicensees to, practice any Intellectual Property Rights licensed to it by Sutro outside the scope of the licenses granted to it under this Agreement.

**Section 2.05 Non-Compete.** Upon the Effective Date and throughout the Term, Licensee shall not, and shall ensure that its Affiliates and Sublicensees do not, engage in, independently or for or with any Third Party, any research, development, manufacture or commercialization of any Competitive Product. In the event that Licensee and/or any of its Affiliates undergoes an acquisition of or merger with a Third Party, which will become an Affiliate of Licensee immediately after closing of such acquisition or merger transaction, and such Third Party is engaging in the development and/or commercialization of any Competitive Products at the time of such transaction, Licensee will notify Sutro immediately after the closing of such transaction to initiate a discussion with Sutro and suspend the development and/or commercialization of such Competitive Products unless and until the Parties reach an agreement on this competitive business during or after such discussion with Licensee in good faith. Notwithstanding the above, in the event that an Affiliate of Licensee is (a)[\*] ; or (b)[\*] .

**Section 2.06 Trademark Rights.**

(a) Sutro Trademarks. Subject to the terms, conditions and limitations set forth in this Agreement, Sutro hereby grants to Licensee a royalty-free exclusive license to use Sutro

Trademarks, including Sutro Product Trademarks and (solely upon Sutro’s prior written consent in each case, which consent shall not be unreasonably withheld) Sutro Corporate Trademarks, solely in connection with the Commercialization of the Product in the Territory. All representations and uses of Sutro Trademarks that Licensee intends to use will first be submitted to Sutro for approval, such approval not to be unreasonably withheld. Sutro will have [\*] to review the representation and uses of the Sutro Trademarks. If Sutro does not provide written notice of its approval or disapproval (together with its reasons for such disapproval) within such [\*] period, Sutro will be deemed to have approved such representation.

(b) In connection with the license granted to Licensee under the Sutro Trademarks as provided in Section 2.06(a), Sutro and Licensee agree that either they or their respective Affiliates will, within [\*] after the Effective Date or otherwise agreed by both Parties, negotiate in good faith the terms of a “**Trademark License Agreement**”, which shall not be inconsistent with the terms and conditions of this Agreement, including this Section 2.06, and shall be filed with the appropriate governmental body in the Territory if required under Applicable Laws.

(c) Notwithstanding the above, Licensee shall have the right to select its own Trademarks and/or apply for new Trademarks in its own name, at its own discretion, to be used for the Commercialization of the Product in the Territory (the “**Licensee Trademarks**”). Licensee shall solely bear the full costs and expense of and be responsible for filing, prosecuting and maintaining all the Licensee Trademarks. Licensee shall, at its sole discretion, protect, defend, and maintain each Licensee Trademark for use with Product in the Territory, and all registrations therefor.

(d) Licensee shall be responsible for and have the discretion in determining the design and procurement of all packaging (non-commercial and commercial) and labeling of the Product.

### **ARTICLE 3 GOVERNANCE**

**Section 3.01 Alliance Manager.** Within [\*] of the Effective Date, each Party will identify and notify the other Party of a representative to act as its informal liaison under this Agreement (the “**Alliance Manager**”). The Alliance Managers will serve as the primary contact points between the Parties regarding the activities contemplated by this Agreement. The Alliance Managers may facilitate the flow of information and otherwise promote communication, coordination and collaboration between the parties, providing single point communication for seeking consensus both internally within each Party’s organization, including facilitating review of external corporate communications, and raising potential disputes in a timely manner. Each Party may change its Alliance Manager by written notice to the other Party.

**Section 3.02 Joint Steering Committee.** Within [\*] of the Effective Date, the Parties shall establish a Joint Steering Committee (the “**JSC**”). Each Party can designate three representatives as the members to the JSC, and such initial members to be nominated by the Parties and listed at Exhibit C herein. Such representatives shall be individuals suitable in seniority and experience and having delegated authority to make decisions of the JSC with respect to matters within the scope of the JSC’s responsibilities. The JSC shall operate in accordance with the provisions of Section 3.03 to Section 3.07, and shall have no authority to alter, amend or waive the terms and conditions

of this Agreement, including any payment conditions or terms, periods of performance, or obligations of the Parties. A Party may change one or more of its representatives serving on the JSC at any time upon written notice to the other Party; provided that such replacement is of comparable authority and scope of functional responsibility within that Party's organization as the person he or she is replacing. At its meetings, the JSC shall discuss the matters described below and such other matters as are reasonably requested by either Party's Alliance Manager. The JSC shall remain in effect as from its establishment through the Term.

**Section 3.03 Responsibilities of JSC.** Except as specifically provided in this Agreement, the role of the JSC shall be advisory in nature, with the main purpose of serving as a forum for the sharing of information and facilitating communications between the Parties regarding Development and Commercialization activities conducted hereunder, including by keeping Sutro reasonably informed and updated regarding (i) the status of Development and Commercialization, (ii) results from any clinical trials, (iii) any adverse events, and (iv) material correspondence with a Regulatory Authority. Subject to Section 3.07, the responsibilities of the JSC will be to:

- (a) review and approve the Development strategy and the Development Plan for the Product in the Territory;
- (b) review and advise on the Commercialization Plan ;
- (c) ensure harmonization of the Product Development and regulatory strategy in the Territory with Sutro's global development and commercialization strategy (for clarity, Sutro shall have no obligation to conduct any global study for the Product);
- (d) review and discuss matters that may have a Material Adverse Impact;
- (e) oversee and advise on all pre-clinical and/or clinical Development activities proposed to be conducted with respect to the Product;
- (f) review and discuss the protocols for each clinical trial of Product proposed to be conducted in the Territory;
- (g) facilitate and approve the exchange of Product-related data and information between the Parties;
- (h) facilitate and approve the clinical trial data publication strategy for trials conducted in the Territory; and
- (i) oversee the implementation of, and the coordination between the Parties of activities to be performed under the Development Plan, Pharmacovigilance Agreement, Supply Agreement, and any other written agreement between the Parties with respect to the subject matter hereof.
- (j) perform such other functions as are specifically designated for the JSC in this Agreement.

**Section 3.04 Co-Chairs.** Each Party shall designate one of its representatives on the JSC to co-chair the meetings for the JSC (each, a "Co-Chair"). The Co-Chairs shall, through and with the assistance of the Alliance Managers, coordinate and prepare the agenda for, and ensure the

orderly conduct of, the meetings of the JSC. The Co-Chairs shall, through and with the assistance of the Alliance Managers, solicit agenda items from the JSC members and provide an agenda, along with appropriate information for such agenda, reasonably in advance of any meeting. Such agenda shall include all items requested by either Co-Chair for inclusion therein. In the event the Co-Chairs or another JSC member from either Party is unable to attend or participate in a meeting of the JSC, the Party whose Co-Chair or member is unable to attend may designate a substitute co-chair or other representative for the meeting.

**Section 3.05 Meetings.** The JSC shall meet at least quarterly, or more or less frequently if determined by the JSC, during the period in which Licensee is Developing the Product in the Territory, and JSC meetings can be called at other times by agreement between the Parties for any reason. JSC meetings may be conducted by telephone, videoconference or in person. Any in-person JSC meetings shall be held on an alternating basis between Sutro's and Licensee's facilities, unless otherwise agreed by the Parties. Each Party shall be responsible for the cost of such Party's own personnel and for its own expenses in attending such meetings and carrying out the other activities contemplated under this Article 3. As appropriate, the JSC may invite a reasonable number of non-voting employees, consultants and scientific advisors to attend its meetings as non-voting observers; provided, that such invitees are bound by confidentiality obligations at least as stringent as the provisions set forth herein. Each Party may also call for special meetings of the JSC to discuss particular matters requested by such Party. The Alliance Managers shall provide the members of the JSC with no less than [\*] notice of each regularly scheduled meeting and, to the extent reasonably practicable under the circumstances, no less than [\*] notice of any special meetings called by either Party.

**Section 3.06 Minutes.** Minutes will be kept of all JSC meetings, with the minutes for each JSC meeting to be the responsibility of the Co-Chair (or his or her designees) of the Party that is hosting such meeting, unless otherwise agreed by the Parties. Draft meeting minutes shall be sent to all members of the JSC by e-mail for review and approval within [\*] after each such meeting. Minutes will be deemed approved unless any member of the JSC objects to the accuracy of such minutes by providing written notice to the other members of the JSC prior to the next meeting. Minutes shall [\*]. In the event of any objection to the minutes that is not resolved by mutual agreement of the Parties, such minutes will be amended to reflect such unresolved dispute.

**Section 3.07 Decision Making of JSC.** Decisions of the JSC shall be made by unanimous vote, with each Party's representatives on the JSC collectively having one vote. Any matter which the JSC is unable to resolve [\*] within [\*] shall be referred to the Parties' Senior Executives as set forth in Section 13.01, provided, however that if the Senior Executives are unable to resolve such matter as set forth in Section 13.01, then: (i) if the matter relates to global Development (including Development activities in the Territory as a part of a global development plan) of the Product, or could otherwise result in a Material Adverse Impact, Sutro shall have the final decision and (ii) [\*] Licensee shall have the final decision. In no event shall either Party be permitted to use its decision making authority under this Section 3.07 to supersede its diligence obligations under this Agreement, and each Party's final decision shall comply with the Applicable Law.

#### **ARTICLE 4 GENERAL PROVISIONS ON DEVELOPMENT AND COMMERCIALIZATION**



**Section 4.01 Record Keeping.** Each Party shall maintain, or cause to be maintained, records of its activities under this Agreement [\*], to the extent related to the Development of the Product in the Territory, which shall be complete and accurate [\*].

**Section 4.02 Development Plan.** Licensee shall be responsible for providing to the JSC for approval reasonably detailed plans specifying the Development activities, including clinical trials and regulatory submissions, planned for the Product in the Territory with respect to each Indication for which it is seeking Regulatory Approval, and the timelines for achieving such activities (the “**Development Plan**”); provided, however, that an initial draft of the Development Plan is attached hereto as Exhibit D. Such initial Development Plan shall be non-binding and may be adjusted according to the liaisons with the Regulatory Authorities in the United States and/or in the Territory, but the subsequent Development Plans provided by Licensee shall be guided by the initial Development Plan, adjusted and finalized according to the approval (or consent in case of no formal approval) of the pivotal clinical trial design by the Regulatory Authorities in the US and in the Territory. Sutro shall have the right to comment, and the Parties shall discuss in good faith, prior to the submission of the Development Plans to the JSC for approval. From time to time, but at least every [\*], Licensee shall propose updates or amendments to the Development Plan in consultation with Sutro to reflect changes in the plans, including timelines for activities therein. Thereafter, Licensee shall submit the proposed updated or amended Development Plan to the JSC for review and approval.

**Section 4.03 Conduct of Certain Development Activities.** Subject to the terms of the Agreement, Licensee shall have the sole right and responsibility for the Development of the Product in the Field throughout the Territory, including the conduct of clinical trials and other Development studies, at its own cost and expense; provided, however, Sutro may sponsor or co-sponsor such clinical studies with respect to the Product pursuant to Applicable Laws as part of a global development plan, in which case Sutro shall use Commercially Reasonable Efforts to cooperate with Licensee to conduct such clinical trials in the Territory. Licensee may support Sutro’s global development of Product by conducting certain Development activities in the Territory as reasonably requested by Sutro, provided that for any such Development activities conducted at Sutro’s request but not required for obtaining the Regulatory Approvals in the Territory (and provided that no resulting data is used for obtaining the Regulatory Approvals in the Territory), Sutro shall reimburse Licensee for all the costs and expenses associated therewith. Any Development activities to be performed by Licensee that relate to Sutro’s global development of the Product may be included in the Development Plan.

**Section 4.04 Diligence Obligations.**

(a) Licensee shall use Commercially Reasonable Efforts in accordance with the Development Plan [\*] to carry out its activities under this Agreement to Develop (in accordance with the Development Plan) and Commercialize the Product in the Territory. For the avoidance of doubt, upon the execution of this Agreement, Licensee shall be responsible for preparing [\*] all Development and Commercialization activities required for commercial success of the Product in the Territory, including but not limited to the following activities:

- (i) prepare the subsequent Development Plan contemplated by Section 4.02 above within [\*] of the Effective Date;

(ii) prepare a preliminary Commercialization Plan contemplated by Section 4.09 hereunder no later than [\*] prior to the anticipated date of filing of the first BLA or Drug Approval Application for the Product in the Territory;

(iii) obtain the first informed consent of the first patient for the first clinical trial for the Product in the Territory within [\*] of obtaining all regulatory clearances required under Applicable Laws to commence such trial, including but not limited to, IND clearance, hospital ethics committee approval and Human Genetic Resources Administration of China approval.

(iv) make timely regulatory submissions and filings in the Territory as is customary with industrial practices in the Field in the Territory; and

(v) within [\*] following receipt of the Regulatory Approval (excluding reimbursement approvals) for the Product in the Field in the PRC, effect the First Commercial Sale of such Product in the PRC, except to the extent [\*] or is due to circumstances beyond the reasonable control of Licensee.

**Section 4.05 Reports of Development Activities.** Licensee shall prepare and provide reports on the Development activities of the Product undertaken by it in the Territory at each meeting of the JSC. [\*] In addition, as reasonably requested by Sutro, Licensee shall, at its own expense, make appropriate scientific and regulatory personnel available at JSC meetings to brief the JSC on Development activities conducted by Licensee. All of the documentation described in this Section 4.05 shall be provided to Sutro in English.

**Section 4.06 Regulatory Matters.**

(a) Sutro acknowledges that Applicable Laws may require that the Product be registered through the imported drug pathway of the NMPA, and Sutro or its designated agent, as the marketing authorization holder in the United States, be the marketing authorization or imported drug license holder of the Product in the Field in the Territory. Notwithstanding the foregoing sentence, however, Sutro shall not have any right to Commercialize the Product in the Field in the Territory, which have been granted to Licensee under Section 2.01. In the event Sutro is no longer required under Applicable Laws to be the marketing authorization or imported drug license holder in the Territory, then Sutro shall promptly transfer the marketing authorization or imported drug license to Licensee (and Licensee shall accept such transfer) and shall not require Licensee to make additional payment on such transfer, except that Licensee shall promptly reimburse Sutro for any and all reasonable expenses ([\*]) that Sutro may incur in being and transferring to Licensee the marketing authorization or imported drug license in the Territory.

(b) Subject to the terms and conditions of this Agreement, Licensee will be responsible, at its sole cost and expense, for all regulatory activities leading up to and including the submitting and obtaining of INDs, Regulatory Documentation, Regulatory Approvals, for the Products in the Field in the Territory from Regulatory Authorities in the Territory, provided that, Licensee will conduct such activities (and any and all regulatory activities delegated to Licensee in this Agreement) (1) in its own name, if Licensee is the holder and legal and beneficial owner of the INDs, Regulatory Documentation, and Regulatory Approvals for the Product in the Field in

the Territory, or (2) as the express and authorized regulatory agent of record for Sutro in the Field in the Territory (unless a mutually agreed upon CRO has been appointed to perform such function as set forth in Section 4.06(d)), if Sutro is the legal and beneficial owner of the INDs, Regulatory Documentation, and Regulatory Approvals for the Product in the Field in the Territory, under which situation such actions will be taken on behalf of Sutro and for the benefit of Licensee in the Field in the Territory.

(c) Licensee shall use Commercially Reasonable Efforts, on behalf of Sutro (if applicable), to apply for the Regulatory Approval for the Product in the Territory for all Indications specified in the Development Plan. Licensee shall be responsible for (i) preparing, translating, filing and submitting all Regulatory Documentation related to the Product with the applicable Regulatory Health Authority(ies) in the Territory, including all applications for Regulatory Approval, at its own cost, (ii) as soon as reasonably practicable, providing to Sutro the English translation of such Regulatory Documentation submitted, to the extent such Regulatory Documentation is not translated from materials provided by Sutro, at its own cost, and (iii) providing to Sutro all correspondence with Regulatory Health Authority(ies) in the Territory (each of the foregoing translated in English), at its own cost. Licensee shall also be responsible for providing, in the format required by the applicable Regulatory Health Authorities, the data and information required to be submitted to such Regulatory Health Authorities for Regulatory Approval of the Product in the Territory, including without limitation data from all clinical trials in the Territory.

(d) As soon as reasonably practicable following the Effective Date, Sutro shall[\*] provide to Licensee, all reasonably necessary data and other clinical development information (including manufacturing batch records) pertaining to the Product and Controlled by Sutro, and all necessary certification documents for IND application, BLA equivalent application or Drug Approval Application in the Territory. The technical documents, including but not limited to spectrum and chromatogram derived from Chemistry, Manufacturing, and Controls (CMC) (excluding, for clarity, data pertaining to Expression Technology), preclinical or clinical studies, provided by Sutro shall be in CTD or eCTD format. Upon request by the applicable Regulatory Health Authorities, Sutro shall also provide, if applicable, available specification validation samples and reference standards for the Product. In addition, to the extent necessary for Licensee to obtain Regulatory Approval of a Product in the Territory, [\*]. Notwithstanding the above, if allowed under Applicable Laws, any access by any Regulatory Health Authority to any information relating to Expression Technology shall be provided via (i) a right of reference to a drug master file (or DMF) (or its equivalent in the applicable Region in the Territory) filed by Sutro in the applicable Region in the Territory or (ii) directly to a Regulatory Health Authority by Sutro [\*].

(e) Sutro shall use Commercially Reasonable Efforts to attend all meetings or hearings where Sutro's presence is specifically requested by the applicable Regulatory Authority, by telephone, videoconference or (if requested by such Regulatory Authority) in person, provided that Licensee shall [\*]. In addition, Sutro acknowledges that the NMPA generally requires applicants to provide responses to its questions and requests within [\*], and shall provide Licensee with all reasonable assistance in responding to questions and requests raised by NMPA and other Regulatory Health Authorities within the required timeframe.

(f) Licensee shall report to Sutro regarding the status of each pending or proposed IND application, BLA equivalent application or Drug Approval Application covering the Product in the Territory. Licensee shall as soon as reasonably practicable furnish Sutro with English language copies of all substantive correspondence Licensee has had with any Regulatory Health Authority, and contact reports concerning substantive conversations or substantive meetings with any Regulatory Health Authority, in each case relating to any such IND, BLA equivalent or Drug Approval Application.

(g) Licensee shall be responsible for [\*], ensuring the accuracy and fidelity of the translation, of any and all documents provided to Regulatory Health Authorities and/or Sutro, as applicable, under this Section 4.06.

(h) Each Party (i) hereby grants to the other Party and its Affiliates a right of reference to all Regulatory Documentation and, Regulatory Approvals Controlled by the first Party and its Affiliates and (ii) will provide to the other Party with access to the Development Data Controlled by the first Party or its Affiliates, in each case under (i) and (ii) to the extent necessary or useful for the Development, Manufacture, Commercialization or other exploitation of the Product in the Field in the other Party's territory, subject in each case to the last sentence of Section 4.06(d). The receiving Party and its Affiliates (A) shall have the right to use such Regulatory Documentation, Regulatory Approvals and Development Data only in connection with the Development, Manufacture, Commercialization or other exploitation of the Product in the Field in such Party's territory, and (B) may sublicense the rights granted to it under this Section 4.06(h) to its licensees (in the case of Sutro) or Sublicensees (in the case of Tasly), provided that such licensees or Sublicensees have granted to Sutro and Tasly a reciprocal, sublicensable right with respect to the Regulatory Documentation, Regulatory Approvals and Development Data of such licensees and Sublicensees, as applicable. Each Party shall use reasonable efforts to obtain the consent of its licensees (in the case of Sutro) and Sublicensees (in the case of Tasly) to grant to the other Party and its Affiliates the rights described above with respect to the Regulatory Documentation, Regulatory Approvals and Development Data of such licensees and Sublicensees, as applicable.

