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, 2024

OR

☐ **TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**

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)**	**47-0926186** **(I.R.S. Employer Identification No.)**
111 Oyster Point Blvd. **South San Francisco, California** **(Address of principal executive offices)**	**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	Trading Symbol	Name of each exchange on which registered
Common stock, $0.001 par value	STRO	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	☐	Accelerated filer	☒
Non-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. ☒

If securities are registered pursuant to Section 12(b) of the Act, indicate by check mark whether the financial statements of the registrant included in the filing reflect the correction of an error to previously issued financial statements. ☐

Indicate by check mark whether any of those error corrections are restatements that required a recovery analysis of incentive-based compensation received by any of the registrant's executive officers during the relevant recovery period pursuant to §240.10D-1(b). ☐

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, 2024 (the last business day of the Registrant's second fiscal quarter), based upon the closing price of $2.93 of the Registrant's common stock as reported on The Nasdaq Global Market, was approximately $237.8 million.

The number of shares of the registrant's common stock outstanding as of March 6, 2025, was 83,775,336.

DOCUMENTS INCORPORATED BY REFERENCE

Portions of the registrant's definitive proxy statement to be filed for its 2025 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, the use and adequacy of our existing cash to achieve our business goals, business strategy, market size for our product candidates, potential future milestone and royalty payments, 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, the timing and results of nonclinical studies and clinical trials, collaboration with third parties, the impact of health pandemics, regional geopolitical conflicts, changes in interest rates, inflation, potential uncertainty with respect to the debt ceiling and potential government shutdown related thereto, 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" in this Annual Report on Form 10-K. Some of these risks include:

- We have 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 sufficient funding may force us to delay, limit or terminate our product development programs, commercialization efforts or other operations. We may have difficulties accessing the required additional capital on reasonable, or even any, terms to continue our product and platform development or other operations, and may have to make difficult prioritization decisions regarding development and potential partnering of our clinical and preclinical product candidates.
- Our product candidates are in development and may fail, be impacted by competitive products or suffer delays that materially and adversely affect their commercial viability.
- Our business is dependent on the success of our product candidates, including STRO-004, which is generated from our proprietary XpressCF® and XpressCF+® platforms.
- If we do not achieve our development goals in the timeframes we anticipate and project, the commercialization of our products may be delayed 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 depend on our information technology systems, and any failure of these systems, or those of our contract research organizations, or 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.
- Our information technology systems could face serious disruptions that could adversely affect our business.
- 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® and XpressCF+® platforms and the product candidates.
- Our inability to manufacture sufficient quantities of our product candidates or such materials, 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.
- Our collaborators may fail to abide by the terms of the agreements with us, which would require us to seek to enforce our agreements in accordance with the dispute resolution procedures set forth therein. These procedures may require us to engage in litigation or arbitration to enforce our rights, which can be expensive, time-consuming, and distracting to our management and Board of Directors and that may ultimately end up being unsuccessful.

- 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. Changes in regulatory policy may render our strategies for obtaining regulatory approval less effective or completely ineffective, preventing us from obtaining regulatory approval for our product candidates on time or at all.

PART I

Item 1. *Business*

Overview

We are an oncology company developing site-specific and novel-format antibody drug conjugates, or ADCs, enabled by our proprietary integrated cell-free protein synthesis platform, XpressCF®, and our site-specific conjugation platform, XpressCF+®. We aim to design and develop therapeutics using the most relevant and potent modalities, including ADCs, bispecific ADCs, immunostimulatory ADCs, or iADCs, and dual conjugate ADCs, or ADC²s. Our molecules are directed primarily against clinically validated targets where the current standard of care is suboptimal. We believe that our platform allows us to accelerate the discovery and development of potential first-in-class and/or 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 creating medicines with improved therapeutic profiles for areas of unmet need.

Our highest priority wholly owned product candidate is STRO-004. This preclinical product candidate is a single homogeneous ADC directed against tissue factor, or TF, which we intend to develop for the treatment of solid tumors. We anticipate submission of an Investigational New Drug Application, or IND, to the U.S. Food and Drug Administration, or FDA, for STRO-004 in the second half of 2025.

Enabled through our proprietary XpressCF® and XpressCF+® platforms, we have entered into multi-target, product-focused collaborations with leading pharmaceutical and biotechnology companies in the field of oncology, including an immunostimulatory ADCs collaboration with Astellas Pharma Inc., or Astellas, 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”), or EMD Serono. Our XpressCF® and XpressCF+® platforms have also supported Vaxcyte, Inc., or Vaxcyte, focused on discovery and development of vaccines for the treatment and prophylaxis of infectious disease. We also have a preclinical product candidate, STRO-003, rights to which we licensed to Ipsen Pharma SAS, or Ipsen, in 2024. STRO-003 is intended to be developed for the treatment of solid tumors and we anticipate submission of an IND in connection with this program in 2025. 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 Ipsen, Astellas, Merck, BMS and EMD Serono. In 2024, we entered into an Exclusive License Agreement with Ipsen granting Ipsen worldwide rights to develop and commercialize STRO-003. In 2022, we entered into a License and Collaboration Agreement with Astellas for the development of immunostimulatory ADCs for up to three biological targets. In 2024, Astellas notified us that it would not be nominating a third target program; preclinical development of the immunostimulatory ADCs directed to the first two targets remains ongoing.

Our research collaborations with Merck, BMS, and EMD Serono all resulted in development candidate molecules that entered clinical development. As part of our partners' strategic portfolio review processes, each elected to terminate further clinical development of the candidate molecules following Phase 1 clinical studies. Through December 31, 2024, we have received an aggregate of approximately $980 million in payments from all of our collaborations, which includes approximately $79 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.

From 2018 through February 2025, we had been developing luveltamab tazevibulin, or STRO-002 or luvelta. In March 2025, we conducted a strategic review of our product portfolio. Following this review, we made the strategic decision to deprioritize additional investment into luvelta development, though we continue to explore potential partnership opportunities to make luvelta available to patients who may benefit from luvelta therapy.

In December 2021, we entered into the Tasly License Agreement, as amended in April 2022, to develop and commercialize luvelta in the Greater China territory.

As discussed above, our most advanced asset in preclinical development is STRO-004. We believe STRO-004 has the potential to be a best-in-class ADC targeting TF. Preclinical data suggest that STRO-004 has potent antitumor activity and potential for a differentiated safety profile.

Beyond these programs and collaborations, we are developing a broader pipeline of next-generation protein therapeutics using our XpressCF® and XpressCF+® 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, with the goal of identifying the best molecule to advance to the clinic. We are also actively pursuing the discovery and development of other novel ADCs and next-generation ADC modalities, including iADCs, bispecific ADCs, and ADC^2s.

Our Strategy

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

- **Advance STRO-004 through clinical development.** We anticipate submission of an IND to the FDA for STRO-004 in the second half of 2025. We intend to develop STRO-004 for the treatment of solid tumors, potentially including cervical cancer, head and neck cancer, non-small cell lung cancer, colorectal cancer, and pancreatic cancer. Given that TF is a clinically validated target for cervical cancer, along with STRO-004's homogeneous design and preclinical anti-tumor activity and toxicity data, we believe it has the potential to be a best-in-class TF-targeted ADC and provide benefit to a broader patient population than approved TF-targeting agents, as well as potentially greater activity, stability and/or safety as compared to other investigational agents in development.

- **Pursue strategic partnerships to maximize the potential value of our pipeline.** 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, or through partnerships, pursue the development and commercialization of our product candidates, to the extent possible. As we continue to advance our product candidates, we may opportunistically pursue additional strategic partnerships that maximize the value of our pipeline, including relationships, when possible, to potentially co-develop and co-commercialize one or more of our product candidates.

- **Develop a diverse pipeline of novel product candidates with optimized therapeutic profiles.** We intend to continue to build a broad pipeline of optimally designed, next-generation protein therapeutics, initially for cancer, using our XpressCF® and XpressCF® platforms. 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, focusing primarily on ADCs, iADCs, bispecific ADCs and ADC^2s, 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® and XpressCF+® platforms.** To maximize the value of our XpressCF® and XpressCF+® platform technology, we have entered into multi-target, product-focused collaborations with leaders in the field of oncology, including an iADC collaboration with Astellas, a cytokine derivatives collaboration with Merck, a BCMA ADC collaboration with BMS and a MUC1-EGFR ADC collaboration with EMD Serono. We intend to selectively enter into additional research collaborations with partners who are seeking efficient and effective drug discovery and manufacturing capabilities for the development of novel therapeutics. We intend to retain, to the extent possible, certain development and commercial rights to maximize the future potential value of product candidates discovered and developed using our XpressCF® platform.

- **Strategically position our XpressCF® platform as a preferred alternative to conventional methods for manufacturing proteins for both research and clinical use.** To further enhance the value of our XpressCF® platform, we intend to explore granting nonexclusive access to our technology platform to potential licensees who are seeking access to efficient and effective drug discovery and manufacturing solutions, particularly those that can benefit from our XpressCF+® conjugation technology.

Cancers Remain a Major Unmet Medical Need

Cancers are the second leading cause of mortality in the United States and the leading cause of death for those under 65 years of age. The American Cancer Society estimated that there would be greater than 2 million new cases of cancer diagnosed and approximately 618,000 people would die of cancer in the United States in 2025.

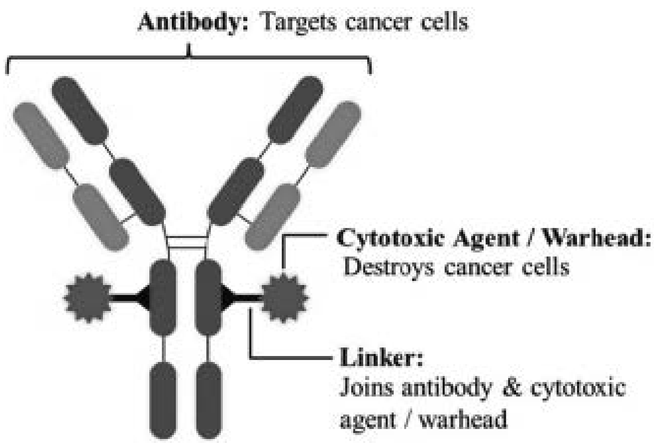
Traditional Cancer Therapeutics

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 ADCs. ADCs have shown promise over the last decade with twelve currently marketed products in the United States and over 200 ADC candidates investigated in the clinic. ADCs use the foundation of monoclonal antibodies and small molecule drugs by targeting the delivery of chemotherapeutics to the tumor. They have shown clinical benefit in hematological and solid tumors and often have a better safety profile than systemically delivered chemotherapeutics. We believe our XpressCF® platform will provide enhanced therapeutic approaches for treating cancer to address these unmet needs and are exploring next generation biologics, including ADCs, iADCs, and ADC^2s. The expectation is that multiple therapeutic modalities will be used in novel combinations to treat patients and provide the most potent anti-cancer effect.

Antibody-Drug Conjugates (ADCs)

ADCs are a highly potent improvement to monoclonal antibody oncology therapies. The key components of ADCs include an antibody, a stable linker, and a cytotoxic agent (warhead). The antibody is used to target and deliver cytotoxic agents 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.

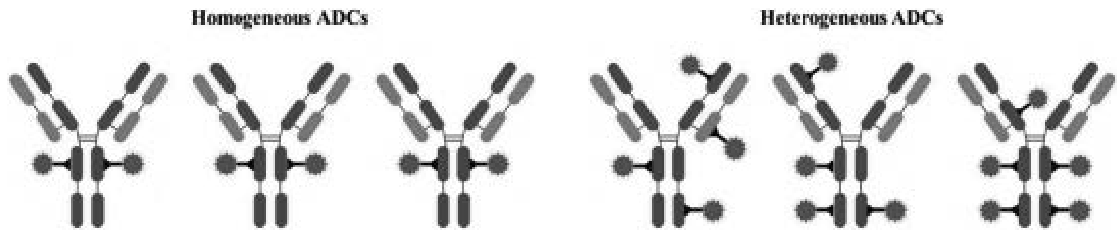


Currently, there are approximately 250 ADCs being investigated in clinical development. Kadcyla and Adcetris were the first of the new generation of ADCs to be approved for the treatment of specific subsets of breast cancer and lymphoma, respectively. Several more ADCs are currently on the market in the U.S.: Besponsa, Mylotarg, 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 as well as gastric and urinary tract cancers respectively; Tivdak was approved for the treatment of cervical cancer; Elahere was approved for the treatment of ovarian cancer; and Datroway was approved for the treatment of a subset of breast cancer in January 2025. 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.* Many ADCs, both those approved and those 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.

- *Lack of Tumor Specificity 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 the tumor microenvironment, 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. In addition, linker chemistries that rely on proteinases preferentially expressed in the tumor such as cathepsin and β-Glucuronidase, can provide more tumor specific release of the active catabolites and a resulting better safety profile.

- *Mechanism of Action of Cytotoxin Payloads.* Beyond potent cytotoxic activity of ADC payloads, there are additional attributes that lead to better efficacy and more durable responses. Payloads that induce bystander activity, which is dependent on the ADC target engagement, but also kills surrounding cells within the tumor, are thought to result in broader activity. Additionally, some payloads can induce immunogenic cell death pathways. These pathways not only cause potent tumor cell killing but also produce an immunological phenotype in the cancer cells, known as immunogenic cell death, or ICD. Different payload types induce variable levels of ICD, which can induce an immune response against endogenous tumor antigens, contributing to tumor elimination and improved outcomes. Importantly, there is an emerging trend in the clinic that ADCs that induce higher levels of ICD combine better with checkpoint inhibitors, including PD-1/L1 antibodies.

- *Limitations of Topo1 inhibitor payloads*. When compared to first generation, tubulin inhibitor-based ADCs such as T-DM1, exatecan-delivering ADCs, such as Enhertu or raludotatug deruxtecan, or R-DXd, display significant improvements in safety and efficacy measures observed in preclinical and clinical studies. Despite the progress made, serious adverse events and efficacy challenges remain. For example, upon prolonged treatment with DXd-based ADCs, a small but significant fraction of patients develop interstitial lung disease, or ILD. This adverse event is observed independent of the tumor antigen targeted by the ADC. ILD is difficult to treat and can be fatal if not detected in a timely manner. One potential cause of ILD is Fc gamma-mediated uptake of ADCs by alveolar macrophages in the lung, causing internalization followed by payload release, ultimately leading to ILD.

- *Low potency of exatecan-delivering ADCs*: Exatecans are, in general, less potent inducers of tumor cell death compared to tubulin inhibitors. Therefore, low copy number tumor antigens and/or antigens with low internalization rates may be poor targets for exatecan-based ADCs due to low potency.

Dual conjugations to enable iADC and ADC² modalities to address current limitations of conventional ADCs and to optimize the therapeutic index, or TI

XpressCF® enables the incorporation of non-natural amino acids into antibody sequences and results in site specific conjugation of drug payloads. More recently, we have developed technology to enable incorporation of two different non-natural amino acids that allows for the site-specific conjugation of two different payloads, providing the opportunity to combine pharmacology into a single molecule. We believe this is the first use of dual conjugation combining a conventional cytotoxin with an immune stimulatory payload to drive not only direct killing of the tumor cells but an immune response against the tumor. These iADC molecules utilize immune agonists such as TLR 7, TLR 8 and STING to induce activation of innate immune cells within the tumor microenvironment and resulted in more complete responses and protective anti-tumor immune responses in preclinical tumor models. This dual conjugation approach is the basis for our research collaboration with Astellas that is focused on the discovery of iADC molecules for solid tumors.

In addition to immune modulators, additional payloads can be incorporated into our dual conjugation approach. These ADC² payloads are focused on validated targets that are upregulated in tumors that do not respond well to existing therapies. Our goal is to provide more durable responses in hard-to-treat tumors by combining two payloads that may overcome the onset of resistance towards single payload ADCs reported in clinical meetings. The therapeutic benefit of combining microtubule inhibitors, or MTIs, with exatecan-based ADCs has been demonstrated in the clinic by admixing of two ADCs with either an MTI or exatecan-based payload. We believe that the use of payloads that induce tumor cell death via different mechanism of action may reduce or delay development of resistance to either one of the payloads. We are also exploring dual-payload concepts combining inhibitors of DNA repair with exatecan-based payloads. We believe that blocking alternative signaling pathways by combining DNA Double-strand repair inhibitors, or DDRis, with exatecan-based payloads is a promising dual payload approach for BRCA1/2 mutant tumors.

Our Proprietary XpressCF® Platform

While ADCs, iADCs, and ADC²s 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.