#### **Section 4.07 Adverse Event Reporting and Product Recall; No Material Adverse Impact**

(a) Each Party agrees to provide the other Party with the necessary safety information required by Regulatory Health Authorities to comply with Applicable Laws. Sutro will hold the safety database for the Product and Licensee will provide safety information as required by Applicable Laws, in a timely manner, subject to a reasonable cost sharing arrangement to be agreed-upon in the Pharmacovigilance Agreement (as defined below). [\*] following the Effective Date, but no later than [\*] after the Effective Date or otherwise agreed by both Parties, the Parties will enter into a detailed pharmacovigilance agreement (the "**Pharmacovigilance Agreement**"), governing, among other things, appropriate adverse event reporting procedures and pharmacovigilance responsibilities of the Parties relating to Product and reflecting the provisions set forth above in this Section 4.07(a).

(b) Each Party will notify the other Party [\*] (in any event within [\*]), if it obtains information indicating that any Product could reasonably be expected to be subject to any recall, corrective action or other regulatory action taken by virtue of Applicable Laws (a "**Remedial**

**Action**”). The Parties will assist each other in gathering and evaluating such information as is necessary to determine the necessity of conducting a Remedial Action. Licensee shall, and shall ensure that its Affiliates and Sublicensees will, maintain adequate records to permit the Parties to trace the packaging, labeling, distribution, sale and use (to the extent possible) of the Product in the Territory. Licensee shall have sole discretion and responsibilities with respect to any matters relating to any Remedial Action in the Territory, including the decision to commence such Remedial Action and the control over such Remedial Action in the Territory; provided, however, if Sutro determines in good faith that any Remedial Action with respect to any Product in the Territory should be commenced or is required by Applicable Laws or Regulatory Authority, (a) Sutro shall discuss such Remedial Action with Licensee and (b) Licensee shall carry out such Remedial Action upon Sutro’s request. Each Party shall provide the other Party with such assistance in connection with a Remedial Action as may be reasonably requested by such other Party. The Party responsible for the related loss, damage, adverse effects, accidents or product liability of any kind whatsoever shall be determined according to the circumstances of the event, including but not limited to: (i) defective quality of Product, (ii) inaccurate advertising, (iii) marketing issues, (iv) improper storage, and (v) infringement, and shall be responsible for and cover all costs and expenses associated with the Remedial Action.

(c) Licensee will [\*] notify Sutro any communication or correspondence with any Regulatory Authority that, to its knowledge, may affect the Development, Manufacture or Commercialization of the Product in the Field outside the Territory. Without limiting the foregoing, in the event that any Development, Manufacture or Commercialization activities hereunder (whether by Licensee, its Affiliates or their respective Sublicensees) could, to Licensee’s knowledge, cause any material delay or material negative consequences on the Development, Manufacture or Commercialization of the Product in or outside the Field anywhere in the world including outside of the Territory (“**Material Adverse Impact**”), Licensee will [\*] notify the JSC of any such activities, and the matter shall be resolved as set forth in Section 3.07. Without limiting the foregoing, unless the Parties otherwise agree in writing: (a) Licensee shall not communicate with any Regulatory Authority having jurisdiction outside the Territory, unless so ordered by such Regulatory Authority, in which case Licensee shall promptly notify Sutro of such order; and (b) Licensee shall not submit any Regulatory Documentation or seek Regulatory Approvals for the Product outside the Territory.

#### **Section 4.08 General Provisions Regarding Commercialization.**

(a) Licensee will control and perform, itself or through its Affiliates, or Sublicensees, the Commercialization of the Product throughout the Territory and, as a result, shall be obligated and responsible for using Commercially Reasonable Efforts to carry out such Commercialization in accordance with the Commercialization Plan (as defined below). Except to the extent otherwise described in this Agreement, Licensee will be solely responsible for, and will bear all costs relating to, the Commercialization of the Product in the Territory.

(b) Sutro shall use Commercially Reasonable Efforts to support Licensee’s post-approval regulatory activities with respect to the Product in the Territory, including those necessary to maintain Regulatory Approvals in the Territory, as reasonably requested by Licensee at Licensee’s cost (provided that internal FTE costs incurred by Sutro shall only be reimbursed to the extent the time cap in Section 4.12 is exceeded).

**Section 4.09 Commercialization Plan.** Licensee shall be responsible for providing to the JSC for review a [\*] plan specifying the major Commercialization activities, including revenue targets and regional price strategy, planned for the Product in the Territory with respect to each Indication for which it is seeking Regulatory Approval, and the timelines for achieving such activities (the “**Commercialization Plan**”). Licensee shall deliver an initial draft of the Commercialization Plan to Sutro for Sutro’s review no later than [\*] prior to the anticipated date of filing of the first BLA or Drug Approval Application for the Product in the Territory. Sutro shall have the right to comment prior to the submission of the Commercialization Plan to the JSC for review. Thereafter, from time to time, but at least every [\*], Licensee shall propose updates or amendments to the Commercialization Plan in consultation with Sutro to reflect changes in the plans, including those in response to changes in the marketplace, relative commercial success of the Product, and other relevant factors that may influence such plan and activities. Licensee shall submit the proposed updated or amended Commercialization Plan to the JSC for review.

**Section 4.10 Reports of Commercialization Activities.** For each Calendar Year following the first Regulatory Approval of the Product in the Territory, Licensee shall provide to Sutro [\*] a written report that summarizes the Commercialization activities performed by or on behalf of Licensee, its Affiliates and Sublicensees in the Territory since the prior report by Licensee. Such report shall contain sufficient detail to enable Sutro to assess Licensee’s compliance with its Commercialization obligations in Section 4.08. Such reports shall be Confidential Information to Licensee pursuant to Article 7. Licensee shall provide updates to any such reports at JSC meetings, as necessary, including quarterly updates on the progress toward achieving Sales Milestones Events under Section 6.03.

**Section 4.11 No Diversion.** Each of Sutro and Licensee hereby covenants and agrees that (a) it shall not, and shall ensure that its Affiliates, subcontractors and (sub)licensees shall not, directly or indirectly, promote, market, distribute, import, sell or have sold the Product, including via internet or mail order, outside its territory; (b) with respect to any country or region outside its territory, it shall not, and shall ensure that its Affiliates, subcontractors and (sub)licensees shall not: (i) unless otherwise agreed by the Parties in writing, establish or maintain any branch, warehouse or distribution facility for Product in such countries (except, in the event such Party is Licensee, Licensee shall have the right to maintain one or more warehouses outside the Territory solely to support the packaging and labelling activities of the Product by Licensee or its Affiliates outside the Territory and, in the event such Party is Sutro, Sutro shall have the right to maintain one or more warehouses in the Territory solely to support its retained rights provided under Section 2.03), (ii) engage in any advertising or promotional activities relating to Product that are directed primarily to customers or other purchaser or users of Product located in such countries, (iii) solicit orders for Product from any prospective purchaser located in such countries, or (iv) sell or distribute Product to any Person in such Party’s territory who, to the knowledge of such Party (following reasonable inquiry), intends to sell or has in the past sold Product in such countries; (c) if a Party receives any order for any Product from a prospective purchaser reasonably believed to be located in a region or country outside its territory, such Party shall promptly refer that order to the other Party, and such Party shall not accept any such orders; (d) neither Party shall deliver or tender (or cause to be delivered or tendered) Product into a country or region outside its territory, except that Sutro shall have the right to do so solely to support its retained rights provided under Section 2.03, and € each Party shall not, and shall ensure that its Affiliates and their respective subcontractors and sublicensees shall not, knowingly restrict or impede in any manner the other

Party's exercise of its rights to Commercialize the Product in the other Party's territory. For the purpose of this Agreement, Licensee's territory shall mean the Territory and Sutro's territory shall mean all countries and regions outside the Territory.

**Section 4.12 Limitation on Sutro's Obligations.** The Parties acknowledge and agree that, notwithstanding anything to the contrary hereunder, Sutro's obligation to provide any form of assistance to Licensee under this Article 4 (including under Sections 4.06 and 4.08(b)) shall be subject to the following: (a) Sutro will provide such assistance [\*] until the [\*], (b) thereafter, Sutro will provide such assistance [\*] for up to [\*] annually, (c) Sutro will provide any such additional assistance, upon Licensee's reasonable request in each case, at the then-applicable Sutro's FTE rate, and (d) [\*] by Sutro in connection with the activities under the foregoing sub-clauses (a)-(c) shall be [\*] reimbursed by Licensee.

## ARTICLE 5 SUPPLY

### Section 5.01 Supply.

(a) Sutro shall be responsible for supplying Product to Licensee to allow Licensee to conduct its Development and Commercialization activities in the Territory under this Agreement, as the Parties shall agree to in separate supply agreements. Within [\*] of the execution of this Agreement, the Parties will negotiate and agree in good faith the terms of, and will enter into, a full, separate manufacturing and supply agreement, covering supplies of Product for the clinical trials in the Territory (the "**Clinical Supply Agreement**"). No later than [\*] prior to the anticipated first Regulatory Approval of the Product in the Territory, and within [\*] following Licensee's written request, the Parties will either revise or enter into a new manufacturing and supply agreement, covering ordering and supplies for Commercialization purposes in the Territory (the "**Commercial Supply Agreement**"). The Clinical Supply Agreement and Commercial Supply Agreement shall provide specific terms and obligations concerning, among other things, forecasts, purchase orders, and supply of Product for the Territory, in accordance with Section 5.01(b)-(d) below, and the Clinical Supply Agreement shall include the material terms set forth on Exhibit F. The Parties shall also enter into a separate Quality Assurance Agreement ("**Quality Agreement**") within [\*] upon the Effective Date or otherwise agreed by both Parties. Such Quality Agreement shall define the manufacturing and supply quality responsibilities negotiated in good faith between the Parties. Sutro shall use Commercially Reasonable Efforts to ensure that any manufacturing agreement entered into with any Third Party to manufacture the Product under this Agreement contain a provision providing Licensee and its Affiliates with industry-standard indemnification, including against product liability claims.

(b) Development Supply. For supply of Product for Development (including all clinical or regulatory supplies necessary to obtain Regulatory Approval in the Territory) in the Territory, Sutro shall supply Product to Licensee for each Indication in accordance with the Clinical Supply Agreement at a price equal to:

(i) For Product (or components thereof) manufactured by Sutro or its Affiliates: [\*] of Sutro's Cost of Goods;

(ii) For Product (or components thereof) sourced by Sutro from one or more CMOs: the [\*] by Sutro to such CMO(s) for the manufacture and supply of such Product, and any associated third-party costs (e.g., insurance and shipping) plus a [\*].

(c) Commercial Supply. For supply of Product for Commercialization purposes, Sutro shall be responsible for supplying such Product to Licensee in accordance with the Commercial Supply Agreement at a price equal to:

(i) For Product (or components thereof) manufactured by Sutro or its Affiliates: [\*] of Sutro's Cost of Goods; (ii) For Product (or components thereof) sourced by Sutro from one or more CMOs: the actual invoiced price paid by Sutro to such CMO(s) for the manufacture and supply of such Product, and any associated third-party costs (e.g., insurance and shipping) plus a [\*].

(d) The Commercial Supply Agreement shall specify, among other things: (i) a rolling forecast with binding periods (subject to mutually agreed upon variances); (ii) a binding purchase order requirement with a sufficient lead time for Sutro to incorporate such orders under its then-current contract manufacturing orders with the Manufacturer(s); and (iii) the Product to be supplied Ex Works (Incoterms 2020).

#### **Section 5.02 Manufacture and Supply.**

(a) Notwithstanding anything to the contrary herein, without Sutro's written consent, Licensee shall not (i) (except following a technology transfer in accordance with Section 5.02(b)) Manufacture or have Manufactured, itself or through an Affiliate or Sublicensee, or authorize or license any Third Party to Manufacture or have Manufactured the Product; (ii) supply any Product it receives from the Manufacturer under this Agreement to any Third Party for any Third Party use, other than Development, compassionate use or patient assistance program and Commercialization of the Product in compliance with this Agreement; or (iii) purchase any Product from any party other than the Manufacturer pursuant to the Supply Agreement.

(b) After the Effective Date, and within [\*] of Licensee's request, the Parties shall use good faith efforts to enter into a manufacturing technology transfer agreement for the Manufacture of the Product ("**Manufacturing Technology Transfer Agreement**"). Under such Manufacturing Technology Transfer Agreement, Sutro shall provide to Licensee (i) all the Sutro Know-How, Sutro Manufacturing Information and any other information and documents, as well as tangible materials, including but not limited to [\*] (in each case, except to the extent commercially available), in each case to the extent Controlled by Sutro and reasonably necessary for Licensee to exercise the Manufacture License (the "**Manufacturing Technology**"), and (ii) such technical assistance and support necessary or reasonably useful for Licensee to Manufacture, or have Manufactured by a Third Party contractor engaged by Licensee and reasonably acceptable to Sutro ("**Licensee CMO**"), the clinical and commercial formulation of the Product. The transfer of Manufacturing Technology to Licensee shall be free of charge, except that Licensee shall pay Sutro's costs of the materials described under the foregoing sub-clause (i), and shall further pay Sutro's FTE costs reasonably incurred in connection with the activities described in the foregoing sub-clause (ii). The Manufacturing Technology Transfer Agreement shall include terms providing Licensee sufficient rights to use the Manufacturing Technology, which shall not be inconsistent



with the terms and conditions in this Agreement. In connection with the execution of the Manufacturing Technology Transfer Agreement, Sutro shall grant Licensee a royalty-free non-exclusive license to Manufacture or have Manufactured the Product during the Term, within the Territory, by itself or through an Affiliate or Sublicensee, or authorize or license any Third Party, under Sutro Know-How, Sutro Patents, Sutro Manufacturing Information and any aspect of the Sutro's Intellectual Property Rights related thereto (the "**Manufacture License**"). Notwithstanding anything to the contrary, the Manufacture License shall not include any right to access or use any Expression Technology, and Sutro shall have no obligation to deliver to Licensee any Sutro Know-How or Sutro Manufacturing Information related to Expression Technology; provided, however, that Sutro shall provide Licensee with the cell extracts for expressing the protein as set forth in a separate supply agreement (the "**Extract Supply Agreement**") under commercially reasonable terms to be separately negotiated by the Parties in good faith (it being understood that the handling fee for supplies sourced from CMOs shall not exceed [\*]). [\*].

(c)[\*].

## **ARTICLE 6 CONSIDERATION**

**Section 6.01 Upfront Payment.** As payment for the rights and licenses granted to Licensee by Sutro under this Agreement, Licensee shall pay to Sutro a non-refundable, upfront payment of Forty Million U.S. Dollars (USD \$40,000,000.00), which will be paid within the earlier of (i) [\*] and (ii) [\*], by wire transfer of immediately available funds denominated in U.S. Dollars to an account designated by Sutro.

**Section 6.02 Development Milestone.** Upon achievement by or on behalf of Licensee, its Affiliates or its or their Sublicensees of any milestone event set forth in this Section 6.02 (each, a "**Development Milestone Event**"), Licensee will (a) notify Sutro in writing thereof within [\*] following such achievement and (b) pay Sutro each of the milestone payments set forth in the table below (each, a "**Development Milestone Payment**"), in each case within [\*] of such achievement. Licensee shall notify Sutro in writing of the achievement of each such Development Milestone Event promptly after the occurrence thereof as set forth above, except that Sutro shall notify Licensee of the achievement of the Development Milestone Events occurring in the U.S. in accordance with the table below (i.e., [\*] and [\*], in each case only to the extent provided for in the table below). For purposes of this Section 6.02, "Regulatory Approval" shall be deemed to exclude pricing and reimbursement approvals.

Development Milestone Event	Development Milestone Payment
<u>Ovarian Cancer</u>	
[*]	[*]
[*]	[*]
[*]	[*]
[*]	[*]
[*]	[*]
[*]	[*]
[*]	[*]
[*]	[*]
[*]	[*]
<u>TNBC</u>	
[*]	[*]
[*]	[*]
<u>Fourth Target Indication (other than the 3 Target Indications set forth above)</u>	
[*]	[*]
[*]	[*]
<b>Total</b>	[*]

[\*]

**Section 6.03 Sales Milestones.** During the Term, Licensee will notify Sutro in writing of its achievement of each of the sales milestones below (each, a “**Sales Milestone Event**”) upon the earlier of (i) within [\*] after the publication of Licensee’s audited annual report for the Calendar Year in which the Sales Milestone Event has occurred , and (ii) with [\*] after the end of the first Calendar Quarter following the end of the Calendar Year in which the Sales Milestone Event has occurred. Licensee will pay to Sutro each of the milestone payments set forth below [\*] after such notification of achievement and after Licensee receives an invoice therefor from Sutro (each, a

“Sales Milestone Payment”). Each of the Sales Milestone Payments for Products set forth in this Section 6.03 is payable only once upon the first achievement of such Sales Milestone Event with respect to all Products, in the aggregate, and none of such Sales Milestone Payments will be payable more than once regardless of how many times such Sales Milestone Event is achieved with respect to all Products, in the aggregate.

Sales Milestone Event	Sales Milestone Payment
[*]	[*]
[*]	[*]
[*]	[*]
[*]	[*]
<b>Total</b>	[*]

Sales between Licensee, its Affiliates and Sublicensees shall not be subject to Sales Milestone Payments hereunder. Sales Milestone Payments shall be calculated on Licensee’s, its Affiliates’ and Sublicensees’ sales of the Product to a Third Party.

**Section 6.04 Royalties.**

(a) Subject to the remainder of this Section 6.04 and Section 6.05, Licensee shall pay to Sutro a royalty on the Annual Net Sales of the Product in the Territory made by Licensee, its Affiliates, or its Sublicensees at the following rates:

Portion	Range of Annual Net Sales (USD)	Royalty Rate
①	[*]	[*]
②	[*]	[*]
③	[*]	[*]

Royalty for a given Calendar Year = [\*]

For avoidance of doubt, each royalty rate set forth in the table above shall apply only to that portion of the Annual Net Sales in the Territory during a given Calendar Year that falls within the indicated range.

(b) Sales between Licensee, its Affiliates and Sublicensees shall not be subject to royalties hereunder. Royalties shall be calculated on Licensee's, its Affiliates' and Sublicensees' (re)sale of the Product to a Third Party.

(c) Royalty Term. The royalty payments payable under this Section 6.04 shall be payable on [\*] until the later of, on [\*]: (i) the [\*]; or (ii) [\*] after the First Commercial Sale of the Product in such Region (the "**Royalty Term**").

(d) Third Party Blocking Patents.