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 an 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 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. Additionally, our dual conjugation ADC^2 technology could enable "mixed payload" ADCs that combine two distinct small molecules with different pharmacologies onto a single antibody.

- *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.

- *Absence of Fc-gamma Receptor Binding.* Antibodies produced using the XpressCF® platform have not been shown to bind the Fc-gamma receptor, and therefore are not subject to Fc-gamma mediated uptake by alveolar macrophages, which we believe results in reduced nonspecific payload release in the lung, reducing the potential for ILD.

- *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 ADCs, iADCs, Bispecific ADCs, and ADC^2 Therapeutics

We believe our technology enables new approaches to ADCs, iADCs, bispecific ADCs, and ADC^2 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, bispecific ADCs and ADC^{2}s. 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 ADC molecules to ensure that we have optimized sites of conjugation, the number of payloads on each antibody (drug-antibody ratio, or DAR) and linker chemistry. We have examples where changing just one of these parameters can significantly impact the safety, efficacy and stability of the ADC. Further, we have demonstrated the ability to introduce more than eight non-natural amino acids into a single antibody structure, without impacting the expression levels of engineered antibodies, permitting ADCs with a DAR of greater than eight. Most conventional conjugation methods are limited by a DAR of eight, due to the availability of only eight interchain cysteines, which are used for conjugation with conventional methods. In addition, our XpressCF+® platform enables integration of two different types of non-natural amino acid, which can be used to precisely conjugate two different payloads to the same antibody, and allows us to engineer additional pharmacological properties, including iADCs and ADC^2 therapeutics.

- *Efficient Transition from Research Scale to Development Scale Protein Production.* Protein therapeutics can encounter obstacles, or even fail, during the transition from research 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, bispecific ADCs and ADC^2s.

- *Manufacturable Dual Conjugations.* Our XpressCF+® platform allows us to manufacture antibodies that contain two different non-natural amino acids that are substrates for mutually orthogonal site-specific conjugation reactions. This advantage permits dual conjugation, resulting in homogenous iADC or ADC^2 dual conjugate molecules with two different precisely placed payloads.

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 ADCs and ADC^2s and transitioning those products to cGMP compliant manufacturing.

Our Collaborations Validate Our Technology

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, 2024, all of our collaborations have provided us with an aggregate of approximately $980 million in payments, which includes approximately $79 million in investments in our stock. Our currently active collaborations include:

- ***Ipsen Relationship.*** We have granted Ipsen the right to develop and commercialize STRO-003, an ADC targeting ROR1.

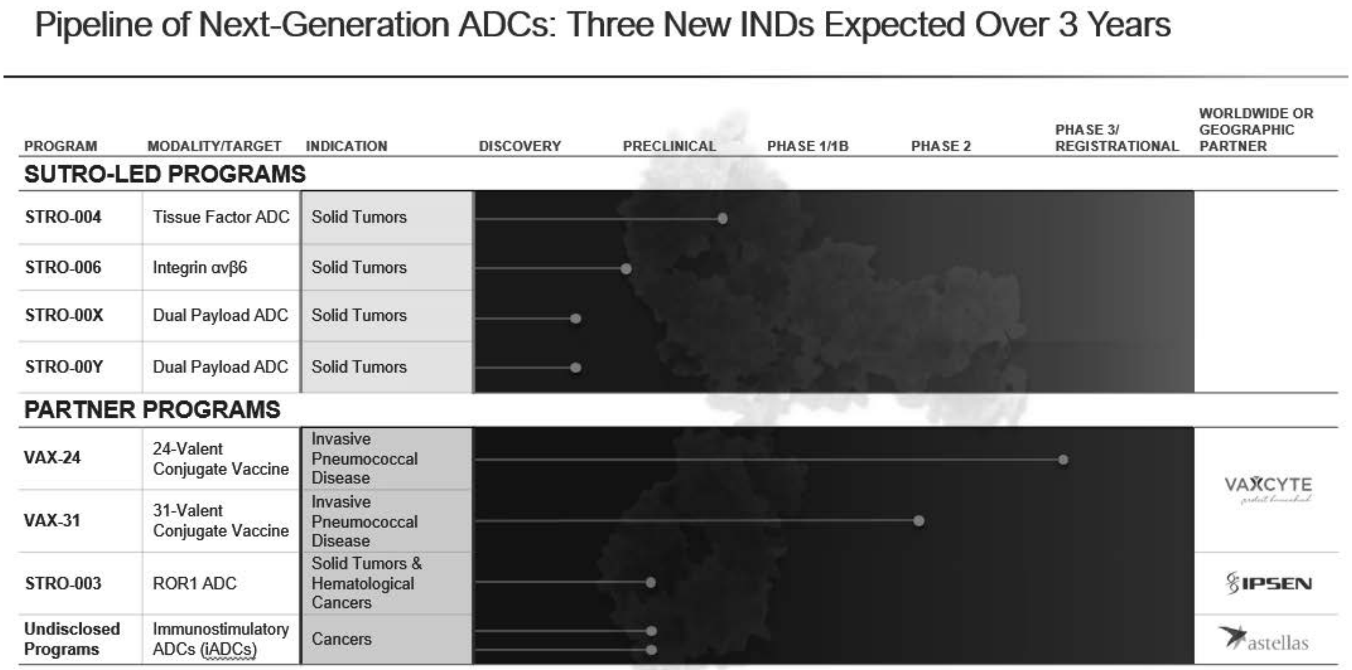
- ***Astellas Collaboration.*** The collaboration and license agreement with Astellas covers the discovery and development of immunostimulatory antibody-drug conjugates for two biological targets.

- ***Vaxcyte Relationship.*** We have granted Vaxcyte the right to discover and develop vaccines for the prophylaxis and treatment of infectious diseases. Vaxcyte's most advanced product candidates are VAX-31 and VAX-24, 31-valent and 24-valent, respectively, pneumococcal conjugate vaccine candidates under investigation for the prevention of invasive pneumococcal disease in adults and adults and infants, respectively. Further, in the fourth quarter of 2023, Vaxcyte exercised an option to obtain development and manufacturing rights for XtractCF® providing Vaxcyte the right to make and source our cell-free extract for research, development, and manufacture of vaccines for the prophylaxis and treatment of infectious disease.

- ***Tasly Relationship.*** We have granted Tasly an exclusive license to the right to develop and commercialize STRO-002 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:



Our Product Candidates

STRO-004, An ADC Directed Against Tissue Factor

Our lead developmental asset is STRO-004. STRO-004 is a TF-targeting ADC for the treatment of TF-expressing solid tumors, potentially including cervical, lung and breast cancer. STRO-004 is an anti-TF human IgG1 antibody conjugated using our XpressCF+® platform technology to a cleavable DBCO-PEGylated β-glucuronidase-exatecan linker-payload, at a DAR of approximately eight. There is an approved ADC targeting TF, TIVDAK®, developed by Seattle Genetics and GenMab A/S, which is approved for the treatment of recurrent or metastatic cervical cancer. In preclinical *in vitro* and *in vivo* studies benchmarking STRO-004 against a TIVDAK® surrogate molecule, we observed comparable antitumor activity but achieved 5- to 10-fold higher dose levels in nonhuman primate safety studies for STRO-004. Therefore, we believe that STRO-004 has the potential for an improved clinical therapeutic index over existing standard of care. We believe these features present a unique opportunity for clinical development of STRO-004 to address unmet medical needs in cervical, lung and breast cancer patients.

We believe STRO-004 has been precisely designed and optimized to provide the potential for a best-in-class ADC targeting TF. Our proprietary non-natural amino acid, which provides the substrate for conjugation to our proprietary β-glucuronidase cleavable exatecan linker warhead, has been placed at what we believe are the optimal sites in the amino acid sequence of our high affinity anti-TF antibody, resulting in enhanced performance and stability in preclinical *in vitro* and *in vivo* models. These models also suggest that our β-glucuronidase cleavable linkers may provide greater tumor specificity and enhanced tolerability relative to a protease-cleavable linker delivering an exatecan payload. In particular, in a nonhuman primate safety study, we did not observe neutropenia, ocular toxicity signals or ILD signals, even in the highest dose cohort for STRO-004. Finally, our preclinical testing has shown that the exatecan payload delivered by STRO-004 elicits potent tumor cell killing, bystander activity and immunogenic cell death, which we believe may provide meaningful clinical benefit to patients.