(i) Process. In the event either Party becomes aware of one or more Patents Controlled by a Third Party that such Party considers necessary to Develop, Manufacture or Commercialize the Product in the Field in the Territory (each a "**Third Party Blocking Patent**"), such Party will provide notice thereof to the other Party ("**Blocking Patent Notice**"), and Sutro will have the first right to obtain a license to the applicable Third Party Blocking Patent(s) from such Third Party. In the event Sutro or any of its Affiliates obtains a license to such Third Party Blocking Patent(s) such that it Controls such Third Party Blocking Patents, such Third Party Blocking Patent(s) will be automatically included in the Sutro Patents, and subject to the Third Party Compensation Reduction (as defined in Section 6.04(d)(ii)), Licensee will be responsible for paying the amounts due under such license in consideration for the practice of such Third Party Blocking Patents under this Agreement, whether by Licensee, its Affiliates or their respective Sublicensees.

(ii) Third Party Compensation. If Licensee determines that it is necessary to obtain a license to one or more Third Party Blocking Patent(s) from any Third Party and Sutro does not obtain such license within [\*] of the date of receipt of the Blocking Patent Notice, Licensee will have the right to obtain a license to such Third Party Blocking Patent(s) from such Third Party. If Licensee is required to pay to Third Party a royalty or other monetary compensation in consideration for the grant of such license or maintenance of the right to Commercialize the Product under such Third Party Blocking Patent(s) ("**Third Party Compensation**"), then, provided that (i) Sutro has consented in writing to the terms (including, without limitation, the payment terms) of such Third Party license, which shall not be unreasonably withheld, delayed or conditioned; or (ii) subject to the result of (x) settlement procedures or litigation under Section 8.04(c) or (y) other settlements, for the period during which Licensee owes royalties to Sutro hereunder, then the royalties that would otherwise be payable on Net Sales in the Territory under Section 6.04(a) shall be reduced by an amount of [\*] of all Third Party Compensation payable by or on behalf of Licensee to such Third Party during the same period, provided that in no event shall such royalties be reduced by more than [\*] of the amounts otherwise payable to Sutro under Section 6.04(a) (such reduction, the "**Third Party Compensation Reduction**").

(e) Biosimilar Competition. If in a particular Calendar Quarter during the Royalty Term, one or more Third Parties is or are selling a Biosimilar Product in any Region within the Territory and the Net Sales of the Product in such Region during such Calendar Quarter (or any Calendar Quarter thereafter) are less than [\*] of the average [\*] of the Product in such Region

over the [\*] immediately prior to the Calendar Quarter during which the first such Biosimilar Product was sold in such Region “**Biosimilar Reduction Trigger**”), then in such case the royalties payable on the Net Sales of the Product in such Region commencing with such Calendar Quarter in which the Biosimilar Reduction Trigger occurred and thereafter for each Calendar Quarter during the Royalty Term in which such Biosimilar Product is sold in such Region, shall be reduced by [\*] of the amounts otherwise payable to Sutro under Section 6.04(a).

(f) Notwithstanding anything to the contrary under this Agreement, in no event shall the royalties payable to Sutro hereunder be reduced by more than [\*] of the amounts set forth in Section 6.04(a).

**Section 6.05 Sales by Sublicensees.** In the event that Licensee grants sublicenses to one or more Sublicensees to sell Product to the extent permitted hereunder, such sublicenses shall include without limitation an obligation for the Sublicensee to account for and report its Net Sales of such Product on the same basis as if such sales were Net Sales by Licensee, and Licensee shall pay royalties and sales milestones to Sutro as if the Net Sales of the Sublicensee were Net Sales of Licensee.

**Section 6.06 Royalty Payments and Reports.** The royalties payable under Section 6.04 shall be calculated quarterly as of the last day of March, June, September and December respectively for the Calendar Quarter ending on that date. Licensee shall deliver to Sutro a report summarizing the Net Sales of Product during each Calendar Quarter following the First Commercial Sale of Product in the Territory, which shall include the number of units of Product sold by Licensee, its Affiliates and its or their Sublicensees in each Region, the gross sales of Product on a Region-by-Region and Product-by-Product basis, an itemized calculation of any deductions taken from such gross sales to arrive at Net Sales for the applicable Calendar Quarter and the calculation of the amount of royalty payment due on such Net Sales. A draft of such report shall be provided within [\*] following the end of each Calendar Quarter for which royalties are due from Licensee to allow Sutro to estimate its royalty payments from Licensee. A final report shall be delivered within [\*] following the end of each Calendar Quarter. Any royalty payable to Sutro or its designee under this Agreement shall be paid with [\*] after the end of each Calendar Quarter. The report for the fourth Calendar Quarter shall summarize the Annual Net Sales of Product in such given Calendar Year and shall calculate all the royalties payable to Sutro or its designee for such given Calendar Year pursuant to Section 6.04(a). The royalties to be paid for the fourth Calendar Quarter under this Section 6.06 shall be the difference between the royalties payable and the royalties already paid for such given Calendar Year. If, however, after all the royalty payment due for a given Calendar Year is paid to Sutro, but the Licensee discovers that the Annual Net Sales number reported in the fourth Calendar Quarter report needs to be adjusted in accordance with the Licensee’s audited annual report for such Calendar Year (provided that, for clarity, such report is consistent with the definition of Net Sales under Section 1.62), then Licensee may, subject to prior review and comments by Sutro, adjust and reconcile any such calculation of Annual Net Sales and/or any such underpayment or overpayment of royalty payments due and report such adjustment to Sutro within [\*] after the Licensee’s audited annual report is publicly disclosed. Any adjustment and reconciliation of royalty payment for the previous Calendar Year shall be reflected in royalty payment due for the Calendar Quarter in which such adjustment and reconciliation is reported to Sutro, and such adjustment and reconciliation (in the case of an underpayment) shall not be considered a late payment under Section 6.12.

## Section 6.07 Taxes.

(a) The royalties, milestones and other amounts payable by Licensee to Sutro pursuant to this Agreement (“**Payments**”), shall not be reduced on account of Taxes unless required by Applicable Laws. Sutro shall pay [\*] Withholding Income Tax up to and including [\*]. Licensee shall pay the Withholding Income Tax exceeding [\*] up to and including [\*]. Any increase beyond [\*] shall be paid for [\*]. In the event Licensee pays any Withholding Income Tax under the preceding sentences, Licensee shall increase the Payments made so that Sutro receives the same amount after tax (taking into account any Taxes on such increased payments) as it would have received had such Withholding Income Taxes not been incurred. Licensee is permitted to reduce the amount of Payments to Sutro equal to the amount of the Withholding Income Tax paid by [\*]. To the extent any Payments made by Licensee pursuant to this Agreement become subject to Withholding Income Tax under Applicable Laws, Licensee shall deduct and withhold the amount of such Taxes from the Payments due Sutro, but only to the extent that Sutro is required to pay such Taxes under this Agreement. Licensee shall remit the amounts of Withholding Income Tax, whether paid by Sutro or Licensee, to the proper governmental authorities in a timely manner and transmit to Sutro an official tax certificate or other evidence of payment of such tax obligations from the relevant governmental authorities. All taxes or duties in connection with payments made by Licensee for Indirect Taxes, including any value added or similar tax or local tax or surcharge on value added taxes and any import duty or fees, shall be paid by Licensee. Notwithstanding the foregoing, if Sutro is entitled (whether under any applicable tax treaty or otherwise under Applicable Laws) to a reduction in the rate of, or the elimination of, Withholding Income Tax, it may deliver to Licensee or the appropriate governmental authority (with the assistance of Licensee to the extent that this is reasonably required and is expressly requested in writing), the prescribed forms necessary to reduce or eliminate the applicable rate of Withholding Income Tax, and Licensee shall apply the reduced rate of withholding, or dispense with withholding, as applicable. Licensee agrees to take all other reasonable and lawful efforts to minimize such Withholding Income Tax, and Licensee shall cooperate with Sutro as reasonably requested in any claim for refund or application to any Tax Authority. If Licensee intends to withhold income Tax from any Payments, Licensee shall inform Sutro reasonably in advance of making such Payments to permit Sutro an opportunity to provide any forms or information or obtain any Tax Authority approval as may be available to reduce or eliminate such withholding.

(b) Tax Gross-up. Notwithstanding anything to the contrary herein, if (i) Licensee redomiciles or assigns its rights or obligations under this Agreement, (ii) as a result of such redomiciliation or assignment, Licensee (or its assignee) is required by Applicable Law to withhold taxes from or in respect of any amount payable under this Agreement, and (iii) such withholding taxes (which would include Withholding Income Tax) exceed the amount of withholding taxes that would have been applicable but for such redomiciliation or assignment, then any such amount payable to Sutro pursuant to this Agreement shall be increased to take into account such withholding taxes as may be necessary so that, after making all required withholdings (including withholdings on the additional amounts payable), as the case may be, Sutro receives an amount equal to the sum it would have received had no such increased withholding been made and no such Indirect Taxes had been imposed. The obligation to pay additional amounts pursuant to the preceding sentence shall not apply, however, to the extent such increased withholding tax would not have been imposed but for the assignment by Sutro of its rights or obligations under this Agreement or the redomiciliation of Sutro outside of the United States, to the extent such

assignment or redomiciliation occurs after the redomiciliation or assignment by Licensee described in the first sentence of this Section 6.07(b). Solely for purposes of this Section 6.07(b), a Party's "**domicile**" shall include its jurisdiction of incorporation or tax residence and a "**redomiciliation**" shall include a reincorporation or other action resulting in a change in tax residence of the applicable Party or its assignee.

(c)Notwithstanding anything to the contrary contained in this Section 6.07 or elsewhere in this Agreement, the following shall apply with respect to Indirect Taxes. If any Indirect Taxes imposed by relevant Regulatory Authorities in the Territory are chargeable in respect of any Payments, Licensee shall be responsible for such Indirect Taxes and shall not reduce any Payments due Sutro hereunder as a result of such Indirect Taxes. The sum of the net amount received by Sutro and the Withholding Income Tax levied by China Tax Authority discussed in Section 6.07(a) above for each payment shall not be less than the amount of the Upfront and Milestone Payments set forth in Section 6.01, Section 6.02 and Section 6.03. The Parties shall issue invoices for all goods and services supplied under this Agreement consistent with Indirect Tax requirements, and to the extent any invoice is not initially issued in an appropriate form, Licensee shall promptly inform Sutro and shall cooperate with Sutro to provide such information or assistance as may be necessary to enable the issuance of such invoice consistent with Indirect Tax requirements.

**Section 6.08 Payments or Reports by Affiliates.** Any Payment required under any provision of this Agreement to be made to Sutro or any report required to be made by Licensee shall be made by an Affiliate of Licensee if such Affiliate is designated by Licensee as the appropriate payer or reporting entity.

**Section 6.09 Mode of Payment.** All payments set forth in this Article 6 shall be remitted by wire transfer to the bank account of Sutro as designated in writing to Licensee.

**Section 6.10 Payment Currency.** All amounts payable and calculations under this Agreement shall be in U.S. Dollars. As applicable, Net Sales and any adjustments to payments under this Agreement shall be translated into United States dollars using the average of the applicable daily foreign exchange rates published in The Wall Street Journal (or any other qualified source that is acceptable to both Parties) for the last day of each month of the Calendar Quarter in which such Net Sales occurred.

**Section 6.11 Imports.** For the avoidance of doubt, the Parties acknowledge and agree that none of the milestones or royalties payable under this Agreement are related to the license (or right) to import or any import of the Product. Licensee shall be responsible for any import clearance, including payment of any import duties and similar charges, in connection with the Product transferred to Licensee under this Agreement. The Parties shall co-operate in accordance with Applicable Laws to ensure where permissible that no import duties are paid on imported materials. Where import duties are payable, the Parties shall co-operate to ensure that the Party responsible for shipping values the materials in accordance with Applicable Laws and minimizes where permissible any such duties and any related import taxes that are not reclaimable from the relevant authorities.

**Section 6.12 Late Payments.** Any payments due under this Agreement shall be due on such date as specified in this Agreement and, in the event such date is not a Business Day, then the next succeeding Business Day. In the event that any payment due under this Agreement is not made when due, the amount due shall accrue interest beginning on the [\*] following the date on which such payment was due, calculated at the annual rate equal to the prime interest rate reported in the Wall Street Journal for the due date plus [\*], calculated from the due date until paid in full. Each payment made after the due date shall be accompanied by all interest so accrued. Notwithstanding the foregoing, a Party shall have recourse to any other remedy available at law or in equity with respect to any delinquent payment, subject to the terms of this Agreement.

## **ARTICLE 7 CONFIDENTIALITY**

**Section 7.01 Confidentiality.** The Parties agree that the Party receiving Confidential Information disclosed by or on behalf of the other Party pursuant to this Agreement is entitled to disclose Confidential Information to its Affiliates, Sublicensees (in the case of Licensee), licensees (in the case of Sutro), contractors, their respective officers, directors, employees, agents, counsels, accountants, other advisors and consultants, only for the purpose of the Agreement on a need-to-know basis, and shall cause the aforesaid persons to keep confidential and not publish or otherwise disclose or use for any purpose other than to conduct its activities under this Agreement or otherwise as expressly authorized by this Agreement any Confidential Information furnished to it by or on behalf of the other Party pursuant to this Agreement.

**Section 7.02 Exceptions.** Notwithstanding the foregoing, the obligations set forth in Section 7.01 shall not apply in respect of Confidential Information to the extent that it can be established by the receiving Party that such Confidential Information:

- (a) was already known to the receiving Party, other than under an obligation of confidentiality, at the time of disclosure by or on behalf of the other Party;
- (b) was generally available to the public or otherwise part of the public domain at the time of its disclosure to the receiving Party;
- (c) was independently developed without use of the disclosing Party's information, as evidenced by contemporaneous written records;
- (d) became generally available to the public or otherwise part of the public domain after its disclosure to the receiving Party and other than through any act or omission of the receiving Party in breach of this Agreement; or
- (e) was disclosed to the receiving Party, other than under an obligation of confidentiality, by a Third Party who had no obligation to the disclosing Party not to disclose such information to others.

**Section 7.03 Receipt of Third Party Information.** Neither Party shall knowingly receive documents relating to the Product under an obligation of confidentiality to Third Parties that requires the Party to withhold access to the other Party without such Party's written consent.



**Section 7.04 Authorized Disclosure.** The receiving Party may disclose Confidential Information of the disclosing Party to a Third Party only upon reasonable advanced notice to the disclosing Party and only to the extent that such disclosure is:

(a) required by law, order, or regulation of a government agency or a court of competent jurisdiction, or by the rules of a securities exchange, provided that the receiving Party required to make such disclosure shall, after providing reasonable advanced notice to the disclosing Party before the disclosure, (i) give the disclosing Party an opportunity to comment on any such required disclosure, (ii) if requested by the disclosing Party, use Commercially Reasonable Efforts to obtain protective orders or any available limitations on or exemptions from such disclosure requirement where applicable and practicable;

(b) made to a patent office for the purposes of filing or enforcing a Patent as permitted in this Agreement, provided, however, the receiving Party (i) receives written consent from the disclosing Party for such disclosure, and (ii) takes reasonable measures to assure confidential treatment of such information, to the extent such protection is available;

(c) made by a Party or its Affiliates, or Sublicensees to the Regulatory Health Authority for the purposes of any filing, application or request for Regulatory Approval for the Product as permitted in this Agreement;

(d) made to advisors, actual or potential Third Party partners, investors, licensees, sublicensees or acquirers of all or substantially all of the assets to which this Agreement relates, solely in connection with due diligence activities; provided, however, the receiving Party takes reasonable measures to assure confidential treatment of such information, to the extent such protection is available;

(e) made by Licensee or its Affiliates, or Sublicensees to Third Parties as may be necessary or useful in connection with the Exploitation and Manufacturing of the Product as contemplated by this Agreement, including subcontracting or sublicensing transactions permitted hereunder in connection therewith; provided that the Party making such disclosures shall ensure that each Third Party recipient is bound by obligations of confidentiality no less restrictive than those contained in this Agreement and shall be liable to the other Party for any breach of such confidentiality obligations by the relevant recipient.

**Section 7.05 Survival.** This Article 7 (other than Section 7.03) shall survive for a period of five (5) years following the termination or expiration of the Agreement, provided however, that all Trade Secret information shall be safeguarded by the receiving Party as required by this Agreement in perpetuity or for so long as such information remains a Trade Secret under Applicable Law.

**Section 7.06 Termination of Prior Agreements.** This Agreement supersedes the Confidentiality Agreement between Sutro and Licensee dated as of June 10, 2021 (the “CDA”). All Information and Materials exchanged between the Parties under the CDA shall be deemed Confidential Information and shall be subject to the terms of this Article 7.

**Section 7.07 Publications.** Except as required by law, Licensee agrees that it shall not publish or publicly present any scientific, technical, or academic information relating to the Product (a) without the prior written consent of Sutro and (b) other than in compliance with this

Section 7.07. For the avoidance of doubt, advertising information shall be subject to this Section 7.07 if it is not in accordance with the approved label or published academic papers. Licensee shall provide to Sutro the opportunity to review any proposed publications, presentations, meeting abstracts, talks or other publicity (including without limitation information to be presented verbally) that relate to the Product as early as reasonably practical, but at least [\*] prior to their intended submission for publication or presentation, and Licensee agrees, upon written request from Sutro within the Review Period (as defined below), not to submit such abstract, manuscript, or other publicity materials for publication or to make such presentation until Sutro agrees, which agreement by Sutro shall not be unreasonably withheld. Sutro shall have [\*] after its receipt of any such publication or presentation (the “**Review Period**”) to notify Licensee in writing of any specific objections to the intended publication or presentation. Licensee shall, in any such publication or presentation, delete from the proposed disclosure any Confidential Information of Sutro. Additionally, if Sutro notifies Licensee within the Review Period that it objects to such disclosure on the basis that a patent application claiming information contained in such disclosure should be filed prior to such disclosure, Licensee agrees to reasonably delay disclosure of the relevant information, for up to [\*] after Sutro’s timely notification of its objection as per the above, or until such application has been filed, if earlier. Once any such abstract or manuscript is accepted for publication, Licensee will provide Sutro with a copy of the final version of the manuscript or abstract.

## **ARTICLE 8 OWNERSHIP OF INTELLECTUAL PROPERTY AND PATENT RIGHTS**

**Section 8.01 Ownership.** Except as expressly provided in this Agreement, Sutro shall retain sole and exclusive Control of the Sutro Technology, including Sutro Know-How, Sutro Patents, and Sutro Trademarks. Except as expressly provided herein, no right, title, or interest is granted by Sutro to Licensee in, to, or under any Sutro Technology, and, except as expressly provided herein, Licensee shall have no right to assign to any Third Party any right or interest received under Sutro Technology under the terms of this Agreement. Licensee shall retain sole and exclusive Control of any Licensee Technology.

**Section 8.02 License of Product-related IPR.** Licensee hereby grants to Sutro a royalty-free, fully paid-up, perpetual, non-terminable, sublicenseable (through multiple tiers) license to use any Product-related IPR that Licensee or its Affiliates or Sublicensees may create or acquire throughout the Term of this Agreement, which license shall be non-exclusive in the Territory and exclusive (including as to Licensee and its Affiliates) outside of the Territory; provided, however, that the license granted to Sutro by Licensee under this Section 8.02 in the Territory is limited to the use of Product-related IPR by Sutro in conducting clinical or manufacturing activities in the Territory for the purpose of Development and Commercialization of the Product outside the Territory. Licensee shall be responsible for ensuring its employees, Affiliates, and Sublicensees are obligated to license and execute appropriate documents consistent with Licensee’s obligations under this Section 8.02.