STRO-004 Business Opportunity

We believe TF is a favorable target for an ADC due to its limited normal tissue expression, as well as its prevalence in solid tumors, including cervical cancer. Its expression is correlated with poor prognosis in different cancers.

STRO-003, An ADC Directed Against ROR-1

In 2022, we nominated STRO-003 for further development and in 2024, we licensed the rights to develop and commercialize STRO-003 to Ipsen. STRO-003 is a ROR1-targeting ADC for the treatment of ROR1-expressing solid tumors, including triple negative breast cancer, or TNBC, non-small cell lung cancer, or NSCLC, and ovarian cancer. STRO-003 is an anti-ROR1 human IgG1 antibody conjugated using our XpressCF+® platform technology to a cleavable DBCO-PEGylated β-glucuronidase-exatecan linker-payload, at a DAR of approximately eight. Currently, there are no therapeutics approved that specifically target ROR1, although there is one ROR1-targeting ADC, zilovertamab vedotin, or ZV, also known as MK-2140, or VLS-101, in Phase 2 testing targeting diffuse large B-cell lymphoma, or DLBCL, mantle cell lymphoma, or MCL, NSCLC, and breast cancer. Based on preclinical *in vitro* and *in vivo* data, we believe that STRO-003 has the potential for an improved therapeutic index compared to ZV. We believe these features present a unique opportunity for clinical development of STRO-003 to address unmet medical needs in hematological malignancies, ovarian cancer, TNBC and NSCLC.

We believe STRO-003 has been precisely designed and optimized to provide the potential for a best-in-class ADC targeting ROR-1. Our proprietary non-natural amino acid, which provides the substrate for conjugation to our proprietary β-glucuronidase cleavable exatecan linker warhead, has been placed at what we believe are the optimal sites in the amino acid sequence of our high affinity anti-ROR1 antibody, resulting in enhanced performance and stability in preclinical *in vitro* and *in vivo* models. These models also suggest that our β-glucuronidase cleavable linkers may provide greater tumor specificity and enhanced tolerability relative to a protease-cleavable linker delivering an exatecan payload. In particular, in a nonhuman primate safety study, we did not observe neutropenia, ocular toxicity signals or lung toxicity signals even in the highest dose cohort for STRO-003. Finally, our preclinical testing has shown that the exatecan payload delivered by STRO-003 elicits potent tumor cell killing, bystander activity and immunogenic cell death, which we believe may provide meaningful clinical benefit to patients.

STRO-003 Business Opportunity

We believe ROR1 is a favorable target for an ADC due to its limited normal tissue expression, as well as its prevalence in solid tumors and B cell malignancies, including chronic lymphocytic leukemia, or CLL, DLBCL, MCL, TNBC, NSCLC, and ovarian cancer. Its expression is correlated with poor prognosis in different cancers. Currently, there are no approved therapeutics that specifically target ROR1, but it is a target of increasing interest with several clinical-stage ADCs in development, including ZV (Phase 2), NBE-002 (Phase 1), and CS5001 (Phase 1). If STRO-003 is successfully developed and commercialized by Ipsen, we will receive development, regulatory and commercialization milestone payments and royalties based on net sales by Ipsen.

Additional Discovery Efforts

We are also actively researching to identify new ADCs and ADC^2s to add to our pipeline. We have multiple ADC discovery programs ongoing using our XpressCF+® platform. Our protein engineering and chemistry efforts are focused on maximizing therapeutic indices, and our technology allows us to rapidly test our therapeutic hypotheses 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 and ADC^2s. For iADCs, our XpressCF+® 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, to 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.

In addition, development of our XpressCF+® platform to enable homogenous, dually-conjugated iADCs also enables us to discover, develop and manufacture ADC^2 molecules. In these ADC^2 molecules, two different linker-warheads are precisely conjugated at specific positions to deliver two different small molecule payloads to a single cancer cell. We are actively investigating different combinations of payloads to identify synergistic pairings with differentiated toxicity profiles. We believe such ADC^2 molecules have the potential to provide the next generation of highly potent cancer therapeutics with acceptable safety and tolerability.

Collaboration and License Agreements

Astellas Agreement

In June 2022, we entered into a license and collaboration agreement with Astellas, or the Astellas Agreement, for the development of immunostimulatory antibody-drug conjugates for up to three biological targets, to be identified by Astellas. In June 2024, Astellas notified us that it would not be nominating a third target program. This decision was based on Astellas' strategic portfolio considerations. We will conduct research and preclinical development of any compound (as designated by Astellas) in each of the two programs in accordance with the terms of a research plan between us and Astellas. Astellas will have an exclusive worldwide license to develop and commercialize any such designated compound, subject to our rights to participate in cost and profit sharing in the United States, as described below.

Pursuant to the Astellas Agreement, we received from Astellas a one-time, nonrefundable, non-creditable, upfront payment of $90.0 million during the year ended December 31, 2022.

We are also eligible to receive up to $422.5 million in development, regulatory and commercial milestone payments for each product candidate, and tiered royalties ranging from low double-digit to mid-teen percentages on worldwide sales of any commercial products that may result from the collaboration, subject to customary deductions under certain circumstances. We can also elect to convert any product candidate into a cost and profit-sharing arrangement, for the United States only. In the event we make such election, we will share commercialization costs and profits relating to such product candidate equally with Astellas in the United States, and no royalties will be due from Astellas for net sales of such product candidates in the United States.

The Astellas Agreement contains customary provisions for termination, including by Astellas for convenience upon 30 days' written notice and by either party for cause, including for material breach (subject to cure). We have certain reversion rights as to product candidates in connection with certain termination events.

Ipsen Agreement

In March 2024, we entered into an Exclusive License Agreement with Ipsen, or the Ipsen License Agreement, pursuant to which we licensed to Ipsen, on an exclusive basis, the right to research, develop, manufacture and commercialize STRO-003.

In consideration for the rights and licenses granted to Ipsen in the Ipsen License Agreement, (i) Ipsen paid the Company an upfront license fee in the amount of $50.0 million in April 2024 and (ii) Ipsen Biopharmaceuticals, Inc. (USA), or Ipsen USA, a fully-owned Affiliate of Ipsen, purchased 4,827,373 shares of the Company's common stock for $25.0 million, at a price of approximately $5.18 per share, in accordance with the terms set forth in a certain investment agreement by and between the Company and Ipsen USA dated March 29, 2024 (the "Ipsen Investment Agreement", and, together with the Ipsen License Agreement, the "Ipsen Agreements").

Further, we are also eligible to receive up to an additional $447.0 million in developmental and regulatory milestone payments, assuming multiple indications, and up to $360.0 million in sales milestone payments, as well as tiered royalty payments ranging from low double-digit to mid-teen digit percentages of annual net sales of STRO-003, subject to certain adjustments specified in the Ipsen License Agreement. The royalty payment obligations under the Ipsen License Agreement expire on a country-by-country basis no earlier than ten years following the first commercial sale of STRO-003 in the applicable country.

Ipsen may terminate the Ipsen License Agreement for convenience with sixty calendar days prior written notice or for certain other specified reasons.

In July 2024, we executed the Transition Services Agreement, or TSA, with Ipsen. The TSA outlines the terms and conditions for transition services requested by Ipsen as part of the Ipsen License Agreement. Further, as part of the transition activities under the TSA, we executed with Ipsen a Material Transfer Agreement, or MTA, to govern the transfer of certain materials to Ipsen for research and development purposes.

In December 2024, we executed the Manufacturing and Supply Agreement, or MSA, with Ipsen. The MSA outlines the terms and conditions for certain manufacturing services, manufacturing transition activities and transfer of the manufacturing technology as part of the Ipsen License Agreement. The pricing is based on an agreed upon cost-plus arrangement.

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, a supply agreement, an option agreement and a manufacturing rights agreement related to certain development and manufacturing rights. 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 programs for Vaxcyte are VAX-31 and VAX-24, its 31-valent and 24-valent, respectively, pneumococcal conjugate vaccine candidates. Vaxcyte is responsible for performing all research and development activities, and we provide technical support and supply XtractCF® and other materials to Vaxcyte.

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.

In December 2022, we entered into a letter agreement, or the Vaxcyte Agreement, with Vaxcyte and granted Vaxcyte an option, or the Option, to obtain development and manufacturing rights for XtractCF® that, when exercised, would grant Vaxcyte the right to make and source our cell-free extract for research, development, and manufacture of vaccines for the prophylaxis and treatment of infectious disease.

Pursuant to the Vaxcyte Agreement, we received a one-time, nonrefundable, non-creditable, upfront payment of $10.0 million in cash, and 167,780 shares of Vaxcyte common stock with a fair value of $7.5 million in December 2022.

Additionally, pursuant to the Vaxcyte Agreement, we and Vaxcyte agreed to negotiate the terms and conditions of a form definitive agreement to be entered into in the event Vaxcyte exercises the Option, or the Form Definitive Agreement. In September 2023, we and Vaxcyte mutually agreed upon the Form Definitive Agreement, and in October 2023, we received a $5.0 million payment from Vaxcyte.

Effective immediately upon agreement to the Form Definitive Agreement, we and Vaxcyte entered into Amendment No 3., or Amendment 3, to that certain license agreement between us and Vaxcyte, dated August 1, 2014, and amended and restated on October 12, 2015, and amended again on May 9, 2018 and May 29, 2018, or the License Agreement. Amendment 3 amended certain terms of the License Agreement including with respect to (i) royalty reduction provisions applicable in the event of expiration of relevant patent claims, which would result in lower royalties payable by Vaxcyte under certain circumstances, (ii) the ownership, prosecution, maintenance and enforcement of certain intellectual property rights licensed or arising under the License Agreement, and (iii) the timing and form for financial reporting of royalty payment calculations.

In November 2023, or the Exercise Date, Vaxcyte exercised the Option by submitting written notice thereof to us and concurrently paid us $50.0 million in cash as the first of two installment payments for the Option exercise price. In May 2024, Vaxcyte paid us an additional $25.0 million in cash as the second of two installment payments for the Option exercise price under the Vaxcyte Agreement. Upon the occurrence of certain regulatory milestones, Vaxcyte would be obligated to pay us certain additional milestone payments totaling up to $60.0 million in cash. In the event that Vaxcyte undergoes a change of control, certain rights and payments may be accelerated.

We are eligible for four percent royalties on worldwide net sales of any vaccine candidates for human health use under the license agreement, except for royalties on sales of vaccines for prophylaxis of invasive pneumococcal disease, such as VAX-24 or VAX-31, which are owned by Blackstone, as discussed below. 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. During 2024, we sold 0.7 million shares of Vaxcyte common stock for net proceeds of $74.0 million, and no longer hold any shares of Vaxcyte common stock.

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 under certain circumstances.

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, NSCLC, TNBC, 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 was 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.

In April 2022, we entered amendment No. 1, or the Tasly Amendment, to the Tasly License Agreement. Pursuant to the Tasly Amendment, the initial nonrefundable upfront payment due by Tasly was amended to $25.0 million, and a $15.0 million payment will become payable to us upon the achievement of certain regulatory milestones. The Tasly Amendment also added an additional regulatory milestone payment to the Tasly License Agreement, providing additional potential payments totaling up to $350.0 million related to development, regulatory and commercialization milestones, beyond the payments described above, and made certain other ministerial edits.

In June 2023, we entered into a Master Development and Clinical Supply Agreement, or the 2023 Tasly Supply Agreement, with Tasly, wherein Tasly requested us to provide development, manufacturing and supply chain management services, including clinical product supply.

In September 2023, we received a $5.0 million contingent payment from Tasly, net of withholding tax of $0.5 million, related to the first patient dosed in the REFRaME-O1 trial for luvelta.

In October 2023, we received a $5.0 million contingent payment from Tasly, net of withholding tax of $0.5 million, after Tasly received its first IND clearance by National Medical Products Administration, or NMPA, in Greater China.

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.

Blackstone Relationship

In June 2023, we entered into a purchase and sale agreement with Blackstone, or the Blackstone Agreement, to sell to Blackstone a revenue interest in our 4% royalty on potential future sales of Vaxcyte's products, including Vaxcyte's pneumococcal conjugate vaccine, or PCV, products such as VAX-24 and its second-generation PCV product, VAX-31.

Under the Blackstone Agreement, Blackstone paid us an initial upfront payment of $140.0 million in June 2023, with potential payments totaling up to $250.0 million triggered at various return thresholds to Blackstone under the Blackstone Agreement. In addition, under the Blackstone Agreement, we agreed to certain covenants with respect to the exercise of its rights under the Vaxcyte License Agreement, including with respect to the right to amend, assign and terminate the Vaxcyte License Agreement. The Blackstone Agreement contains other customary terms and conditions, including representations and warranties, covenants and indemnification obligations in favor of each party.

Following agreement with Vaxcyte on the Form Definitive Agreement and upon effectiveness of the Amendment, the revenue interest in the 4% royalty on potential future sales of Vaxcyte products other than Vaxcyte's PCV products reverted to us. As such, we retain the revenue interest in royalties from Vaxcyte on sales of all products other than a PCV product, such as VAX-24 or VAX-31.

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 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.

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 GMP manufacturing.

Extract and Reagents

We have historically manufactured our cell-free extract and related reagents in our GMP manufacturing facility in San Carlos, California for our clinical trials and supply commitments. We have identified a contract manufacturing organization, or CMO, to serve as our strategic partner for the production of cell-free extract and have initiated technology transfer to this CMO. Similarly, we have identified a CMO to produce custom reagents used in our cell-free production and have initiated this technology transfer as well. The technology transfer for production of custom reagents was substantially completed in 2023 and the technology transfer for production of cell-free extract was substantially completed in 2024. Given the success of these technology transfers, we are transitioning our extract and reagent manufacturing strategy to an outsourced model and plan to wind down our manufacturing activities in our San Carlos facility no later than the end of 2025.

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 in 2025 will be done by either us or CMOs, depending on our internal cGMP production capacity. We expect to transition these activities entirely to our CMO network by the end of 2025. We have identified multiple CMOs with the ability to produce the antibody component of our products at different scales and we have successfully completed technology transfer of the manufacturing process to one or more of these CMOs. 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+® 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 cytotoxic agents, large scale manufacture of antibodies, conjugation and fill-finish of 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® 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, 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 therapeutics include a range of biologic modalities with the top selling products by class spanning tumor targeting monoclonal antibodies, to ADCs, to immune checkpoint inhibitors, to T cell-engager immunotherapies, to CAR-T cell therapies. In addition, numerous compounds are in clinical development for cancer treatment. The clinical development pipeline for cancer includes small molecules, antibodies, vaccines, cell therapies and immunotherapies from a variety of companies and institutions.

We also face substantial competition from biotechnology and biopharmaceutical companies developing products with TF-targeted therapies. The most advanced clinically active agent targeting TF to date has been TIVDAK® (tisotumab vedotin-tftv; TF-011-MMAE), an ADC currently approved for recurrent or metastatic cervical cancer that is composed of a TF-binding antibody linked to the tubulin-disrupting antimitotic agent, MMAE, via a cleavable linker. Other pharmaceutical companies are developing TF-targeted ADCs for the treatment of a broad range of advanced or metastatic cancers, including the indications we may select for STRO-004 development.

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.

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, 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, XpressCF+® platform, and product candidates. Our patent portfolio as of December 31, 2024, contained 32 U.S. issued patents and 239 patents issued in ex-U.S. jurisdictions, including Europe, China, Japan, Australia and Singapore, and 46 U.S. pending applications, as well as 121 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:

Our patent portfolio includes the following families and/or groups of families:

- **XpressCF® Platform**. We have approximately 9 patent families related to our XpressCF® platform, which include claims directed to certain bacterial strains and extracts prepared therefrom and methods of producing thereof, extract formulations and methods of making thereof, methods of producing antibodies using prefabricated light chain, and methods of producing high cell density fermentations and extracts prepared therewith. Our issued patents, and any patents that may issue from our pending patent applications, related to our XpressCF® platform are expected to remain in force until various times between October 2033 and December 2045, absent any patent term adjustments or extensions.

- **XpressCF+® Platform and ADC Platform**. We have approximately 12 patent families related to our XpressCF+® platform and ADC platform, which include claims directed to para-azidomethylphenylalanine (pAMF) and proteins comprising pAMF, non-natural amino acid tRNA synthetases, antibodies with engineered CH2 domains, antibodies with site-specific glutamine tags, antibodies and antibody fragments containing one or more non-natural amino acids at defined positions in their amino acid sequences, dual conjugates (including iADC and ADC^2), and high drug antibody ratio (DAR) conjugates and methods of treating therewith. Our issued patents, and any patents that may issue from our pending patent applications, related to our XpressCF+® platform and ADC platform are expected to remain in force until various times between June 2033 and October 2045, absent any patent term adjustments or extensions.