### **Section 8.03 Prosecution and Maintenance of Patents.**

(a) Sutro shall be primarily responsible for and control the preparation, filing, prosecution, and maintenance of the Sutro Patents in the Territory. Sutro shall, at its own cost, file,

prosecute, and maintain all Sutro Patents in the Territory after taking into account Licensee's reasonable interests and requests after reasonable consultation with Licensee. Sutro shall provide Licensee with advance copies of, and a reasonable opportunity to comment upon, proposed patent filings, related prosecution strategies and proposed correspondence with patent officials, all to the extent in the Territory and relating to any Sutro Patents, and will consider comments received from Licensee with respect to such proposed filings, strategies and correspondence in the Territory in good faith. Sutro agrees to discuss in good faith any changes reasonably requested by Licensee to such filings, strategies and correspondence in the Territory upon their being received. As relevant to the activities and interests of Licensee under this Agreement, Sutro shall promptly inform Licensee in writing of any change in the status of the Sutro Patents in the Territory.

(b) If, during the Term, Sutro decides that it is no longer interested in the prosecution or maintenance of a particular Sutro Patent in the Territory, then, unless Sutro has a strategic rationale for ceasing such prosecution or maintenance, it will provide written notice to Licensee of such decision at least [\*] prior to the date that such Sutro Patent will become abandoned. Licensee may, upon written notice to Sutro, cause Sutro not to cease the prosecution or maintenance of any such Sutro Patent with respect to which Sutro does not have a strategic rationale for the abandonment thereof.

#### **Section 8.04 Enforcement Rights.**

(a) **Infringement by Third Parties in the Territory.** Sutro shall have the initial right, but not the obligation, at its expense and in its own name or in the name of any of its Affiliates, to initiate, maintain, and control any legal action on account of any infringement within the Territory of any Sutro Patent or Sutro Trademark by a Third Party, by counsel of its own choice. Sutro shall promptly notify Licensee in writing its intention to initiate legal action against a Third Party for such infringement within the Territory. If Sutro exercises its first right, Licensee will, at Sutro's expense, provide Sutro cooperation as reasonably necessary, including being named as a party. With respect to actions, proceedings or settlements in the Territory, Licensee shall have the right, in Licensee's sole discretion and at Licensee's expense, to join or otherwise participate in such legal action in the Territory with legal counsel selected by Licensee. If Sutro does not intend to exercise its first right, then Sutro shall so notify Licensee in writing within [\*] of receiving notice or otherwise becoming aware that the applicable infringement exists. Licensee will thereafter have the right, but not the obligation, at its expense and in its own name or in the name of any of its Affiliates, to initiate, maintain, and control such legal action on Sutro's behalf by counsel of its choice. In the event that Licensee initiates and thereafter maintains such legal action against a Third Party for infringement of a Sutro Patent or Sutro Trademark in the Territory, Sutro, at Licensee's expense, will provide Licensee cooperation as reasonably necessary, including agreeing to be named as a party to such legal action.

(b) The Party first having Knowledge that any Sutro Technology is infringed, or misappropriated by a Third Party, or suspected of being infringed or misappropriated by a Third Party in the Territory shall promptly notify the other Party thereof in writing. Such notice shall set forth the facts of that infringement, misappropriation, or suspected infringement or misappropriation in reasonable detail.

(c)**Allocation of Expenses and Recoveries.** Except as otherwise agreed by the Parties in this Agreement or otherwise in writing, the Party controlling the legal action under Section 8.04 (a) shall be solely responsible for any expenses incurred by such Party as a result of such action. If the Parties are recovered monetary damages in such action, such amounts shall be allocated first to the reimbursement of any expenses incurred by the Parties in such action, and any remaining amounts shall be [\*] between the Parties, provided that if Licensee is the enforcing Party, then such remaining amounts will be treated as Net Sales in the period in which payment of such recovery was received for purposes of the royalty obligations under Section 6.04. If such recovery is insufficient to reimburse the expenses of the Parties, then each Party shall receive a pro rata portion of the recovery based on each Party's expenses incurred in such action.

(d)**Oppositions by Parties.** If either Party desires to bring an opposition, action for declaratory judgment, nullity action, interference, reexamination, or other attack upon the validity, title, or enforceability of any Patents Controlled by a Third Party in the Territory that claim the Development or Commercialization or other exploitation of the Product, such Party shall so notify the other Party in writing, and the Parties shall promptly confer to discuss whether to bring such action or the manner in which to settle such action; provided, if the Parties cannot reach agreement on whether to bring such action within [\*] of such written notice, then such issue shall be subject to the dispute resolution procedures of Article 13. The Party not bringing an action under this Section 8.04(d) shall be entitled to separate representation in such proceeding by counsel of its own choice and at its own expense, and shall otherwise cooperate fully with the Party bringing such action at the other Party's expense.

### **Section 8.05 Third Party Claims Against Product in the Territory.**

(a) If a Third Party asserts that a Patent or other right owned or controlled by it is infringed by the Development, Manufacture or Commercialization of the Product in the Territory, the Party first having notice of the claim or assertion shall promptly notify the other Party, and the Parties shall promptly confer to consider the claim or assertion and the appropriate course of action. Unless the Parties otherwise agree in writing, each Party shall have the right to defend itself against a suit that names it as a defendant (the "**Defending Party**"), provided that (i) neither Party shall enter into any settlement of any claim described in this Section 8.05(a) or make any admissions or assert any positions in such defense proceeding in a manner that could reasonably be expected to adversely affect the rights or interests of the other Party, including with respect to the Product or the Development, Manufacture, or Commercialization of the Product within the other Party's territory, without the prior written consent of the other Party, and (ii) Licensee may not enforce any Sutro Patent in connection with such suit without Sutro's consent, not to be unreasonably withheld, conditioned or delayed. In any event, the other Party shall reasonably assist the Defending Party and cooperate in any such litigation at the Defending Party's reasonable request and expense.

If as a result of settlement procedures or litigation under this Section 8.05(a), Licensee is required to pay the Third Party a royalty or make any payment of any kind for the right to sell the Product in the Territory, such payments shall be considered Third Party Compensation under Section

6.04(d) and Licensee may deduct such Third Party Compensation from its royalty payment obligations to Sutro in accordance with Section 6.04(d).

(b)**Oppositions by Third Parties.** If any Sutro Patent in the Territory becomes the subject of any proceeding commenced by a Third Party in connection with an opposition, reexamination request, action for declaratory judgment, nullity action, third party observation interference, or other attack upon the validity, title, or enforceability thereof in the Territory, then Sutro shall control such defense, at its sole cost, provided that, Licensee shall have the right to participate in the proceeding to the extent permissible under law, and to be represented by its own counsel in such proceeding, at its sole cost. Licensee shall reasonably cooperate with Sutro in such proceeding. Any recoveries obtained in such action shall be shared, as set forth in Section 8.04(c).

(c)**Protective Order.** If, in any action brought pursuant to Section 8.04 and this Section 8.05 any information is the subject of a protective order that may be reviewed by counsel only, the Parties will endeavor to structure such protective order so as to enable their respective internal counsel to be included as permitted reviewers of such information.

## **ARTICLE 9 REPRESENTATIONS, WARRANTIES, AND COVENANTS**

### **Section 9.01 Representations, Warranties, and Covenants.**

(a) Each of the Parties hereby represents and warrants to the other Party that:

(i) It is a corporation or limited company duly organized, validly existing, and in good standing under the laws of the jurisdiction of its organization, and it has the full right, power and authority to enter into this Agreement and to perform its obligations hereunder.

(ii) All consents, approvals, and authorizations from all Regulatory Authorities or other Third Parties required to be obtained by such Party to execute this Agreement have been obtained.

(iii) This Agreement has been duly executed by it and is legally binding upon it, enforceable in accordance with its terms, and does not conflict with any agreement, instrument or understanding, oral or written, to which it is a party or by which it may be bound, nor violate any Applicable Law or regulation of any court, governmental body, or administrative or other agency having jurisdiction over it.

(b) Sutro represents, warrants and covenants as of the Effective Date (or as of such other/additional time as may be explicitly specified below) to Licensee that:

(i) Sutro Controls the Sutro Technology, and has the right to grant to Licensee the licenses that it purports to grant hereunder.

(ii) Sutro has not granted, and shall not grant during the Term, to any Third Party any rights would be in conflict with the rights granted to Licensee under this Agreement.

(iii) Sutro is the sole and exclusive owner of the entire right, title and interest in the Sutro Patents. All Sutro Patents as of the Effective Date are listed in Exhibit A. To Sutro's

knowledge, the Sutro Patents are (a) subsisting and in good standing and (b) being diligently prosecuted in the respective patent offices in accordance with Applicable Laws, and have been filed and maintained properly and correctly.

(iv) To Sutro's Knowledge, the Sutro Know-How has not infringed and, if used in accordance with this Agreement, will not infringe any Intellectual Property Rights of any Third Party in the Territory.

(v) To Sutro's Knowledge, all applicable fees due to patent authorities with respect to the filing and prosecution of the Sutro Patents existing as of the Effective Date have been paid on or before the due date for payment (as such due date may be extended in accordance with Applicable Law or patent authority rules and regulations) and will be paid in time during the Term.

(vi) As of the Effective Date, to Sutro's Knowledge, there is no actual or threatened infringement or misappropriation of the Sutro Technology in the Territory by any Person.

(vii) There is no action, suit, inquiry, investigation or other proceeding threatened, pending, or ongoing by any Third Party that challenges or threatens the validity, enforceability or Sutro's Control of any of the Sutro Patents or Sutro Trademarks in the Territory. In the event that Sutro receives notice of any such action or proceeding, it shall notify Licensee promptly in writing.

(viii) There is no pending or, to its knowledge, threatened, litigation or arbitration which alleges, or any written communication alleging, that Sutro's activities with respect to the Sutro Know-How or the Licensed Compound have infringed or misappropriated any of the Intellectual Property Rights of any Third Party.

(ix) Sutro has not been debarred by the FDA, is not subject to any similar sanction of other Regulatory Health Authorities in the Territory, and is not subject to any such debarment or similar sanction by any such Regulatory Health Authority, and Sutro has not used, and will not engage, in any capacity, in connection with this Agreement, any Person who either has been debarred by such a Regulatory Health Authority, or is the subject of a conviction described in Section 306 of the FDCA (21 U.S.C. §335a). Sutro shall inform Licensee in writing immediately if it or any Person engaged by Sutro who is performing services under this Agreement is debarred or is the subject of a conviction described in Section 306 of the FDCA (21 U.S.C. §335a) or if any action, suit, claim, investigation or legal or administrative proceeding is pending or, to Sutro's Knowledge, is threatened, relating to the debarment or conviction of Sutro or any such Person performing services hereunder.

(x) Sutro shall perform its obligations and responsibilities under this Agreement in compliance with this Agreement, all Applicable Laws, applicable FDA (or foreign equivalent) requirements, including, to the extent applicable, then-current GLP and GCP.

(xi) To Sutro's knowledge (after reasonable inquiry) Sutro has disclosed or made available to Licensee for review all Sutro Development Data, Regulatory Documentation, and other material information relating to the safety and efficacy of the Licensed Compound, and all such information is complete and accurate in all material respects.

(xii) To Sutro's knowledge (after reasonable inquiry), the Licensed Compound and the cell extracts under the Extract Supply Agreement, as well as the Sutro Technology and Sutro's Intellectual Property Rights related to the Manufacture License, do not require a license or other authorization for export to the Territory under any Export Controls and Economic Sanctions Laws. Sutro agrees that if such a license or other authorization is required anytime during the Term, Sutro shall use Commercially Reasonable Efforts to obtain such license or authorization.

(xiii) Other than the Upstream Agreement, there is no agreement between Sutro or its Affiliates with any other Third Party pursuant to which Licensor or any of its Affiliates obtains any license to Sutro Technology. Sutro has achieved all the milestones specified in the Upstream Agreement on schedule and Sutro and its Affiliates are in material compliance with the Upstream Agreement.

(xiv) Sutro shall maintain the Upstream Agreement in full force and effect and shall not terminate, amend, waive or otherwise modify (or consent to any of the foregoing) its rights under the Upstream Agreement in any manner that diminishes the rights or licenses granted to Licensee or increases or generates any new obligation (including any payment obligation) under the Upstream Agreement that would apply to Licensee, without Licensee's express written consent.

(xv) Within [\*] after the Effective Date, Sutro shall enter into an agreement with [\*] whereby (i) Sutro would agree to fund the development of the CDx, (ii) [\*] would agree to obtain any necessary regulatory approvals and commercialize the CDx in the Territory, whether on its own or through its Affiliates or one or more designated Third Party(ies), provided that any associated costs that are specific to the Territory will be borne by Licensee. Sutro acknowledges that the failure to comply with this Section 9.01(b) shall constitute a material breach of this Agreement and Licensee shall have the right to terminate this Agreement in accordance with Section 11.02(a).

(c) Licensee represents, warrants and covenants as of the Effective Date (or as of such other/additional time as may be explicitly specified below) to Sutro that:

(i) Licensee has not been debarred by the FDA (and is not subject to any similar sanction of other Regulatory Health Authorities in the Territory), and is not subject to any such debarment or similar sanction by any such Regulatory Health Authority, and Licensee has not used, and will not engage, in any capacity, in connection with this Agreement, any Person who either has been debarred by such a Regulatory Health Authority, or is the subject of a conviction described in Section 306 of the FFDCA (21 U.S.C. §335a). Licensee shall inform Sutro in writing immediately if it or any Person engaged by Licensee who is performing services under this Agreement is debarred or is the subject of a conviction described in Section 306 of the FFDCA (21 U.S.C. §335a), or if any action, suit, claim, investigation or legal or administrative proceeding is pending or, to Licensee's Knowledge, is threatened, relating to the debarment or conviction of Licensee or any such Person performing services hereunder.

(ii) To the extent permissible under Applicable Laws, each employee and contractor of Licensee performing obligations under this Agreement shall be required to, prior to conducting any such obligations hereunder, be obligated by Applicable Law, or written contract, to (i) promptly disclose to Licensee of all inventions and Know-How conceived or reduced to practice by such employee or contractor during any performance under this Agreement, (ii) automatically assign to Licensee all right, title and interest in and to all such inventions and Know-How and all Intellectual Property Rights therein, including all Product-related IPR and Product-related data, and (iii) adhere to obligations of confidentiality at least as stringent as those set forth in this Agreement.

(iii) Licensee shall perform, or cause its Affiliates or Sublicensee to perform, its obligations and responsibilities under this Agreement in compliance with this Agreement, all Applicable Laws, applicable NMPA (or foreign equivalent) requirements, including, without limitation, then-current GLP and GCP.

(iv) Licensee affirms that it is not subject to sanctions or export restrictions under Export Controls and Economic Sanctions Laws that would require U.S. government authorization for it to receive any U.S. origin services, goods, software, or technology, and it further affirms that its use, transfer, or re-export of the Licensed Compound and the cell extracts under the Extract Supply Agreement will comply with Export Controls and Economic Sanctions Laws.

**Section 9.02 No Debarment.** In the course of the Development of the Product in the Territory in accordance with this Agreement and during the term of this Agreement, neither Party will use, any employee or consultant that is debarred by any Regulatory Health Authority or, to the best of such Party's Knowledge, is the subject of debarment proceedings by any Regulatory Health Authority. If either Party learns that its employee or consultant performing on behalf under this Agreement has been debarred by any Regulatory Health Authority, or has become the subject of debarment proceedings by any Regulatory Health Authority, such Party shall so promptly notify the other Party and shall prohibit such employee or consultant from performing on its behalf under this Agreement. The foregoing shall be without prejudice to the warranties stipulated in Section 9.01(b)(iv).

**Section 9.03 Privacy, Anti-Bribery, and Anti-Corruption Compliance.**

(a) Compliance with Privacy Laws. Each Party shall implement appropriate processes and controls with respect to technology and workflow methodologies in connection with its activities under or in connection with this Agreement so as to protect the security and privacy of personally identifiable information exchanged under this Agreement in accordance with Applicable Law.

(b) Compliance with Applicable Anti-Corruption Laws. Each party understands and agrees that it has complied and will continue to comply with all applicable Anti-Corruption Laws in connection with this Agreement.

(i) Each Party represents and warrants that no payments of money or anything of value have been or will be offered, promised, or paid, whether directly or indirectly, by any of



its directors, officers, employees, Affiliates, or third party representatives to any Government Official in connection with this Agreement: (a) to influence any official act or decision of any Government Official; (b) to induce any Government Official to do or omit to do any act in violation of lawful duty; (c) to secure any improper business advantage; or (d) to obtain or retain business for, or otherwise direct business to, any Party in connection with this Agreement.

(ii) Each Party warrants and represents that, in connection with this Agreement, such Party, its directors, officers, employees, and third party representatives: (a) have not and will not request, accept, offer, promise, or give any bribe, kickback, or other corrupt payment to any person, including any representative of any commercial entity, in violation of any applicable Anti-Corruption Law; and (b) have not and will not request, offer, promise, or give any financial or other advantage to induce another person to perform a function or activity in order to obtain or retain an improper business advantage in any way relating to this Agreement.

(iii) Each Party warrants and represents that (a) it does not have any interest which directly or indirectly conflicts with its proper and ethical performance of the Agreement, and (b) it shall maintain arms-length relations with all Third Parties with which it deals for or on behalf of the other party in performance of the Agreement.

(c) Notification of Investigations into Potential Non-Compliance with Applicable Anti-Corruption Laws. Each Party warrants and represents that it will promptly inform the other party if such party, or any of its directors, officers, employees, Affiliates, third party representatives, or Sublicensees becomes subject to any investigation relating to any actual or potential violation of any applicable Anti-Corruption Law in connection with this Agreement, including any meeting, interview, inspection, or audit requested by any Regulatory Authority.

(d) Cooperation with Due Diligence and Investigations. Each Party will provide reasonable cooperation in connection with any good faith investigation conducted by the other party into potential violations of applicable Anti-Corruption Laws in connection with this Agreement.

(e) Compliance Program. Each Party will adopt, implement, and/or update and, throughout the course of this Agreement, have, maintain, and enforce an appropriate and risk-based anti-corruption compliance program designed to reasonably ensure compliance with the representations contained in this Section 9.03 of the Agreement and all applicable Anti-Corruption Laws.

(f) Periodic Compliance Certifications. On an [\*] basis following the execution of this Agreement, or as reasonably requested in good faith by the other Party, each Party agrees to submit a compliance certificate to the other Party which restates the representations and warranties that are set forth in this Section 9.03 and provides certification by such Party that it has adhered, during the period covered by the compliance certificate, to the representations and warranties.

## **ARTICLE 10**

### **RECORD RETENTION, AUDIT AND USE OF NAME**

### **Section 10.01 Records Retention; Audit.**

(a) Each Party shall keep or cause to be kept accurate records of account in accordance with P.R.C GAAP, in the case of Licensee, and in accordance with U.S. GAAP, in the case of Sutro, showing information that is necessary for the accurate determination of (in the case of Licensee) the royalties and other payments due under Article 6, or any other payment due hereunder and (b) (in the case of Sutro) the applicable Cost of Goods. Such records or books of account shall be kept until the [\*] in which the relevant Product is sold (in the case of royalty or other payments due under Section 6.04) or in the period for which any other payment hereunder is required to be made. For clarity, Licensee shall cause its Affiliates to keep, and shall require pursuant to a written agreement that any Sublicensee or subcontractor performing activities hereunder keep accurate records or books of account in a manner that will permit such Party to comply with its obligations under the foregoing sentence.