- **STRO-004**. We have approximately 2 patent families related to STRO-004, which include composition of matter and methods of treatment claims directed to our lead product candidate, STRO-004, and composition of matter, methods of treatment, and methods of making claims to exatecan linker-payloads and conjugates. Any patents that issue from these patent applications will expire between June 2043 and October 2044, absent any patent term adjustments or extensions.

- **STRO-003**. We have approximately 2 patent families related to STRO-003, which include composition of matter and methods of treatment claims directed to our lead product candidate, STRO-003, and composition of matter, methods of treatment, and methods of making claims to exatecan linker-payloads and conjugates. Our issued patent, and any patents that may issue from our pending patent applications, related to our STRO-003 are expected to remain in force until 2043, absent any patent term adjustments or extensions.

In addition, we have exclusively licensed the following patent portfolio from Stanford: 9 U.S. issued patents and 21 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® platform and XpressCF+® platform when discovering, developing and manufacturing our product candidates.

Remaining patents in our patent portfolio licensed from Stanford are expected to expire between March 2025 and January 2028, absent any patent term adjustments or extensions.

As for the XpressCF® platform, XpressCF+® 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.

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 2033 to 2043, 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 2045, 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® platform, XpressCF+® platform, 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® platform, XpressCF+® platform, 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® platform, XpressCF+® platform, 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."

In addition to patent protection, we also rely on trademark registration, trade secrets, know how, other proprietary information and continuing technological innovation to develop and maintain our competitive position. We seek to protect and maintain the confidentiality of proprietary information to protect aspects of our business that are not amenable to, or that we do not consider appropriate for, patent protection. Although we take steps to protect our confidential and proprietary information as trade secrets, including through contractual means with our employees, consultants, partners, and contractors, 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.

Information Security

We 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. Our Infosec Governance Committee, comprising senior executives and facilities and information technology employees, and under the supervision of our Audit Committee of our Board of Directors, is responsible for designing, implementing, monitoring and improving the security of our confidential and/or proprietary information. We conduct regular audits of our information security systems, including our on-site and cloud-based information systems and strive to continuously improve the robustness of our security and information recovery systems in the event of, for example, a cyberattack or natural disaster that compromises our data integrity. As part of our security framework, we review publicly available cybersecurity assessments of our third-party partners and vendors to evaluate potential risks. In addition, we conduct regular training and testing of our employees to identify, and report cyberattacks, including phishing and other forms of social engineering. We also maintain a limited insurance policy against cyberattacks that may provide a measure of compensation in the event that we are harmed by an information security attack. Although we have confidence in these individuals, organizations, and systems, our security measures have been breached in the past and may again be breached in the future, 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 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 and placed the IND on clinical hold 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 may be sufficient in certain oncological conditions, including (i) 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 or (ii) when in conjunction with confirmatory evidence.

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 $4,310,000 for Fiscal Year 2025. The applicant under an approved BLA is also subject to an annual program fee, currently exceeding $403,000 per prescription drug product for Fiscal Year 2025. 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. The FDA may refuse to file any BLA that it deems incomplete or not properly reviewable at the time of submission and may request additional information. In that event, the BLA must be resubmitted with the additional information. The resubmitted application also is subject to review before the FDA files it. 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 submission 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, the FDA determines after preliminary evaluation of clinical data submitted by the sponsor that the product may be effective, 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. The Food and Drug Omnibus Reform Act, or FDORA, included provisions related to the accelerated approval pathway. Pursuant to FDORA, the FDA is authorized to require a post-approval study to be underway prior to approval or within a specified time period following approval. FDORA also requires the FDA to specify conditions of any required post-approval study, which may include milestones such as a target date of study completion and requires sponsors to submit progress reports for required post-approval studies and any conditions required by the FDA not later than 180 days following approval and not less frequently than every 180 days thereafter until completion or termination of the study. FDORA enables the FDA to initiate enforcement action for the failure to conduct with due diligence a required post-approval study, including a failure to meet any required conditions specified by the FDA or to submit timely reports.

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 and 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 the same drug 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. In the case of a biological product, the same drug is a drug that contains the same principal molecular structural features. 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.

The Best Pharmaceuticals for Children Act, or BPCA, provides a six-month extension of any non-patent exclusivity for a biologic if certain conditions are met. Conditions for exclusivity include the FDA’s determination that information relating to the use of a new biologic in the pediatric population may produce health benefits in that population, FDA making a written request for pediatric studies, and the applicant agreeing to perform, and reporting on, the requested studies within the statutory timeframe. Applications under the BPCA are treated as priority applications, with all of the benefits that designation confers.

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 products 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 $540,000 for most PMAs for Fiscal Year 2025. 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. 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. In addition, many state laws govern the privacy and security of health information in certain circumstances, many of which differ from each other in significant ways and may not have the same effect, and often are not preempted by HIPAA. For example, the California Consumer Privacy Act ("CCPA"), which went into effect on January 1, 2020, creates new data privacy obligations for covered companies and provides new privacy rights to California residents. On January 1, 2023, the California Privacy Rights Act ("CPRA"), which substantially amends the CCPA, went into effect. The CCPA and CPRA provide for unlimited civil penalties for violations, as well as a private right of action for data breaches that is expected to increase data breach litigation. Virginia's Consumer Data Protection Act, which took effect on January 1, 2023, requires businesses subject to the legislation to conduct data protection assessments in certain circumstances and requires opt-in consent from consumers to acquire and process their sensitive personal information, which includes information revealing a consumer's physical and mental health diagnosis and genetic and biometric information that can identify a consumer. Colorado enacted the Colorado Privacy Act, and Connecticut enacted the Connecticut Data Privacy Act, each of which took effect on July 1, 2023, and Utah enacted the Consumer Privacy Act, which became effective on December 31, 2023, and each of these laws may increase the complexity, variation in requirements, restrictions, and potential legal risks, and could require increased compliance costs and changes in business practices and policies. Other states have also enacted, proposed, or are considering proposing, data privacy laws, which could further complicate compliance efforts, increase our potential liability and adversely affect our business.

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. A growing number of states require the reporting of certain pricing information, including information pertaining to and justifying price increases and introductory prices for new drugs. In addition, certain states require pharmaceutical companies to implement compliance programs and/or marketing codes. Additional states and local jurisdictions, such as Nevada, Connecticut, the City of Chicago and the District of Columbia, require pharmaceutical sales representatives to be registered, licensed and/or 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.

Coverage, Pricing and Reimbursement

The regulations that govern coverage, pricing and reimbursement for new pharmaceutical products vary widely from country to country. Some countries require approval of the sale price of a pharmaceutical product before it can be marketed. In many countries, the pricing review period begins after marketing approval is granted. In some foreign markets, prescription pharmaceutical pricing remains subject to continuing governmental control even after initial approval is granted. As a result, a pharmaceutical 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 pharmaceutical 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. The process for determining whether a third-party payor will provide coverage for a product may be separate from the process for setting the price of a product or for establishing the reimbursement rate that such a payor will pay for the product. 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 pharmaceutical companies provide them with predetermined discounts from list prices and are seeking to reduce the prices charged or the amounts reimbursed for biopharmaceutical products.

Moreover, one payor's determination to provide coverage for a product does not assure that an adequate reimbursement rate will be approved, or that other payors will also provide coverage for the product. 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.

Significant delays can occur in obtaining reimbursement for newly approved pharmaceutical products, and coverage may be more limited than the purposes for which product is approved by the FDA or similar foreign regulatory authorities. Interim reimbursement levels, if applicable, may also be insufficient to cover a pharmaceutical company's costs and may not be made permanent. Moreover, eligibility for reimbursement does not imply that any pharmaceutical product will be reimbursed in all cases or at a rate that covers a pharmaceutical company's costs, including research, development, manufacture, sale and distribution. In addition, coverage policies and third-party reimbursement rates may change at any time.