(b) Upon the written request of the other Party, each Party shall permit an internationally-recognized, certified public accounting firm acceptable to both Parties to inspect during regular business hours and no more than once a year and once in any given Calendar Year, and going back no more than [\*] preceding the current Calendar Year, all or any part of the audited Party's records and books necessary to check the accuracy of any Cost of Goods calculated or payments made or required to be made hereunder. The accounting firm shall enter into appropriate obligations with the audited Party to treat all information it receives during its inspection in confidence. The accounting firm shall disclose to Sutro and Licensee only whether Cost of Goods calculated or the payments made are correct and details concerning any discrepancies, but no other information shall be disclosed to the Party requesting the inspection. The charges of the accounting firm shall be paid by the Party requesting the inspection, except that if the Cost of Goods being audited have been overcalculated, or the payments being audited have been underpaid or the costs being reimbursed have been overstated, in each case by more than [\*], the charges will be paid by the Party whose records and books are being inspected. If the final result of the audit reveals an undisputed underpayment or overpayment, (i) Licensee shall pay to Sutro any underpayment discovered by such audit within [\*] after the accounting firm's report, and the part of underpayment that is within [\*] of the original payment amount due shall not be considered a late payment under Section 6.12, (ii) in the case of an overpayment by Licensee, then Licensee may take a credit for such overpayment against any future payments due to Sutro, or if no future payments are due to Sutro then Sutro shall pay to Licensee any overpayment discovered by such audit within [\*] after the accounting firm's report. Any failure by a Party to exercise its rights under this Section 10.01 with respect to a Calendar Year within the [\*] period allotted therefor shall constitute a waiver by such Party of its right to later object to any payments made by the other Party under this Agreement during such Calendar Year.

**Section 10.02 Publicity Review.** Subject to the further provisions of this Section 10.02, no Party shall originate any written publicity, news release, or other announcement relating to this Agreement or to performance hereunder or the existence of an arrangement between the Parties (collectively, "**Written Disclosure**"), without the prior prompt review of a copy of the materials proposed to be disclosed and written approval of the other Party. This Section 10.02, shall not prohibit the disclosure under Section 7.04(a). Notwithstanding the foregoing provisions of this Section 10.02, each Party may make any public Written Disclosure it believes in good faith based upon the advice of counsel is required under the Securities Laws of the United States, Hong Kong

SAR or P. R. China, or any listing or trading agreement concerning its publicly traded securities, or under any applicable securities laws, or any rule or order of stock exchange; provided that, prior to making such Written Disclosure, Sutro or Licensee shall, where reasonably practicable and legally permitted, provide the other Party with a copy of the materials proposed to be disclosed and an opportunity to promptly review and comment on the proposed Written Disclosure. To the extent that Licensee reasonably requests that any information in the materials proposed to be disclosed be deleted, Sutro shall use reasonable efforts to request confidential treatment of such information pursuant to Rule 406 of the Securities Act of 1933 or Rule 24b-2 of the Securities Exchange Act of 1934, as applicable (or any other applicable regulation relating to the confidential treatment of information) so that any information that Licensee reasonably requests to be deleted, to the extent permitted by the applicable government agency, are omitted from such materials. Notwithstanding the foregoing, each Party may issue an individual press release regarding the transaction contemplated by this Agreement, subject to the other Party's right to review and comment such press release prior to publication. For clarity, Sutro shall have the right to issue press releases and other public announcements regarding the Development or Commercialization of the Product outside of the Territory without the prior review or written approval of Licensee.

**Section 10.03 Use of Names.** Neither Party shall use the name, insignia, symbol, trademark, trade name or logotype of the other Party or its Affiliates in relation to this transaction or otherwise in any public announcement, press release, or other public document without the prior written consent of such other Party; provided, however, that either Party may use the name of the other Party in any document required to be filed with any government authority, including without limitation the FDA and the Securities and Exchange Commission, or foreign equivalent bodies, or otherwise as may be required by Applicable Law, provided that such disclosure shall be governed by Section 7.04. Further, the restrictions imposed on each Party under this Section 10.03 are not intended, and shall not be construed, to prohibit a Party from identifying the other Party in its internal business communications, provided that any Confidential Information in such communications remains subject to Article 7.

## **ARTICLE 11 TERM AND TERMINATION**

**Section 11.01 Term.** The term of this Agreement shall commence as of the Effective Date and, unless sooner terminated as provided herein, shall continue in effect until the expiration of the Royalty Term, on a Region-by-Region basis (the "**Term**"). On a Region-by-Region basis, following the expiration (but not early termination) of the Term in the applicable Region, the licenses granted to Licensee under this Agreement (including the Manufacture License) shall become exclusive, fully-paid, royalty-free, perpetual and irrevocable with respect to such Region, and the sales of the Product in such Region shall not be included in the calculation of Net Sales.

### **Section 11.02 Termination Rights.**

(a) **Termination for Cause.** This Agreement may be terminated in its entirety at any time during the Term upon written notice by either Party (the "**Non-Breaching Party**") if the other Party (the "**Breaching Party**") is in material breach of this Agreement and, in each case, has not cured such breach within [\*] after notice requesting cure of the breach. Notwithstanding the foregoing, in the event there is a good faith dispute as to whether a material breach exists, the

dispute shall be resolved pursuant to Section 13.02, in which case if (a) the Breaching Party is determined in accordance with Section 13.02 to be in material breach of one (1) or more of its obligations under this Agreement, and (b) the Breaching Party fails to complete the actions specified by such adverse ruling to cure such material breach in accordance with any procedures or timeframes established by the tribunal, then the Non-Breaching Party may terminate this Agreement upon written notice to the Breaching Party. . During the pendency of such a dispute, all of the terms and conditions of this Agreement shall remain in effect and the Parties shall continue to perform all of their respective obligations hereunder.

(b)**Termination for Challenge of Sutro Patents.** Prior to its expiration, Sutro may terminate this Agreement in its entirety by written notice to Licensee if (i) Licensee or its Affiliates challenges the validity, scope or enforceability of or otherwise opposes any Sutro Patent inside or outside the Territory and (ii) Licensee does not cause such challenge to be withdrawn within [\*] after having received written notice thereof from Sutro requesting such challenge to be withdrawn. If a Sublicensee challenges the validity, scope, or enforceability of or otherwise opposes any Sutro Patent inside or outside of the Territory, then Licensee shall, upon written notice from Sutro, terminate such sublicense or cause the Sublicensee to withdraw such challenge within [\*]. Licensee shall include provisions in all agreements under which a Sublicensee obtains a sublicense under any Sutro Patent providing that, if the Sublicensee challenges the validity, scope or enforceability of or otherwise opposes any Sutro Patent inside or outside the Territory, Licensee may terminate such sublicense.

(c)**Termination for Insolvency.** A Party may terminate this Agreement effective immediately upon written notice to the other Party if at any time during the Term, the other Party (the “**Debtor**”) (i) becomes insolvent, (ii) has a case commenced by or against it under the Bankruptcy Code, (iii) files for or is subject to the institution of bankruptcy, liquidation or receivership proceedings, (iv) assigns all or a substantial portion of its assets for the benefit of creditors, (v) has a receiver or custodian appointed for the Debtor’s business, or (vi) has a substantial part of its business being subject to attachment or similar process; provided, however, that in the event of any involuntary case under the Bankruptcy Code, the first Party shall not be entitled to terminate this Agreement pursuant to this Section 11.02(c) if the case is dismissed within [\*] after the commencement thereof.

(d)**Termination for Convenience.** Prior to its expiration, this Agreement may be terminated in its entirety at any time by Licensee effective upon ninety (90) days’ (or such longer period as Licensee may elect at its sole discretion) prior written notice to Sutro.

(e)**Termination for Safety/Efficacy Issue.** In the event that Licensee believes in good faith a Safety/Efficacy Issue exists, as a result of which a company in the biopharmaceutical industry in the Territory would reasonably be expected to elect not to continue to fund or conduct the development or commercialization of the Product, Licensee may terminate this Agreement in its entirety or in part with respect to the affected Product upon [\*] (or such longer period as Licensee may elect at its sole discretion) prior written notice to Sutro.

**Section 11.03 Consequences of a Licensee Triggered Termination.** In the event (a) Sutro terminates this Agreement pursuant to Section 11.02(a) for Licensee’s material breach; (b) Sutro terminates this Agreement pursuant to Section 11.02(b) for patent challenge by Licensee;

(c) Sutro terminates this Agreement pursuant to Section 11.02(c) for Licensee's insolvency; or (d) Licensee terminates this Agreement pursuant to Sections 11.02(d), or 11.02(e) (a termination as per (a) through (e) being a "**Licensee Triggered Termination**"), both Sutro and Licensee shall, subject to Section 11.03(a), continue to be obligated during the termination notice period (as applicable) to perform as far as reasonably practicable all of its obligations under this Agreement and any other agreements concluded between the Parties in accordance with this Agreement. In addition, as a result of a Licensee Triggered Termination the following shall apply (without prejudice to the terminating party's other rights and remedies at law or in equity):

(a) All licenses and rights to the Sutro Technology granted to Licensee (together with all sublicenses granted by Licensee) hereunder shall terminate automatically without further action required on the part of Sutro as of the effective date of such termination, except to the extent and for so long as is necessary to permit Licensee to finish work-in-progress, sell any inventory of Product that remains on hand as of the date of the termination and otherwise perform any responsibilities in connection with any then ongoing clinical trial or other activity that cannot be terminated as of such date under Applicable Laws, including GCP, it being agreed that all such activities and responsibilities shall be discontinued and ceased (unless otherwise agreed or required under Applicable Laws by transitioning such activities and responsibilities to Sutro) as promptly as possible, subject to Applicable Laws, including GCP. At Sutro's request, Licensee and Sutro shall reasonably cooperate to transfer the Development and Commercialization activities pertaining to the Product in the Territory to Sutro in an orderly fashion. The license granted under Section 8.02 shall automatically be expanded to become exclusive also within the Territory (including as to Licensee and its Affiliates).

(b) Each Party shall return or destroy all tangible materials in its possession or control containing or comprising the other Party's Confidential Information to which such first Party does not retain rights hereunder (except one copy thereof, which may be retained by the returning Party solely for legal archive purposes). Notwithstanding any provision to the contrary set forth in this Agreement, the returning Party will not be required to destroy electronic files containing such Confidential Information that are made in the ordinary course of its business information back-up procedures pursuant to its electronic record retention and destruction practices that apply to its own general electronic files and information.

(c) Licensee shall, in accordance with Applicable Laws, as promptly as reasonably practical transfer to Sutro all of Licensee's rights, title, and interests in and to INDs, BLAs, Drug Approval Applications, and Regulatory Approvals (and any other permits or licenses necessary to Develop, Manufacture or Commercialize the Product in the Territory) with respect to the Product in the Territory, and shall take such other actions and execute such other instruments, assignments, and documents as may be necessary to effect the transfer of rights hereunder to Sutro. Without limiting the generality of the foregoing, Licensee (if it is the marketing authorization holder at such time) agrees to submit to the NMPA and other Regulatory Authorities in jurisdictions in which any regulatory filings have been made with respect to the Product, within [\*] after the effective date of such termination, a letter (with copy to Sutro) notifying the NMPA and such other Regulatory Authorities of the transfer of any regulatory filings for the Product in such jurisdictions from Licensee to Sutro. Additionally, (i) Licensee will provide Sutro with copies of regulatory filings necessary to practice the rights granted to it under this Section 11.03(c) and (ii) Sutro will be allowed to use the Licensee Development Data also in the Territory.

(d) Upon Sutro's request, Licensee will assign (or cause its Affiliates to assign) to Sutro, at Sutro's request, all of Licensee's (or its Affiliates') rights and obligations under agreements with Third Parties with respect to (i) the conduct of clinical trials for the Product, including Agreements with CROs, clinical sites and investigators that relate to clinical trials in support of Regulatory Approvals in the Territory, and (ii) any other Third Party agreements involving the Development or Commercialization of the Product, unless in each of (i) or (ii), such agreement is not permitted to be assigned pursuant to its terms or relates to products other than the Product, in which case Licensee will cooperate with Sutro in all reasonable respects to transfer as promptly as reasonably practical to Sutro the benefit of such contract in another mutually acceptable manner and upon Sutro's request facilitate discussions between Sutro and such Third Parties to assist Sutro in entering into a direct agreement with such Third Parties.

(e) To the extent they are assignable and as requested by Sutro, Licensee shall execute any documents necessary to transfer to Sutro rights under any Third Party licenses obtained by Licensee pursuant to and during the course of the term of this Agreement for the purpose of Exploiting the Product, and Sutro shall thereafter be responsible for all costs, expenses and obligations associated with such Third Party licenses.

(f) Except where expressly provided for otherwise in this Agreement, termination of this Agreement shall not relieve the Parties of any liability, including without limitation any obligation to make payments hereunder, which accrued hereunder prior to the effective date of such termination, nor preclude any Party from pursuing all rights and remedies it may have hereunder or at law or in equity with respect to any breach of this Agreement, nor prejudice any Party's right to obtain performance of any obligation. In the event of such termination, this Section 11.03(f) shall survive in addition to others specified in this Agreement to survive in such event.

(g) Licensee shall be entitled, during a period of [\*] following the Licensee Triggered Termination to sell any inventory of Product that remains on hand as of the date of the termination, so long as Licensee pays to Sutro the royalties applicable to said subsequent sales in accordance with the terms and conditions set forth in this Agreement.

(h) Notwithstanding anything else set forth in this Agreement, (i) Licensee shall not have any obligations to continue any Development or Commercialization with respect to particular doses of the Product if Licensee has terminated this Agreement pursuant to Section 11.02(d) with reference to any material safety concerns regarding such doses, as determined by the JSC; and (ii) should Sutro elect to pursue any Development or Commercialization of Product following any such termination by Licensee, Sutro shall, without prejudice to or limitation of any other or further obligations under this Agreement (including Section 12.01(b)), indemnify Licensee for any Third Party Claims arising from Sutro's Development or Commercialization after the effective date of such termination as set forth in Section 12.01(b).

**Section 11.04. Consequences of Termination by Licensee for Sutro's Breach or Insolvency.** If Licensee terminates this Agreement pursuant to Section 11.02(a) as a result of a material breach by Sutro or Section 11.02(c) for an insolvency or other transaction described therein affecting Sutro, the terms and obligations under Section 11.03 shall apply as if such termination were a Licensee Triggered Termination, except that notwithstanding anything set forth to the contrary in Section 11.03: (i) Sutro shall be responsible for any and all reasonable costs and

expenses associated with the discontinuation of the Development and Commercialization activities by Licensee and the transfer of such activities to Sutro pursuant to Section 11.03(a), including without limitation, costs and expenses of clinical trials incurred by Licensee's after the termination date and reasonable costs and expenses associated with the winding down of ongoing clinical trials, (ii) Sutro shall be responsible for any and all reasonable costs and expenses associated with the transfer of regulatory filings pursuant to Section 11.03(c), the assignment or transfer of Third Party agreements and licenses pursuant to Section 11.03(d) and Section 11.03(e). The foregoing shall be in addition and without prejudice to any other remedies that may be available to Licensee due to Sutro's breach, including any money damages that may be awarded to Licensee in connection with its termination pursuant to Section 11.02(a).

**Section 11.05 Bankruptcy.** All rights and licenses granted under or pursuant to this Agreement by a Party are, and shall otherwise be deemed to be, for the purposes of Section 365(n) of the United States Bankruptcy Code (to the extent applicable), licenses of rights to "intellectual property" as defined under Section 101 of the United States Bankruptcy Code or equivalent provisions of applicable legislation in any other jurisdiction. The Parties agree that the Parties, as licensees of such rights under this Agreement, shall retain and may fully exercise all of their rights and elections under the United States Bankruptcy Code, or equivalent provisions of applicable legislation in any other jurisdiction. The Parties further agree that, in the event of the commencement of a bankruptcy proceeding by or against either Party under the United States Bankruptcy Code or equivalent provisions of applicable legislation in any other jurisdiction, the Party that is not a party to such proceeding shall be entitled to a complete duplicate of (or complete access to, as appropriate) any such intellectual property and all embodiments of such intellectual property, which, if not already in the non-subject Party's possession, shall be promptly delivered to it (a) upon any such commencement of a bankruptcy proceeding upon the non-subject Party's written request therefor, unless the Party subject to such proceeding elects to continue to perform all of its obligations under this Agreement, or (b) if not delivered under subsection (a) above, following the rejection of this Agreement by or on behalf of the Party subject to such proceeding upon written request therefor by the non-subject Party.

**Section 11.06 Surviving Rights and Obligations.** The rights and obligations set forth in this Agreement shall extend beyond the expiration or termination of the Agreement only to the extent expressly provided for herein, or to the extent that the survival of such rights or obligations are necessary to permit their complete fulfillment or discharge. Without limiting the foregoing, the Parties have identified various rights and obligations which are understood to survive, as follows: Article 1 (to the extent applicable to surviving provisions), Article 6 (limited to Net Sales realized prior to, and payments due as of, the expiration or termination of this Agreement), Article 7 (for the time periods specified in Section 7.05), Section 8.01, Section 8.02, Section 8.04 (limited to proceedings commenced before expiration or termination of this Agreement), Article 10, Section 11.03, Section 11.04, Section 11.06, Section 11.07, Article 12, Article 13, and Article 14.

**Section 11.07 Accrued Rights.** Termination, relinquishment, or expiration of the Agreement for any reason shall be without prejudice to any rights that shall have accrued to the benefit of either Party prior to such termination, relinquishment, or expiration, including without limitation damages arising from any breach hereunder. Such termination, relinquishment, or expiration shall not relieve either Party from obligations that are expressly indicated to survive termination or expiration of the Agreement.

**ARTICLE 12**  
**INDEMNIFICATION**

**Section 12.01 Indemnification.**

(a) Licensee hereby agrees to indemnify, defend, and hold harmless Sutro, its Affiliates, and each of its and their respective employees, officers, directors and agents from and against any and all Losses incurred by them resulting from or arising out of or in connection with any suits, claims, actions or demands made or brought by a Sublicensee or other Third Party (collectively, “**Third Party Claims**”) against Sutro, its Affiliates or their respective employees, officers, directors or agents, that result from or arise out of: (i) activities by Licensee, its Affiliates or Sublicensees with respect to the Development, Manufacture, and Commercialization of the Product or the exercise of their rights or performance of their obligations related thereto, including the activities taken on behalf of Sutro under Section 4.06; (ii) any violation of Applicable Law by Licensee, its Affiliates or Sublicensees in performing Licensee’s obligation under this Agreement; and (iii) any material breach by Licensee, its Affiliates or Sublicensees of Licensee’s representations, warranties and/or obligations under this Agreement; except in any case, to the extent such Losses are Losses for which Sutro has an obligation to indemnify Licensee, its Affiliates or their respective employees, officers, directors or agents pursuant to Section 12.01(b), as to which Losses each Party shall indemnify the other to the extent of their respective liability for such Losses.