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. Several healthcare reform proposals culminated in the enactment of Inflation Reduction Act, or IRA, which among other things, allows the Department of Health and Human Services, or HHS, to directly negotiate the selling price of a statutorily specified number of drugs and biologics each year that CMS reimburses under Medicare Part B and Part D. The negotiated price may not exceed a statutory ceiling price. Only high-expenditure single-source biologics that have been approved for at least 11 years (7 years for drugs) can be selected by CMS for negotiation, with the negotiated price taking effect two years after the selection year. For 2026, the first year in which negotiated prices become effective, CMS selected 10 high-cost Medicare Part D products in 2024, and the negotiated maximum fair price for each product has been announced. CMS has selected 15 additional Medicare Part D drugs for negotiated maximum fair pricing in 2027. For 2028, an additional 15 drugs, which may be covered under either Medicare Part B or Part D, will be selected, and for 2029 and subsequent years, 20 Part B or Part D drugs will be selected. A drug or biological product that has an orphan drug designation for only one rare disease or condition will be excluded from the IRA's price negotiation requirements, but will lose that exclusion if it receives designations for more than one rare disease or condition, or if it is approved for an indication that is not within that single designated rare disease or condition, unless such additional designation or such disqualifying approvals are withdrawn by the time CMS evaluates the drug for selection for negotiation. The IRA also impose rebates on Medicare Part D and Part B drugs whose prices have increased at a rate greater than the rate of inflation, and in November 2024, CMS finalized regulations for the Medicare Part B and Part D inflation rebates. The IRA also extends enhanced subsidies for individuals purchasing health insurance coverage in ACA marketplaces through plan year 2025. The IRA permits the Secretary of HHS to implement many of these provisions through guidance, as opposed to regulation, for the initial years. Manufacturers that fail to comply with the IRA may be subject to various penalties, including civil monetary penalties. These provisions have been and may continue to be subject to legal challenges. For example, the provisions related to the negotiation of selling prices of high-expenditure single-source drugs and biologics have been challenged in multiple lawsuits brought by pharmaceutical manufacturers. Thus, while it is unclear how the IRA will be implemented, it will likely have a significant impact on the biopharmaceutical industry and the pricing of prescription drug products.

At the state level, legislatures have increasingly passed legislation and implemented regulations designed to control pharmaceutical 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.

Human Capital Resources

As of December 31, 2024, we had 310 full-time employees and 28 full-time contract employees. Of these employees, 83 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. However, in March 2025, we executed a significant reduction in workforce, which may negatively impact our relationship with our employees going forward.

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.

We also recognize that maintaining continuity of management in the event of the departure of one or more of our senior executives is critical to the continued success of the organization. To this end, we have prepared a formal written succession plan for our senior executives and to provide guidance for the next generation of our leaders to ensure an orderly and smooth transition in the event of an executive departure. While senior management is primarily responsible for developing our succession plan, our Nominating and Corporate

Governance Committee of our Board of Directors (with respect to the CEO) and Compensation Committee of our Board of Directors (with respect to other executives) oversee and guide our process and thinking.

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. 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. Copies of each of our filings with the SEC can also be viewed and downloaded free of charge at our website, 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 on Form 10-K, 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 an early stage biopharmaceutical company with 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 an early stage biopharmaceutical company. Biotechnology product development is a highly speculative undertaking and involves a substantial degree of risk.

To date, we have no products approved for commercial sale, have not generated any revenue from commercial product sales and, as of December 31, 2024, had an accumulated deficit of $786.9 million. For the years ended December 31, 2024 and December 31, 2023, our net loss was $227.5 million and $106.8 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. In addition, our expenses could increase beyond expectations if we are required by the FDA, or foreign regulatory agencies, to perform studies or clinical trials in addition to those studies and clinical trials that we currently anticipate conducting for our product candidates, or if there are any delays in our or our partners completing clinical trials or the development of any of our product candidates. Our technologies and product candidates are in varying 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 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 and manufacturing clinical and early commercial supply of our product candidates. We expect our net losses to increase substantially as we progress further into 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. We may never generate revenues from the commercial sale of our or our collaborators’ products. 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.

We will need substantial additional funds to advance development of our product candidates and failure to obtain sufficient funding may force us to delay, limit or terminate our product development programs, commercialization efforts or other operations. We may have difficulty accessing additional capital on reasonable, or even any, terms to continue our product and platform development or other operations and may have to make difficult prioritization decisions regarding development and potential partnering of our clinical and preclinical product candidates.

The development of biopharmaceutical product candidates is capital-intensive. As our product candidates 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, to manufacture extract and products, if any, which may be approved for commercial sale, to establish marketing and sales capabilities to commercialize our product candidates, and to provide support to our collaborators in the development of their products. In addition, we expect to continue 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 preclinical and clinical-stage product candidates and the development of our technology platform, including our in-house manufacturing capabilities. Preclinical studies and clinical trials for our product candidates have required substantial funds to date and will continue to require substantial funds to complete. As of December 31, 2024, we had $316.9 million in cash, cash equivalents and marketable securities. We expect to incur substantial expenditures in the foreseeable future as we seek to advance multiple 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. For example, the timing and amount of our operating expenditures will depend largely on:

- the timing, progress and results of preclinical and worldwide 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 and/or research and development agreements;
- our ability to establish and maintain collaborations, strategic partnerships or marketing, distribution, licensing or other strategic arrangements with third parties on favorable terms, if at all;
- our ability to achieve sufficient market acceptance, adequate coverage and reimbursement from third-party payors and adequate market share and revenue for any approved product candidates;
- 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;
- our efforts to enhance operational systems and hire and retain key personnel, including personnel to support development of our product candidates and satisfy our obligations as a public company; and
- general economic, industry and market conditions, including market volatility, high levels of inflation, changes in interest rates, changes in tariffs and trade restrictions, uncertainty with respect to the federal debt ceiling and budget and potential government shutdowns related thereto.

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 cannot provide assurance that anticipated collaborator payments will, in fact, be received. 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 and other associated agreements, the sale of equity securities, debt financing and a royalty monetization agreement. 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, royalty monetization or a combination of one or more of these funding sources. Additional funds may not be available to us on acceptable terms or at all.

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. Any 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 varying development stages and may fail in development or be impacted by competitive products 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 internal product candidates for cancer therapy are in preclinical development, including our most advanced candidate, STRO-004. Additionally, we have programs that are being evaluated by partners in clinical trials and by us 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, or our licensees' 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, or transfer to third-parties, of our internal manufacturing processes, including process development and scale-up activities to supply products for preclinical studies, clinical trials and commercial sale;
- 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 or high drop-out rates in our clinical trials;
- 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 and potential effects on our business, clinical trial sites, highly complex supply chain and manufacturing facilities;
- greater than anticipated costs of our preclinical studies and clinical programs;
- harmful side effects or inability of our product candidates to meet efficacy endpoints during clinical trials, which can be unpredictable even in light of earlier non-clinical and clinical data;
- 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, including STRO-004, which are generated from our proprietary XpressCF® and XpressCF+® platforms. 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® and XpressCF+® platforms and our proprietary product candidates, including STRO-004. 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 our product candidates. 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-004 and our other future proprietary 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, manufacturing, 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 potential licensees,
- 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, including those that have not yet entered the market;
- maintaining an acceptable safety profile of our product candidates through clinical trials and following regulatory approval; and
- achieving commercially relevant success in the market post approval.

Many of these factors are out of our control and 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.

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.

Additionally, we have in the past and may in the future create benchmark molecules for comparative purposes. For example, we have created a benchmark FRα targeting antibody-drug conjugate, or ADC, using conventional technology that results in a heterogeneous ADC mixture. 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 anticipate and project, 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, such as health epidemics and pandemics, global instability and geopolitical conflicts within regions where our clinical trials are conducted. For example, we may open clinical trial sites in jurisdictions that may face enrollment, operational or other difficulties due to conflicts within the region. In addition, we rely on third party vendors, contractors and consultants to provide services in connection with our clinical trials. If these third parties do not perform their services in a timely or workmanlike manner, our clinical studies may be delayed. 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, including unprecedented Immunostimulatory Antibody Drug Conjugate, or iADC, and dual Antibody Drug Conjugates, or ADC² technology, that are unproven and may not result in marketable products.

We are developing a pipeline of product candidates using our proprietary XpressCF® and XpressCF+® 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® and XpressCF+® platforms is ongoing. Further, the scientific evidence to support the feasibility of developing therapeutic treatments based on our XpressCF® and XpressCF+® platforms is both preliminary and limited.