(b) Sutro hereby agrees to indemnify, defend and hold harmless Licensee, its Affiliates, and each of its and their respective employees, officers, directors and agents from and against any and all Losses incurred by them resulting from or arising out of or in connection with any Third Party Claims against Licensee, its Affiliates or their respective employees, officers, directors or agents, that result from or arise out of: (i) activities by Sutro, its Affiliates or subcontractors with respect to the Development, Manufacture, and Commercialization of the Product or the exercise of their rights or performance of their obligations related thereto, provided that, the activities taken by Licensee on behalf of Sutro under Section 4.06 shall not be considered activities by Sutro, its Affiliates or subcontractors; (ii) any violation of Applicable Law by Sutro or its Affiliates in performing Sutro’s obligations under this Agreement; and (iii) any material breach by Sutro or its Affiliates of Sutro’s representations, warranties and/or obligations under this Agreement; except in any case, to the extent such Losses are Losses for which Licensee has an obligation to indemnify Sutro, its Affiliates or their respective employees, officers, directors or agents pursuant to Section 12.01(a), as to which Losses each Party shall indemnify the other to the extent of their respective liability for such Losses.

**Section 12.02 Mechanism.**

(a) In the event that a Party (the “**Indemnified Party**”) is seeking indemnification under Section 12.01(a) or Section 12.01(b), it shall notify the other Party (the “**Indemnifying Party**”) in writing of the relevant Third Party Claim and the relevant Loss for which indemnification is being sought as soon as reasonably practicable after it becomes aware of such claim. Each such notice shall contain a description of the Third Party Claim and the nature and amount of the Loss claimed (to the extent that the nature and amount of such Loss is known at such time). The Indemnified Party shall furnish promptly to the Indemnifying Party copies of all



papers and official documents received in respect of any such Third Party Claim or Losses. For the avoidance of doubt, all indemnification claims in respect of a Party, its Affiliates, and each of its and their respective employees, officers, directors and agents shall be made solely by such Party to this Agreement. The Indemnified Party shall permit the Indemnifying Party to assume direction and control of the defense of the relevant Third Party Claim (including without limitation the right to settle the claim solely for monetary consideration), and shall cooperate as requested (at the expense of the Indemnifying Party) in the defense of the claim. The assumption of the defense of a Third Party Claim by the Indemnifying Party shall not be construed as an acknowledgement that the Indemnifying Party is liable to indemnify any Indemnified Party in respect of the Third Party Claim, nor shall it constitute a waiver by the Indemnifying Party of any defenses it may assert against any Indemnified Party's claim for indemnification.

(b) Notwithstanding Section 12.01, the failure to give timely notice to the Indemnifying Party shall not release the Indemnifying Party from any liability to the Indemnified Party to the extent the Indemnifying Party is not materially prejudiced thereby and, for the avoidance of doubt, the Indemnifying Party shall not be liable to the extent any Loss is caused by any delay by the Indemnified Party in providing such notice. Notwithstanding the provisions of Section 12.02(a) requiring the Indemnified Party to tender to the Indemnifying Party the exclusive ability to defend such claim, if the Indemnifying Party declines to or fails to timely assume control of the relevant Third Party Claim, the Indemnified Party shall be entitled to assume such control, conduct the defense of, and settle such claim, all at the sole costs and expense of the declining or failing Party; provided, however, that neither Party shall settle or dispose of any such claim in any manner that would adversely affect the rights or interests or admit fault, of the other Party without the prior written consent of such other Party, which shall not be unreasonably withheld, delayed or conditioned. Each Party, at the other Party's expense and reasonable request, shall cooperate with such other Party and its counsel in the course of the defense or settlement of any such claim, such cooperation to include without limitation using reasonable efforts to provide or make available documents, information, and witnesses.

**Section 12.03 Mitigation of Loss.** Each Indemnified Party shall take and shall ensure that its Affiliates take all such reasonable steps and action as are reasonably necessary or as the Indemnifying Party may reasonably require in order to mitigate any claims (or potential losses or damages) under this Article 12. Nothing in this Agreement shall or shall be deemed to relieve any Party of any common law or other duty to mitigate any losses incurred by it.

**Section 12.04 Insurance.** Both Parties shall use Commercially Reasonable Efforts, at their own discretion, to procure and maintain insurance, including product liability insurance, with respect to its activities hereunder and which is consistent with normal and customary business practices in the pharmaceutical industry for Persons similarly situated, and shall upon request provide the other Party with a copy of its policies of insurance in that regard, along with any amendments and revisions thereto. Each party shall still be responsible for its liability at its own risk whether it does or doesn't procure or maintain such insurance. Such insurance shall not be construed to create a limit of both Party's liability with respect to its indemnification obligations under this Article 12.

**ARTICLE 13**  
**DISPUTE RESOLUTION**

**Section 13.01 Referral of Disputes to the Parties Senior Executives.** Subject to the applicable provisions in Article 13, in the event of any dispute between the Parties arising out of or in connection with this Agreement, either Party may, by written notice to the other, have such dispute referred to the Senior Executives for attempted resolution by good faith negotiations within [\*] after such notice is received. If the Senior Executives fail to resolve such matter within [\*] after the date on which the matter is referred to the Senior Executives (unless a longer period is agreed to by the Parties), then, either Party may submit the dispute for final resolution by binding arbitration in accordance with Section 13.02.

**Section 13.02 Arbitration.** Except as set forth in this Section 13.02, any dispute, difference, controversy or claim arising in connection with or related or incidental to, or question occurring under, this Agreement or the subject matter hereof that cannot be resolved pursuant to Section 13.01, will be referred to and finally resolved by arbitration in accordance with this Section 13.02. A Party may submit such dispute to arbitration at [\*] (“SIAC”) by notifying the other Party, in writing, of such dispute. Within [\*] after receipt of such notice, the Parties will each designate in writing an arbitrator to resolve the dispute. Both of the designated arbitrators will elect a third arbitrator; provided, however, that if the designated arbitrators cannot agree on a third arbitrator within [\*] after both arbitrators have been designated, the third arbitrator will be selected by the SIAC. The arbitrators will be a lawyer with biotechnology and/or pharmaceutical industry legal experience, and will not be an Affiliate, employee, consultant, officer, director or stockholder of any Party. The arbitration will be conducted in [\*] for the time being in force, which rules are deemed to be incorporated by reference in this clause, except to the extent such rules are inconsistent with this Section 13.02, in which case this Section 13.02 will control. All arbitration proceedings will be conducted in the English language. The arbitrators will consider grants of equitable relief and orders for specific performance as co-equal remedies along with awards of monetary damages. The arbitrators will have no authority to award punitive damages. The prevailing Party of the arbitration shall be entitled to recover from the other any and all costs and expenses incurred by the prevailing Party in connection with the arbitration, including reasonable attorneys’ fees. The Parties hereby agree that the arbitrators have authority to issue rulings and orders regarding all procedural and evidentiary matters that the arbitrators deem reasonable and necessary with or without petition therefore by the Parties as well as the final ruling and judgment. All rulings by the arbitrators will be final. Notwithstanding any contrary provision of this Agreement, any Party may seek equitable measures of protection in the form of attachment of assets or injunctive relief (including specific performance and injunctive relief) in any matter relating to the proprietary rights and interests of either Party from any court of competent jurisdiction, pending a decision by the arbitral tribunal in accordance with this Section 13.02. The Parties hereby exclude any right of appeal to any court on the merits of such matter. The provisions of this Section 13.02 may be enforced and judgment on the award (including equitable remedies) granted in any arbitration hereunder may be entered in any court having jurisdiction over the award or any of the Parties or any of their respective assets. Except to the extent necessary to confirm an award or as may be required by Laws, neither a Party nor an arbitrator may disclose the existence, content, or results of an arbitration without the prior written consent of both Parties. The Parties agree that, in the event of a dispute over the nature or quality of performance under this Agreement, neither Party may terminate this Agreement until final resolution of the dispute through arbitration

or other judicial determination. Nothing in this Section 13.02 will preclude either Party from seeking interim or provisional relief from a court of competent jurisdiction, including a temporary restraining order, preliminary injunction or other interim equitable relief, concerning a dispute either prior to or during any arbitration if necessary to protect the interests of such Party or to preserve the status quo pending the arbitration proceeding. Notwithstanding the Parties' agreement to arbitrate, unless the Parties agree in writing in any particular case, claims and disputes between the Parties relating to or arising out of, or for which resolution depends in whole or in part on a determination of the interpretation, scope, validity, enforceability or infringement of, Patents or of any Trademark rights relating to the Product, or misappropriation of any Know-How, will not be subject to arbitration under this Agreement, and the Parties may pursue whatever rights and remedies may be available to them under law or equity, including litigation in a court of competent jurisdiction, with respect to such claims and disputes.

**Section 13.03 Preliminary Injunctions.** Notwithstanding anything to the contrary, a Party may seek a temporary restraining order or a preliminary injunction from any court of competent jurisdiction in order to prevent immediate and irreparable injury, loss, or damage on a provisional basis, pending the decision of the arbitrator(s) on the ultimate merits of any dispute.

**Section 13.04 Patent Disputes.** Notwithstanding anything to the contrary, any and all issues regarding the scope, inventorship, construction, validity, or enforceability of Patents shall be by the competent Court(s) under the local patent laws of the jurisdictions having issued the Patents in question.

**Section 13.05 Confidentiality.** All proceedings and decisions of a mediator or arbitrator(s) in connection with proceedings pursuant to Section 13.02 shall be deemed Confidential Information of each of the Parties and shall be subject to Article 7.

## **ARTICLE 14 MISCELLANEOUS**

### **Section 14.01 Assignment; Performance by Affiliates.**

(a) Neither Party may assign any of its rights or obligations under this Agreement in any Region in whole or in part without the prior written consent of the other Party, except that each Party shall have the right, without such consent, (i) to perform any of its obligations and exercise any of its rights under this Agreement through, and to assign all of its rights and obligations under this Agreement to, any of its Affiliates, provided that such performance or exercise by such Affiliate, or such assignment, as applicable, could not reasonably be expected to subject the other Party to any adverse Tax consequences with regard to any payments under this Agreement; and (ii) on written notice to the other Party, to assign all of its rights and obligations under this Agreement to a non-Affiliate successor in interest, whether by a Change of Control transaction or otherwise, to all or substantially all of the business to which this Agreement relates; however, provided that both under (i) and (ii) the assignee shall have at least the same capability and capacity of such Party to perform any obligations and exercise any rights under this Agreement. In the event that a Party performs its obligations or exercises its rights under this Agreement through an Affiliate (without having assigned all of its rights and obligations to such Affiliate as permitted under this Section 14.01), doing so shall not relieve the relevant Party of its

responsibilities for the performance of its obligations under this Agreement, and the relevant Party shall remain responsible for the performance by its Affiliates and shall cause its Affiliates to comply with the provisions of this Agreement in connection with such performance.

(b) This Agreement shall survive any succession of interest permitted pursuant to Section 14.01(a)(ii), whether by merger, consolidation, reorganization, acquisition, stock purchase, asset purchase or other Change of Control transaction.

(c) This Agreement shall be binding upon and inure to the benefit of the successors, and permitted assigns of the Parties. Any assignment not in accordance with this Agreement shall be void.

**Section 14.02 Force Majeure.** In this Agreement, “**Force Majeure**” means an event which is beyond a non-performing Party’s reasonable control, including an act of God, strike, lock-out or other industrial/labor disputes (whether involving the workforce of the Party so prevented or of any other Person), war, riot, civil commotion, terrorist act, epidemic (including the COVID-19), quarantine, fire, flood, storm, earthquake, natural disaster, act of government or compliance with any law or governmental order, rule, regulation or direction, whether or not it is later held to be invalid. A Party that is prevented or delayed in its performance under this Agreement by an event of Force Majeure (a “**Force Majeure Party**”) shall, as soon as reasonably practical but no later than [\*] after the occurrence of a Force Majeure event, give notice in writing to the other Party specifying the nature and extent of the event of Force Majeure, its anticipated duration and any action being taken to avoid or minimize its effect, except if the action of giving such notice is also not practical or practicable. Subject to providing such notice unless excepted and to this Section 14.02, the Force Majeure Party shall not be liable for delay in performance or for non-performance of its obligations under this Agreement, in whole or in part, except as otherwise provided in this Agreement, where non-performance or delay in performance has resulted from an event of Force Majeure. The suspension of performance allowed hereunder shall be of no greater scope and no longer duration than is reasonably required and the Force Majeure Party shall exert all reasonable efforts to avoid or remedy such Force Majeure. Notwithstanding the foregoing, a Party shall not be excused from making payments owed hereunder at the time of such Force Majeure because of such Force Majeure. If a Force Majeure persists for more than [\*], the Parties will discuss in good faith the modification of the Parties’ obligations under this Agreement to mitigate the delays caused by such Force Majeure.

**Section 14.03 Further Actions.** Each Party agrees to execute, acknowledge, and deliver such further instruments, and to do all such other acts, as may be necessary or appropriate in order to carry out the purposes and intent of this Agreement.

**Section 14.04 Notices.** All notices, requests, waivers and other communications made hereunder shall be in writing and shall be deemed given (a) upon delivery, if delivered personally; (b) upon confirmation of receipt, if by electronic mail during normal business hours of the recipient, and if not sent during normal business hours, then on the recipient’s next Business Day, (c) [\*] after deposit in the mail as registered or certified mail (unless earlier return receipt requested), (d) [\*] after deposit with postage prepaid, or sent by internationally recognized overnight delivery service that maintains earlier records of delivery, to the Parties at the following

addresses (or at such other address for a Party as shall be specified by like notice; provided, that notices of a change of address shall be effective only upon receipt thereof).

If to Sutro, addressed to:

SUTRO Biopharma, Inc.  
111 Oyster Point Boulevard  
South San Francisco, CA 94080  
Attention: General Counsel  
Email: [\*]

If to Licensee, addressed to:

Tasly Biopharmaceuticals Co., Ltd.  
280 JuLi Road,  
China (Shanghai) Pilot Free Trade Zone, P.C.201203  
Attention: [\*]  
Email: [\*]

**Section 14.05Waiver.** Except as specifically provided for herein, the waiver from time to time by either of the Parties of any of their rights or their failure to exercise any remedy shall not operate or be construed as a waiver of any other of such Party's rights or remedies provided in this Agreement.

**Section 14.06Severability.** If any term, covenant or condition of this Agreement or the application thereof to any Party or circumstance shall, to any extent, be held to be invalid or unenforceable, then (a) the remainder of this Agreement, or the application of such term, covenant, or condition to Parties or circumstances other than those as to which it is held invalid or unenforceable, shall not be affected thereby, and each term, covenant, or condition of this Agreement shall be valid and be enforced to the fullest extent permitted by law, and (b) the Parties covenant and agree to renegotiate any such term, covenant, or application thereof in good faith in order to provide a reasonably acceptable alternative to the term, covenant, or condition of this Agreement or the application thereof that is invalid or unenforceable, it being the intent of the Parties that the basic purposes of this Agreement are to be effectuated.

**Section 14.07Governing Law.** This Agreement shall be governed by and interpreted under the laws of the State of New York, USA, without giving effect to any conflict of law principle that would otherwise result in the application of the laws of any State or jurisdiction other than the State of New York, USA.

**Section 14.08Counterparts.** This Agreement may be executed in two or more counterparts, each of which shall be deemed an original, but all of which together shall constitute one and the same instrument.

**Section 14.09Entire Agreement.** This Agreement, including without limitation all exhibits attached hereto, sets forth all the covenants, promises, agreements, warranties,

representations, conditions, and understandings between the Parties and supersedes and terminates all prior and contemporaneous agreements and understanding between the Parties, including without limitation the agreements and amendments set forth in Section 7.06. There are no covenants, promises, agreements, warranties, representations, conditions, or understandings, either oral or written, between the Parties other than as set forth in this Agreement. No subsequent alteration, amendment, change, or addition to this Agreement shall be binding upon the Parties unless reduced to writing and signed by the respective authorized officers of the Parties.

**Section 14.10 Limitation of Liability.** EXCEPT IN CIRCUMSTANCES OF GROSS NEGLIGENCE OR INTENTIONAL MISCONDUCT BY A PARTY OR ITS AFFILIATES, OR WITH RESPECT TO THIRD PARTY CLAIMS UNDER SECTION 12.01, IN NO EVENT SHALL EITHER PARTY OR ITS RESPECTIVE AFFILIATES AND SUBLICENSEES BE LIABLE FOR SPECIAL, INDIRECT, INCIDENTAL OR CONSEQUENTIAL DAMAGES, WHETHER IN CONTRACT, WARRANTY, TORT, STRICT LIABILITY, OR OTHERWISE, INCLUDING BUT NOT LIMITED TO LOSS OF PROFITS, REV ENUE, MILESTONES OR ROYALTIES. This Section 14.10 shall not limit either Party's obligations under Article 12.

**Section 14.11 No Partnership.** It is expressly agreed that the relationship between Sutro and Licensee shall not constitute a partnership, joint venture, or agency. Neither Sutro nor Licensee shall have the authority to make any statements, representations, or commitments of any kind, or to take any action, which shall be binding on the other Party, without the prior consent of such other Party to do so.

*[SIGNATURE PAGE FOLLOWS]*

IN WITNESS WHEREOF, the Parties hereto have caused this Agreement to be executed in duplicate by their respective duly authorized officers or representatives.

**Sutro Biopharma, Inc.**

By: \_\_\_\_\_  
Name: William Newell  
Title: Chief Executive Officer

**Tasly Biopharmaceuticals Co., Ltd.**

By: \_\_\_\_\_  
Name: Kaijing Yan  
Title: Chairman of the Board

**EXHIBIT A**

*(Sutro Patents)*  
[\*]



**EXHIBIT B**

*(Licensed Compound)*  
[\*]

**EXHIBIT C**

*(List of JSC Members)*

[\*]

**EXHIBIT D**

*(Development Plan)[\*]*

**EXHIBIT E**

*(Sutro Trademarks)*  
[\*]

**EXHIBIT F**  
*(Terms for Clinical Supply Agreement)*

[\*]





May 23, 2021

Jane Chung, RPh  
[Private Address]

Dear Jane:

We are pleased to offer you a position with Sutro Biopharma, Inc. (the "Company"), as Chief Commercial Officer, reporting to William Newell, Chief Executive Officer, effective August 1, 2021. The Company is excited to have you join our exceptional team and we look forward to a purposeful and productive relationship. You should note that the Company may modify job titles, salaries and benefits from time to time as it deems necessary.

### **1. Compensation**

- a. **Base Pay.** In this position you will earn an annual salary of \$475,000, which will be paid semi-monthly in accordance with the Company's normal payroll procedures. Your base pay will be periodically reviewed as a part of the Company's regular reviews of compensation.
- b. **Bonus Eligibility.** In each calendar year during your employment with the Company, you will be eligible to receive an annual bonus dependent on performance objectives, which will be based on company objectives established by Sutro's Board of Directors, in their discretion. Your target bonus will be up to forty percent (40%) of your base salary, assuming the achievement of such performance objectives as determined solely by the Company's Board of Directors. You will be eligible for bonus consideration, with the beginning of the 2021 performance year. Any bonus that you earn will be paid to you within two and one-half (2-1/2) months of the end of the calendar year in which it is earned, and shall be paid in cash, less any usual, required withholding.
- c. **Sign-on Bonus.** You will receive an initial sign on bonus of \$300,000, less applicable taxes, on the first payroll period following your start date. In addition, you will receive a bonus of \$150,000, less applicable taxes on your first-year anniversary. These bonus payments will be fully repayable should you choose to leave the company prior to your second anniversary of employment.

### **2. Stock Equity**

a. If you decide to join the Company, it will be recommended on the 15<sup>th</sup> of the month following your start date (or the first trading day following your start date), that the Company grant you an option to purchase 160,000 publicly traded shares of the Company's Common Stock at a price per share equal to the fair market value per share of the Common Stock on the date of grant, as approved by the Company's Board of Directors. Twenty-five percent (25%) of the shares subject to the option shall vest 12 months after the date your vesting begins subject to your continuing employment with the Company, and no shares shall vest before such date. The remaining shares shall vest monthly over the next 36 months in equal monthly amounts subject to your continuing employment with the company. This option grant shall be subject to the terms and conditions of the company's Stock Option Plan and Stock Option Agreement, including vesting requirements. No right to any stock is earned or accrued until such time that vesting occurs, nor does the grant confer any right to continue vesting or employment. In addition to your option grant, you will receive a grant of 75,000 shares of Restricted Stock (RSU's). This grant will vest annually, from your start date, over 4 years at the rate of 25% each year. No right to any stock is earned or accrued until such time that vesting occurs, nor does the grant confer any right to continue vesting or employment.

### **3. Housing Subsidy and Relocation**

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a. Beginning with the commencement of your employment, Sutro we will provide you with a monthly housing subsidy. Here are the details of these allowances: Subject to your continuing employment with the Company, the Company will provide you with a four-year housing subsidy as follows, commencing on your first day of employment and payable on the first paycheck of each month, thereafter. This housing subsidy will be in the amount of \$8,500 per month in years one and two and \$6,500 a month in years three and four. This housing subsidy will be taxable income to you. The Company will engage with a relocation company who will work directly with you to manage the details of your move to the San Francisco Bay Area and will provide you with the assistance you may need in finding a residence in the San Francisco Bay Area. We will reimburse you for customary closing costs associated with the purchase of a residence within a commutable distance to South San Francisco. Sutro will provide a one-time tax gross up for your relocation related expenses incurred in conjunction with your move. This will include moving your household goods, storage of your household goods (as needed), and closing costs associated with the purchase of a residence in the San Francisco Bay Area.

#### **4. Employee Benefits**

- a. **Group Plans.** As an employee, you will be eligible to receive certain employee benefits including health insurance, life insurance and disability insurance, with reasonable and customary coverages and deductibles or co-payments.
- b. **Paid Time Off.** Subject to the Company's PTO Policy, you will be eligible for 20 days Paid Time Off (PTO), accrued on a monthly basis at the rate of 13.34 hours per month. You will also be eligible for 9 paid holidays per year.
- c. **401k.** The Company will provide you with the opportunity to participate in the Sutro's 401k plan. The plan will match 50% of your first 6% of contribution up to the IRS maximum deferral allowed. You are eligible to enroll the first of the month after your hire date and must be an active employee on 12/31 of the plan year to be eligible for the Company contribution.
- d. **Employee Stock Purchase Program (ESPP).** Eligible employees can acquire Sutro stock through after-tax payroll deductions at a discounted purchase price. Offering periods run for a six-month period and occur twice each year on March 15th and September 15th.

#### **5. Change of Control/Severance Eligibility**

Effective with your first date of employment you will be a participant in Sutro's Change of Control and Severance plan with the provisions provided under Tier 2 of the Plan. We have included a copy of the plan document for your reference.

#### **6. Additional Important Information**

- a. **At-Will Employment.** You should be aware that your employment with the Company is for no specified period and constitutes at-will employment. As a result, you are free to resign at any time, for any reason or for no reason. Similarly, the Company is free to conclude its employment relationship with you at any time, with or without cause, and with or without notice. We request that, in the event of resignation, you give the Company at least two weeks' notice.
- b. **Confidentiality & Arbitration Agreement.** As a condition of your employment, you are also required to sign and comply with an At-Will Employment, Confidential Information, Invention Assignment and Arbitration Agreement which requires, among other provisions, the assignment of patent rights to any invention made during your employment at the Company, and non-disclosure of company proprietary information. In the event of any dispute or claim relating to or arising out of our employment relationship, you and the Company agree that (i) any and all disputes between you and the Company shall be fully and finally resolved by binding arbitration, (ii) you are waiving any and all rights to a jury trial but all court remedies will be available in arbitration, (iii) all disputes shall be resolved by a neutral arbitrator who shall issue a written opinion, (iv) the arbitration shall provide for adequate
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discovery, and (v) the Company shall pay all but the first \$125 of the arbitration fees. Please note that we must receive your signed Agreement before your first day of employment.

c. **Verification of Information.** The Company reserves the right to conduct background investigations and/or reference checks on all of its potential employees. Your job offer, therefore, is contingent upon a clearance of such a background investigation and/or reference check, if any.

d. **Right to Work.** For purposes of federal immigration law, you will be required to provide to the Company documentary evidence of your identity and eligibility for employment in the United States. Such documentation must be provided to us within three (3) business days of your date of hire, or our employment relationship with you may be terminated.

e. **No Conflicting Obligations.** We also ask that, if you have not already done so, you disclose to the Company any and all agreements relating to your prior employment that may affect your eligibility to be employed by the Company or limit the manner in which you may be employed. It is the Company's understanding that any such agreements will not prevent you from performing the duties of your position and you represent that such is the case. Moreover, you agree that, during the term of your employment with the company, you will not engage in any other employment, occupation, consulting or other business activity directly related to the business in which the Company is now involved or becomes involved during the term of your employment, nor will you engage in any other activities that conflict with your obligations to the Company. Similarly, you agree not to bring any third party confidential information to the Company, including that of your former employer, and that in performing your duties for the Company you will not in any way utilize any such information.

f. **General Obligations.** As a Company employee, you will be expected to abide by the company's rules and standards. Specifically, you will be required to sign an acknowledgment that you have read and that you understand the Company's rules of conduct, which are included in the Company Handbook.

To accept the Company's offer, please sign and date this letter in the space provided below. This letter, along with any agreements relating to proprietary rights between you and the Company, set forth the terms of your employment with the Company and supersede any prior representations or agreements including, but not limited to, any representations made during your recruitment, interviews or pre-employment negotiations, whether written or oral. This letter, including, but not limited to, its at-will employment provision, may not be modified or amended except by a written agreement signed by the CEO of the Company and you. This offer of employment will terminate if it is not accepted, signed and returned by **June 4, 2021**.

We look forward to your favorable reply and to working with you at Sutro Biopharma.

*[signature page follows]*

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To indicate your acceptance of the Company's offer, please sign and date this letter in the space provided below and return it to me.

Sincerely,

\_\_\_\_\_  
William J. Newell

CEO

ACCEPTED AND AGREED:

Signature: \_\_\_\_

Printed Name: \_\_\_\_

Date: \_\_\_\_

Enclosures:

Exhibit A: General Release of All Claims

Exhibit B: Section 409A Provisions

Sutro Severance and Change of Control Plan

Sutro Biopharma 2021 Benefits Guide

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**EXHIBIT A**

**GENERAL RELEASE OF ALL CLAIMS**

In consideration of the severance benefits to be provided to **Jane Chung** by Sutro Biopharma, Inc. (the "Company"), pursuant to the terms of the letter you entered into with the Company dated as of **May 21, 2021** (the "Agreement"), you, on your own behalf and on behalf of your heirs, executors, administrators, and assigns, hereby fully and forever release and discharge the Company and its directors, officers, employees, agents, successors, predecessors, subsidiaries, parent, stockholders, employee benefit plans and assigns (together called "the Releases"), from all known and unknown claims and causes of action including, without limitation, any claims or causes of action arising out of or relating in any way to your employment with the Company, including the termination of that employment.

Eight days after you sign (and do not revoke) this General Release of All Claims ("Release"), provided that it is not signed earlier than your cessation of employment, you will be entitled to the severance benefits or change of control benefits set forth in the Agreement, subject to any other requirements set forth therein or on Exhibit B thereto, that are conditioned on this Release.

You understand and agree that this Release is a full and complete waiver of all claims, including (without limitation) claims to attorneys' fees or costs, claims of wrongful discharge, constructive discharge, breach of contract, breach of the covenant of good faith and fair dealing, harassment, retaliation, discrimination, violation of public policy, defamation, invasion of privacy, interference with a leave of absence, personal injury, fraud or emotional distress and any claims of discrimination or harassment based on sex, age, race, national origin, disability or any other basis under Title VII of the Civil Rights Act of 1964, the Fair Labor Standards Act, the Equal Pay Act of 1963, the Americans With Disabilities Act, the Age Discrimination in Employment Act of 1967 (ADEA), the California Labor Code, the California Fair Employment and Housing Act, the California Family Rights Act, the Family Medical Leave Act or any other federal or state law or regulation relating to employment or employment discrimination. You further understand and agree that this waiver includes all claims, known and unknown, to the greatest extent permitted by applicable law.

You also hereby agree that nothing contained in this Release shall constitute or be treated as an admission of liability or wrongdoing by the Releasees or you.

In addition, you hereby expressly waive any and all rights and benefits conferred upon you by the provisions of Section 1542 of the Civil Code of the State of California, which states as follows:

A general release does not extend to claims which the creditor does not know or suspect to exist in his or her favor at the time of executing the release, which if known by him or her must have materially affected his or her settlement with the debtor.

If any provision of this Release is found to be unenforceable, it shall not affect the enforceability of the remaining provisions and the court shall enforce all remaining provisions to the full extent permitted by law.

You agree to provide, at the Company's expense, including reimbursement of your time and/or the reasonable fees and expenses of your counsel, reasonable cooperation and complete and accurate information to the Company (voluntarily, without requiring a subpoena or other compulsion of law) in the event of litigation against the Company and/or its officers or directors. You also agree that you will not assist any person in bringing or pursuing any claim or action of any kind against the Company, unless pursuant to subpoena or other compulsion of law.

This Release constitutes the entire agreement between you and Releasees' with regard to the subject matter of this Release. It supersedes any other agreements, representations or understandings, whether oral or written and whether express or implied, which relate to the subject matter of this Release except as otherwise set forth in the Agreement. However, this Release covers only those claims that arose prior to the execution of this Release. Execution of this Release does not bar any claim that arises hereafter, including (without limitation) a claim for breach of the Agreement.

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You understand that you have the right to consult with an attorney before signing this Release. You have 21 days after receipt of this Release to review and consider this Release, discuss it with an attorney of your own choosing, and decide to execute it or not execute it. You also understand that you may revoke this Release during a period of seven days after you sign it and that this Release will not become effective for seven days after you sign it (and then only if you do not revoke it). In any event, this Release is not to be signed, and will not become effective, prior to your cessation of employment. In order to revoke this Release, within seven days after you execute this Release you must deliver to William Newell, at the Company, a letter stating that you are revoking it.

You understand that if you choose to revoke this Release within seven days after you sign it, you will not receive the severance benefits set forth in the Agreement that are conditioned on this Release and the Release will have no effect.

You agree not to disclose to others the terms of this Release, except that you may disclose such information to your spouse and to your attorney or accountant in order for such attorney or accountant to render services to you related to this Release.

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You state that before signing this Release, you:

- Have read it,
- Understand it,
- Know that you are giving up important rights,
- Are aware of your right to consult an attorney before signing it, and
- Have signed it knowingly and voluntarily.

Date:

By: \_

**Jane Chung**

TO BE SIGNED UPON CESSATION OF EMPLOYMENT

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**EXHIBIT B**

**SECTION 409A**

(a) Notwithstanding anything to the contrary in the letter, no Deferred Compensation Separation Benefits (as defined below) will become payable under the letter until you have a "separation from service" within the meaning of Section 409A of the Internal Revenue Code of 1986, as amended (the "Code"), and any proposed or final regulations and guidance promulgated thereunder ("Section 409"). Further, if you are a "specified employee" within the meaning of Section 409A at the time of your termination (other than due to death), and the severance or other benefits payable to you, if any, pursuant to the letter, when considered together with any other severance payments or separation benefits, are considered deferred compensation under Section 409A (together, the "Deferred Compensation Separation Benefits"), such Deferred Compensation Separation Payments that are otherwise payable within the first fifteen (15) months following your termination of employment will become payable on the first payroll date that occurs on or after the date NUMBER (#) months and one (1) day following the date of your termination of employment (or such later date as is required to avoid the imposition of additional tax under Section 409A). All subsequent Deferred Compensation Separation Benefits, if any, will be payable in accordance with the payment schedule applicable to each payment or benefit. Notwithstanding anything herein to the contrary, if you die following your termination but prior to the fifteen (15) month anniversary of your termination (or any later delay date), then any payments delayed in accordance with this paragraph will be payable in a lump sum as soon as administratively practicable after the date of your death and all other Deferred Compensation Separation Benefits will be payable in accordance with the payment schedule applicable to each payment or benefit. Each payment and benefit payable under the letter are intended to constitute separate payments for purposes of Section 1.409A-2(b)(2) of the Treasury Regulations.

(b) Any amount paid under the letter that satisfies the requirements of the "short-term deferral" rule set forth in Section 1.409A-(b)(4) of the Treasury Regulations shall not constitute Deferred Compensation Separation Benefits for purposes of section (a) above.

(c) Any amount paid under the letter that qualifies as a payment made as a result of an involuntary separation from service pursuant to Section 1.409A-(b)(9)(iii) of the Treasury Regulations that does not exceed the Section 409A Limit shall not constitute Deferred Compensation Separation Benefits for purposes of section (a) above. For purposes of this section (c), "Section 409A Limit" will mean the lesser of two (2) times: (i) your annualized compensation based upon the annual rate of pay paid to you during the Company's taxable year preceding the Company's taxable year of your termination of employment as determined under Treasury Regulation 1.409A-1(b)(9)(iii)(A)(I) and any Internal Revenue Service guidance issued with respect thereto; or (ii) the maximum amount that may be taken into account under a qualified plan pursuant to Section 401(a)(17) of the Code for the year in which your employment is terminated.

(d) For purposes of Section 409A, any right to receive any installment payments pursuant to this letter will be treated as a right to receive a series of separate and distinct payments under Section 1.409A-2(b)(2)(iii) of the Treasury Regulations.

(e) Reimbursement. To the extent that any taxable reimbursements of expenses or in kind benefits are provided, they shall be made in accordance with Section 409A, including, but not limited to the following provisions:

- i) The amount of any such expense reimbursement or in-kind benefit provided during a service provider's taxable year shall not affect any expenses eligible for reimbursement in any other taxable year;
  - ii) The reimbursement of the eligible expense shall be made no later than the last day of the service provider's taxable year that immediately follows the taxable year in which the expense was incurred; and
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iii) The right to any reimbursement shall not be subject to liquidation or exchange for another benefit or payment.

(e) The foregoing provisions are intended to comply with the requirements of Section 409A so that none of the severance payments and benefits to be provided under the letter will be subject to the additional tax imposed under Section 409A, and any ambiguities herein will be interpreted to so comply. You and the Company agree to work together in good faith to consider amendments to the letter and to take such reasonable actions which are necessary, appropriate or desirable to avoid imposition of any additional tax or income recognition prior to actual payment to you under Section 409A.

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December 11, 2015

Arturo Molina, M.D  
[Private Address]

Dear Arturo,

We are very pleased to present this revised offer of employment to you for the position of Chief Medical Officer at Sutro Biopharma (the "Company"), reporting to William J. Newell, Chief Executive Officer. This letter sets forth the terms and conditions of our proposal for your employment. You may accept this offer by signing and returning a copy of it to me as provided below.

You will receive an annual salary of \$415,000.00 which will be paid semi-monthly in accordance with the Company's normal payroll procedures. Furthermore, in each calendar year during your employment with the Company, you will be eligible to receive an annual bonus dependent on performance objectives, which will be based on company objectives established by the Company's Board of Directors in their discretion. Your target bonus will be equal to forty percent (40%) of your base salary, assuming the achievement of such performance objectives as determined solely by the Company's Board of Directors. Any bonus that you earn will be paid to you within two and one-half (2-1/2) months of the end of the calendar year in which it is earned, and shall be paid in cash, less any usual, required withholding. As an employee, you will also be eligible to receive certain employee benefits including health insurance, life insurance and disability insurance, with reasonable and customary coverages and deductibles or copayments. Annually, you will receive 20 days of Paid Time Off (PTO) which will be earned and accrued at the rate of 1.66 days per month. A summary of the Company's benefits is included with this letter.

You will also receive a \$150,000 signing bonus, subject to applicable taxes and withholdings, to be paid to you on your first pay period following your start date of employment.

In addition to the above salary and other consideration, at the next regularly scheduled meeting of the Company's Board of Directors, following your commencement of employment, you will be granted a stock option to purchase the number of shares of the Company's common stock equal to 1.50% of the Company's capital stock calculated on a fully diluted basis at the time of grant. The price per share shall be equal to the fair market value per share of the Company's Common Stock on the grant date as determined by the Company's Board of Directors. For this grant, you will be 25% vested on the anniversary of your first year of employment. The remaining shares, subject to your stock option grant, will vest over the following three years of your employment at the rate of 1/36 per month in equal monthly installments subject to your continuous service with the Company. You will be eligible to receive additional stock option grants in the future at the discretion of the Company's Board of Directors.

This option grant shall be subject to the terms and conditions of the Company's Stock Option Plan and Stock Option Agreement, including vesting requirements which require your continued employment with the Company. No right to any stock is earned or accrued until such time that vesting occurs, nor does the grant confer any right to continue vesting or employment.

The Company will indemnify you to the maximum extent that its officers and employees are entitled to indemnification pursuant to the Company's Certificate of Incorporation and bylaws for any acts

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or omissions by reason of being an officer or employee of the Company during your employment. At all times during your employment, the Company shall maintain in effect a directors and officers liability insurance policy with you as a covered officer.

If your employment with the Company is terminated by the Company due to an Involuntary Termination (as defined below), you will receive: (i) continued payment of your base salary (less applicable tax withholdings) for twelve (12) months following such termination, with such amounts to be paid in accordance with the Company's normal payroll policies; *provided, however*, that any payments otherwise scheduled to be made prior to the effective date of the Release (namely, the date it can no longer be revoked) shall accrue and be paid in the first payroll date that follows such effective date with subsequent payments occurring on each subsequent Company payroll date; (ii) twelve (12) months of accelerated vesting on all outstanding Company stock options; and (iii) payment of a pro-rata portion of the your annual bonus (less applicable tax withholdings) for the performance year in which your termination occurs, with such pro-rata portion calculated based upon the number of days that you were employed during such performance year divided by the total number of days in such performance year, payable as a lump sum payment on the Release effective date (namely, the date it can no longer be revoked); and (iv) reimbursement for premiums paid for continued health benefits for you (and any eligible dependents) under the Company's health plans until the earlier of (A) twelve (12) months following your termination date or (B) the date upon which you and your eligible dependents become covered under similar plans; provided, however, that you validly elect to continue coverage under the Consolidated Omnibus Budget Reconciliation Act of 1985, as amended. Reimbursements for health premiums will be made as soon as administratively practicable following approval of the reimbursement (or, if later, following the date you are first entitled to such reimbursements under this paragraph) and to the extent that such amounts are taxable not later than the end of the calendar year in which the expense was incurred.

If your employment with the Company is terminated by the Company due to an Involuntary Termination (as defined below) and such termination occurs on or within twelve (12) months following a Change of Control (as defined below), then, you will receive accelerated vesting as to 100% of any then non-exercisable option shares under any of your option grants.

The receipt of any benefits pursuant to the two prior paragraphs above will be subject to you signing and not revoking a separation agreement and release of claims substantially in the form attached to this offer letter as Exhibit A (the "Release"), provided that such release becomes effective no later than sixty (60) days following your termination date or such earlier date required by the Release (such deadline, the "Release Deadline"). If the Release does not become effective by the Release Deadline, you will forfeit any rights to severance or benefits under this letter, and in no event will severance payments or benefits be paid or provided until the Release actually becomes effective. In the event your termination occurs at a time during the calendar year where the Release could become effective in the calendar year following the calendar year in which your termination occurs, then any severance payments or benefits under this letter that would be considered Deferred Compensation Separation Benefits (as defined on Exhibit B hereto) will be paid on the first payroll date to occur during the calendar year following the calendar year in which such termination occurs, or, if later, (i) the Release Deadline, (ii) such time as required by the payment schedule applicable to each payment or benefit as set forth in Exhibit B, or (iii) such time as required by this paragraph.

For the purposes of this offer letter, "Involuntary Termination" means (i) your involuntary discharge by the Company for reasons other than Cause (as defined below); or (ii) your voluntary resignation within ninety (90) days following the end of the Cure Period (as defined below) as a result of the occurrence of any of the following without your consent: (a) a material diminution in your authority, duties or responsibilities; (b) a material breach of this letter agreement by the Company; or (c) a material

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diminution in your base compensation (other than a reduction generally applicable to executive officers of the Company implemented for expense management purposes); or (d) a requirement for Employee to relocate to an office that is more than fifty (50) miles from the location of the Company's principal offices at the time of such relocation; provided, however, that you must provide written notice to the Company of the condition that could constitute an "Involuntary Termination" event pursuant to the provisions of section (ii) of this paragraph within ninety (90) days of the initial existence of such condition and such condition must not have been remedied by the Company within thirty (30) days (the "Cure Period") of such written notice.

"Change of Control" means the occurrence of any of the following events: (i) any consolidation or merger of the Company with or into any other corporation or other entity or person, or any other corporate reorganization, in which the stockholders of the Company immediately prior to such consolidation, merger or reorganization, own less than fifty percent (50%) of the voting power of the surviving entity (or if the surviving entity is a wholly-owned subsidiary, its parent) immediately after such consolidation, merger or reorganization; (ii) a transaction or series of related transactions to which the Company is a party or a tender offer in which in excess of fifty percent (50%) of the Company's voting power is transferred; or (iii) a sale, lease conveyance or other disposition of all or substantially all of the assets of the Company that occurs over a period of not more than twelve (12) months. Notwithstanding the foregoing, in no event shall (A) an initial public offering of Common Stock pursuant to a registration statement filed with the Securities and Exchange Commission; (B) any equity financing (including the issuance of convertible debt) of the Company in a single transaction or a series of transactions; or (C) a transaction whose primary purpose is to change the state of the Company's incorporation and/or to create a holding company that will be owned in substantially the same proportions by the persons who held the Company's securities before such transaction constitute a Change of Control for purposes of this offer letter.

"Cause" means (i) an unauthorized use or disclosure of the Company's confidential information or trade secrets, which use or disclosure causes material harm to the Company; (ii) a deliberate material failure in the performance of your duties as Chief Medical Officer or any other duties as pertaining to employees of the Company generally, which is not cured within fifteen (15) days after receiving written notification of such failure from the Board of Directors or the Chief Executive Officer; (iii) conviction of, or pleas of "guilty" or "no contest" to, a felony (other than one related to vehicular or vicarious liability) under the laws of the United States or any state thereof; (iv) gross misconduct, which is not cured within fifteen (15) days after receiving written notification of such misconduct from the Board of Directors or the Chief Executive Officer; or (v) a continued failure to perform assigned duties customarily performed by a Chief Medical Officer of a corporation of similar size, which is not cured within fifteen (15) days after receiving written notification of such failure from the Board of Directors or the Chief Executive Officer.

The Company is excited about your joining and looks forward to a beneficial and productive relationship. Nevertheless, you should be aware that your employment with the Company is for no specified period and constitutes at-will employment. As a result, you are free to resign at any time, for any reason or for no reason. Similarly, the Company is free to conclude its employment relationship with you at any time, with or without cause, and with or without notice. We request that, in the event of resignation, you give the Company at least two weeks' notice. You should also note that the Company may modify job titles, salaries and benefits from time to time as it deems necessary.

The Company reserves the right to conduct background investigations and/or reference checks on all of its potential employees. Your job offer, therefore, is contingent upon a clearance of such a background investigation and/or reference check, if any.

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For purposes of federal immigration law, you will be required to provide to the Company documentary evidence of your identity and eligibility for employment in the United States. Such documentation must be provided to us within three (3) business days of your date of hire, or our employment relationship with you may be terminated.

We also ask that, if you have not already done so, you disclose to the Company any and all agreements relating to your prior employment that may affect your eligibility to be employed by the Company or limit the manner in which you may be employed. It is the Company's understanding that any such agreements will not prevent you from performing the duties of your position and you represent that such is the case. Moreover, you agree that, during the term of your employment with the Company, you will not engage in any other employment, occupation, consulting or other business activity directly related to the business in which the Company is now involved or becomes involved during the term of your employment, nor will you engage in any other activities that conflict with your obligations to the Company without the prior written consent of the Chief Executive Officer; provided, however, that your continuing involvement with the American Society of Hematology/AMFDP National Advisory Committee/Robert Wood John Foundation shall not require further written consent. Similarly, you agree not to bring any third party confidential information to the Company, including that of your former employer, and that in performing your duties for the Company you will not in any way utilize any such information.

As a Company employee, you will be expected to abide by the Company's rules and standards. Specifically, you will be required to sign an acknowledgment that you have read and that you understand the Company's rules of conduct, which are included in the Company Handbook.

As a condition of your employment, you are also required to sign and comply with an At-Will Employment, Confidential Information, Invention Assignment and Arbitration Agreement which requires, among other provisions, the assignment of patent rights to any invention made during your employment at the Company, and non-disclosure of Company proprietary information. In the event of any dispute or claim relating to or arising out of our employment relationship, you and the Company agree that (i) any and all disputes between you and the Company shall be fully and finally resolved by binding arbitration, (ii) you are waiving any and all rights to a jury trial but all court remedies will be available in arbitration, (iii) all disputes shall be resolved by a neutral arbitrator who shall issue a written opinion, (iv) the arbitration shall provide for adequate discovery, and (v) the Company shall pay all costs associated with arbitration fees. Please note that we must receive your signed Agreement before your first day of employment.

Notwithstanding anything to the contrary in this letter, any severance or other benefits to which you may become entitled to pursuant to this letter will be subject to the terms provided in Exhibit B hereto.

We would propose that your first day of employment will be on or before February 11, 2016, and we request that you inform us as soon as you can of your exact start date. This letter, along with any agreements relating to proprietary rights between you and the Company, set forth the terms of your employment with the Company and supersede any prior representations or agreements including, but not limited to, any representations made during your recruitment, interviews or pre-employment negotiations, whether written or oral. This letter, including, but not limited to, its at-will employment provision, may not be modified or amended except by a written agreement signed by the Chief Executive Officer of the Company and you. This offer of employment will terminate if it is not accepted, signed and returned by January 20, 2016.

We look forward to your favorable reply and to working with you at Sutro Biopharma.

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*[signature page follows]*

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To indicate your acceptance of the letter, please sign and date this letter in the space provided below and return it to me. A duplicate original is enclosed for your records.

Sincerely,

\_\_\_\_\_  
William J. Newell  
Chief Executive Officer

Agreed to and accepted:

Signature: \_

Printed Name: \_

Date: \_

Enclosures:

Duplicate Original Letter

Exhibit A: General Release of All Claims

Exhibit B: Section 409A Provisions

At-Will Employment, Confidential Information, Invention Assignment and  
Arbitration Agreement

Sutro Biopharma Benefits Guide

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## EXHIBIT A

### GENERAL RELEASE OF ALL CLAIMS

In consideration of the severance benefits to be provided to Arturo Molina by Sutro Biopharma, Inc. (the "Company"), pursuant to the terms of the letter you entered into with the Company dated as of December 11, 2015 (the "Agreement"), you, on your own behalf and on behalf of your heirs, executors, administrators, and assigns, hereby fully and forever release and discharge the Company and its directors, officers, employees, agents, successors, predecessors, subsidiaries, parent, stockholders, employee benefit plans and assigns (together called "the Releasees"), from all known and unknown claims and causes of action including, without limitation, any claims or causes of action arising out of or relating in any way to your employment with the Company, including the termination of that employment.

Eight days after you sign (and do not revoke) this General Release of All Claims ("Release"), provided that it is not signed earlier than your cessation of employment, you will be entitled to the severance benefits or change of control benefits set forth in the Agreement, subject to any other requirements set forth therein or on Exhibit B thereto, that are conditioned on this Release.

You understand and agree that this Release is a full and complete waiver of all claims, including (without limitation) claims to attorneys' fees or costs, claims of wrongful discharge, constructive discharge, breach of contract, breach of the covenant of good faith and fair dealing, harassment, retaliation, discrimination, violation of public policy, defamation, invasion of privacy, interference with a leave of absence, personal injury, fraud or emotional distress and any claims of discrimination or harassment based on sex, age, race, national origin, disability or any other basis under Title VII of the Civil Rights Act of 1964, the Fair Labor Standards Act, the Equal Pay Act of 1963, the Americans With Disabilities Act, the Age Discrimination in Employment Act of 1967 (ADEA), the California Labor Code, the California Fair Employment and Housing Act, the California • Family Rights Act, the Family Medical Leave Act or any other federal or state law or regulation relating to employment or employment discrimination. You further understand and agree that this waiver includes all claims, known and unknown, to the greatest extent permitted by applicable law.

You also hereby agree that nothing contained in this Release shall constitute or be treated as an admission of liability or wrongdoing by the Releasees or you.

In addition, you hereby expressly waive any and all rights and benefits conferred upon you by the provisions of Section 1542 of the Civil Code of the State of California, which states as follows:

A general release does not extend to claims which the creditor does not know or suspect to exist in his or her favor at the time of executing the release, which if known by him or her must have materially affected his or her settlement with the debtor.

If any provision of this Release is found to be unenforceable, it shall not affect the enforceability of the remaining provisions and the court shall enforce all remaining provisions to the full extent permitted by law.

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You agree to provide, at the Company's expense, including reimbursement of your time and/or the reasonable fees and expenses of your counsel, reasonable cooperation and complete and accurate information to the Company (voluntarily, without requiring a subpoena or other compulsion of law) in the event of litigation against the Company and/or its officers or directors. You also agree that you will not assist any person in bringing or pursuing any claim or action of any kind against the Company, unless pursuant to subpoena or other compulsion of law.

This Release constitutes the entire agreement between you and Releasees with regard to the subject matter of this Release. It supersedes any other agreements, representations or understandings, whether oral or written and whether express or implied, which relate to the subject matter of this Release except as otherwise set forth in the Agreement. However, this Release covers only those claims that arose prior to the execution of this Release. Execution of this Release does not bar any claim that arises hereafter, including (without limitation) a claim for breach of the Agreement.

You understand that you have the right to consult with an attorney before signing this Release. You have 21 days after receipt of this Release to review and consider this Release, discuss it with an attorney of your own choosing, and decide to execute it or not execute it. You also understand that you may revoke this Release during a period of seven days after you sign it and that this Release will not become effective for seven days after you sign it (and then only if you do not revoke it). In any event, this Release is not to be signed, and will not become effective, prior to your cessation of employment. In order to revoke this Release, within seven days after you execute this Release you must deliver to William Newell, at the Company, a letter stating that you are revoking it.

You understand that if you choose to revoke this Release within seven days after you sign it, you will not receive the severance benefits set forth in the Agreement that are conditioned on this Release and the Release will have no effect.

You agree not to disclose to others the terms of this Release, except that you may disclose such information to your spouse and to your attorney or accountant in order for such attorney or accountant to render services to you related to this Release.

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You state that before signing this Release, you:

- Have read it,
- Understand it,
- Know that you are giving up important rights,
- Are aware of your right to consult an attorney before signing it, and
- Have signed it knowingly and voluntarily.

Date:

By: \_  
Arturo Molina

TO BE SIGNED UPON CESSATION OF EMPLOYMENT

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**EXHIBIT B**

**SECTION 409A**

(a) Notwithstanding anything to the contrary in the letter, no Deferred Compensation Separation Benefits (as defined below) will become payable under the letter until you have a “separation from service” within the meaning of Section 409A of the Internal Revenue Code of 1986, as amended (the “Code”), and any proposed or final regulations and guidance promulgated thereunder (“Section 409”). Further, if you are a “specified employee” within the meaning of Section 409A at the time of your termination (other than due to death), and the severance or other benefits payable to you, if any, pursuant to the letter, when considered together with any other severance payments or separation benefits, are considered deferred compensation under Section 409A (together, the “Deferred Compensation Separation Benefits”), such Deferred Compensation Separation Payments that are otherwise payable within the first six (6) months following your termination of employment will become payable on the first payroll date that occurs on or after the date six (6) months and one (1) day following the date of your termination of employment (or such later date as is required to avoid the imposition of additional tax under Section 409A). All subsequent Deferred Compensation Separation Benefits, if any, will be payable in accordance with the payment schedule applicable to each payment or benefit. Notwithstanding anything herein to the contrary, if you die following your termination but prior to the six (6) month anniversary of your termination (or any later delay date), then any payments delayed in accordance with this paragraph will be payable in a lump sum as soon as administratively practicable after the date of your death and all other Deferred Compensation Separation Benefits will be payable in accordance with the payment schedule applicable to each payment or benefit. Each payment and benefit payable under the letter is intended to constitute separate payments for purposes of Section 1.409A-2(b)(2) of the Treasury Regulations.

(b) Any amount paid under the letter that satisfies the requirements of the “short-term deferral” rule set forth in Section 1.409A-1(b)(4) of the Treasury Regulations shall not constitute Deferred Compensation Separation Benefits for purposes of section (a) above.

(c) Any amount paid under the letter that qualifies as a payment made as a result of an involuntary separation from service pursuant to Section 1.409A-1(b)(9)(iii) of the Treasury Regulations that does not exceed the Section 409A Limit shall not constitute Deferred Compensation Separation Benefits for purposes of section (a) above. For purposes of this section (c), “Section 409A Limit” will mean the lesser of two (2) times: (i) your annualized compensation based upon the annual rate of pay paid to you during the Company’s taxable year preceding the Company’s taxable year of your termination of employment as determined under Treasury Regulation 1.409A-1(b)(9)(iii)(A)(1) and any Internal Revenue Service guidance issued with respect thereto; or (ii) the maximum amount that may be taken into account under a qualified plan pursuant to Section 401(a)(17) of the Code for the year in which your employment is terminated.

(d) For purposes of Section 409A, any right to receive any installment payments pursuant to this letter will be treated as a right to receive a series of separate and distinct payments under Section 1.409A-2(b)(2)(iii) of the Treasury Regulations.

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(e) Reimbursement. To the extent that any taxable reimbursements of expenses or in kind benefits are provided, they shall be made in accordance with Section 409A, including, but not limited to the following provisions:

- i) The amount of any such expense reimbursement or in-kind benefit provided during a service provider's taxable year shall not affect any expenses eligible for reimbursement in any other taxable year;
- ii) The reimbursement of the eligible expense shall be made no later than the last day of the service provider's taxable year that immediately follows the taxable year in which the expense was incurred; and
- iii) The right to any reimbursement shall not be subject to liquidation or exchange for another benefit or payment.

(e) The foregoing provisions are intended to comply with the requirements of Section 409A so that none of the severance payments and benefits to be provided under the letter will be subject to the additional tax imposed under Section 409A, and any ambiguities herein will be interpreted to so comply. You and the Company agree to work together in good faith to consider amendments to the letter and to take such reasonable actions which are necessary, appropriate or desirable to avoid imposition of any additional tax or income recognition prior to actual payment to you under Section 409A.

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**CONSENT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM**

We consent to the incorporation by reference in the Registration Statements (Form S-8 Nos. 333-227551, 333-230641, 333-237202, 333-254456 and 333-258603) of Sutro Biopharma, Inc. and the Registration Statement (Form S-3 No. 333-255014) and related base prospectus and sales agreement prospectus of Sutro Biopharma, Inc. of our reports dated February 28, 2022, with respect to the financial statements of Sutro Biopharma, Inc., and the effectiveness of internal control over financial reporting of Sutro Biopharma, Inc. included in this Annual Report (Form 10-K) for the year ended December 31, 2021.

/s/ Ernst & Young LLP

Redwood City, California  
February 28, 2022

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**CERTIFICATION PURSUANT TO RULE 13a-14(a) OR 15d-14(a) OF  
THE SECURITIES EXCHANGE ACT OF 1934,  
AS ADOPTED PURSUANT TO SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002**

I, William J. Newell certify that:

- 1.I have reviewed this Annual Report on Form 10-K of Sutro Biopharma, Inc.;
- 2.Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
- 3.Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
- 4.The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:
  - a.designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
  - b.designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;
  - c.evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
  - d.disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
- 5.The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):
  - a.all significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting, which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
  - b.any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: February 28, 2022

/s/ William J. Newell  
William J. Newell  
*Chief Executive Officer*  
*(Principal Executive Officer)*

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**CERTIFICATION PURSUANT TO RULE 13a-14(a) OR 15d-14(a) OF  
THE SECURITIES EXCHANGE ACT OF 1934,  
AS ADOPTED PURSUANT TO SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002**

I, Edward C. Albini, certify that:

1. I have reviewed this Annual Report on Form 10-K of Sutro Biopharma, Inc.;
2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:
  - a. designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
  - b. designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;
  - c. evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
  - d. disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):
  - a. all significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting, which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
  - b. any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: February 28, 2022

/s/ Edward C. Albini  
Edward C. Albini  
*Chief Financial Officer*  
*(Principal Accounting Officer and Principal Financial Officer)*

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**CERTIFICATION PURSUANT TO  
18 U.S.C. SECTION 1350, AS ADOPTED PURSUANT TO  
SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002**

I, William J. Newell, Chief Executive Officer of Sutro Biopharma, Inc. (the "Company"), do hereby certify, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that to the best of my knowledge:

- 1.the Annual Report on Form 10-K of the Company for the fiscal year ended December 31, 2021 (the "Report") fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934, as amended; and
- 2.the information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Dated: February 28, 2022

/s/ William J. Newell  
William J. Newell  
*Chief Executive Officer*  
*(Principal Executive Officer)*

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**CERTIFICATION PURSUANT TO  
18 U.S.C. SECTION 1350, AS ADOPTED PURSUANT TO  
SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002**

I, Edward C. Albini, Chief Financial Officer of Sutro Biopharma, Inc. (the “Company”), do hereby certify, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that to the best of my knowledge:

- 1.the Annual Report on Form 10-K of the Company for the fiscal year ended December 31, 2021 (the “Report”) fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934, as amended; and
- 2.the information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Dated: February 28, 2022

/s/ Edward C. Albini  
Edward C. Albini  
*Chief Financial Officer*  
*(Principal Financial Officer and Principal Accounting Officer)*

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