Our current and prior product candidates have been tested in a relatively limited number of clinical trial patients. We may ultimately discover that our XpressCF® and XpressCF+® platforms and any product candidates resulting therefrom do not possess certain properties required for therapeutic effectiveness. XpressCF® and XpressCF+® 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® and XpressCF+® 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® and XpressCF+® platforms may demonstrate different chemical and pharmacological properties in patients than they do in laboratory studies. Although our XpressCF® and XpressCF+® 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.

Results of our clinical trials could reveal a high and unacceptable severity and prevalence of side effects or unexpected characteristics. Undesirable side effects could result in the delay, suspension or termination of clinical trials by us or regulatory authorities for a number of reasons. In our clinical trials to date, our product candidates have been generally well tolerated, and the most common treatment-emergent adverse events, or TEAEs, that resulted in a treatment delay or dose reduction were reversible neutropenia and myalgia/arthralgia. It is possible that, as we test our product candidates in larger, longer and more extensive clinical trials or as the use of our product candidates becomes more widespread following any regulatory approval, illnesses, injuries, discomforts and other adverse events that were observed in earlier trials, as well as conditions that did not occur or went undetected in previous trials, will be reported by patients. If such side effects become known later in development or upon approval, if any, such findings may harm our business, financial condition, results of operations and prospects significantly.

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, iADC or ADC² 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 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® and 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, current 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. 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. 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.

Interim, top-line, or preliminary data from our clinical trials that we announce may change as more patient data become available and are subject to audit and verification procedures that could result in material changes in the final data.

From time to time, we have publicly disclosed, and in the future will disclose, interim, top-line, or preliminary data from our preclinical studies and clinical trials, which are based on preliminary analyses of then-available data, and the results and related findings and conclusions are subject to change following a more comprehensive review and/or maturation of the data related to the particular study or trial. We also make assumptions, estimations, calculations, and conclusions as part of our analyses of data, and we may not have received or had the opportunity to fully and carefully evaluate all data. Therefore, final results from the studies may differ from the top-line results initially reported, and the final results may indicate different conclusions once additional data have been evaluated. As such, top-line data should be viewed with caution until the final data are available. In addition, the information we choose to publicly disclose regarding a particular study or clinical trial is based on what is typically extensive data, and you or others may not agree with what we determine is material or otherwise appropriate information to include in our disclosure. If the final results differ from the interim, top-line, or preliminary data, or if others, including regulatory authorities, disagree with the conclusions reached, our ability to obtain approval for, and to commercialize, our product candidates may be harmed, which may negatively affect our business, financial condition, results of operations, and prospects. Further, disclosure of interim data by us or by our competitors could result in volatility in the price of our common stock.

Further, others, including regulatory agencies, may not accept or agree with our assumptions, estimates, calculations, conclusions, or analyses, or may interpret or weigh the importance of data differently, which could negatively affect the approvability or commercialization of the particular product candidate.

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® and XpressCF+® 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 the medical community and third-party payors may not be compelled 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 the following, 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 availability of a commercially approved companion diagnostic or assay or biomarker to appropriately identify patients that will benefit from treatment;
- 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.

iADC and ADC^2 are novel technologies, which makes it difficult to predict the time, risks and cost of development and of subsequently obtaining regulatory approval of these potential product candidates.

Certain of our preclinical product candidates are based on our proprietary iADC and ADC^2 technology. Some of our future success depends on the successful development of this technology and products based on it. To our knowledge, no regulatory authority has granted approval to any person or entity, including us, to market and commercialize therapeutics using our novel and unprecedented iADC or ADC^2 technology. We may never receive approval to market and commercialize any potential iADC or ADC^2 product candidate.

If we uncover any previously unknown risks related to our iADC and ADC^2 technology, or if we experience unanticipated or unsolvable problems or delays in developing our iADC or ADC^2 product candidates, we may be unable to complete our preclinical studies and clinical trials, meet the obligations of our collaboration and license agreements, or commercialize our product candidates on a timely or profitable basis. If serious adverse events or unacceptable side effects are observed in preclinical studies or clinical trials of a product candidate based on our iADC or ADC^2 technology, or if iADCs or ADC^2s were shown to have limited efficacy, our ability to develop other product candidates based on our iADC or ADC^2 technology would be adversely affected.

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® and XpressCF+® platforms. 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® and XpressCF+® platforms and resulting product candidates.

Since 2014, we have entered into several collaborations to develop and commercialize certain cancer and other therapeutics. Our XpressCF® and XpressCF+® platforms have also supported a spin-out company, now known as 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.

Our existing collaborations with Astellas, Ipsen, Vaxcyte 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. A substantial portion of our revenue to date has been derived from our collaborations, and a significant portion of our future revenue and cash resources is expected to be derived from some of these agreements, our royalty monetization agreement, or Purchase Agreement, with an affiliate of Blackstone Life Sciences, or Blackstone, 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 or royalty monetization agreement, 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, each of EMD Serono, BMS and Merck elected not to continue the development of their licensed candidates, and our existing collaborator, Astellas, decided not to nominate a third program under our collaboration; each such decision was noted as based on strategic portfolio considerations. 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. Our collaborators may fail to live up to the terms of their agreements with us, which would require us to seek to enforce our agreements in accordance with the dispute resolution procedures set forth therein. These procedures may require us to engage in litigation or arbitration to enforce our rights, which can be expensive, time-consuming and distracting to our management and Board of Directors. Further, the type and timing of resolution of such disputes are difficult to predict; and there is the potential that we could fail to enforce our rights either in part or in whole. Lastly, even if we successfully enforce our rights under our agreements with our collaborators, there is the possibility that we could fail to recover our expectancy following the litigation or arbitration, particularly for collaborators that are not subject to the jurisdiction of U.S. courts.

In addition, from time to time we may have disputes with our collaborators. Any dispute or litigation proceedings we may have with our collaborators could delay development programs, reduce or eliminate potential milestone or other payments, create uncertainty as to ownership of intellectual property rights, distract management from other business activities and generate substantial expense.

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 or sales 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. Additionally, antitrust or other competition laws including increased enforcement within the United States in the healthcare space may also limit our ability to enter into collaborations with certain businesses or to fully realize the benefits of strategic transactions. 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.

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.

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® and XpressCF+® platforms 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, proprietary cell-free production technologies to supply our planned preclinical and clinical trials; however, we are transitioning our extract and reagent manufacturing strategy to an outsourced model and plan to wind down our manufacturing activities in our San Carlos facility no later than the end of 2025.

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 clinical trial use of our product candidates and others of our or our partners' product candidates; 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 have ongoing technology transfers to enable large scale manufacture of extract and the reagents necessary to manufacture our products using our XpressCF® and XpressCF+® platforms. 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.

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 do not have the ability to independently conduct all aspects of our preclinical testing or clinical trials ourselves. We have accordingly relied in some cases and intend to rely in the future on third-party clinical investigators, 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.

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, including raw and intermediate materials, are manufactured at qualified third-party CMOs. We intend to decommission or otherwise exit our manufacturing facility in San Carlos by the end of 2025 and rely on an external manufacturing strategy where all elements of our product candidates and platform reagents are manufactured by qualified third-party CMOs. It is possible that our operations in the San Carlos facility will be negatively affected by the planned shutdown, impacting the amount or quality of our products made and potentially delaying our clinical trials or otherwise impacting our business.

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. 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. 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. 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 an existing or future collaborator;
- losses resulting from an inability to utilize reserved manufacturing capacity because of delays or difficulties encountered in the supply chain;
- 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 or failures or delays in our manufacturing supply chain. For example, restrictions on travel imposed by governments, including China, or restrictions on person-in-plant permissions imposed by our contract manufacturers may limit the ability of our subject matter experts to visit our manufacturers and assist with technology transfers. Further, legislation has been introduced in Congress to limit certain U.S. biotechnology companies from using equipment or services produced or provided by select Chinese biotechnology companies, and others in Congress have advocated for the use of existing executive branch authorities to limit those Chinese service providers' ability to engage in business in the U.S. We cannot predict what actions may ultimately be taken with respect to trade relations between the United States and China or other countries, what products and services may be subject to such actions or what actions may be taken by the other countries in retaliation. 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 or materials used to manufacture components 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, or materials used in manufacturing components 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 and materials used to manufacture components of our products can be 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 and materials used to manufacture components 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 and specifications, 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-004 is our most advanced preclinical stage program, 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. For example, in June 2023, we announced our Purchase Agreement with Blackstone and in April 2024 we announced our License Agreement with Ipsen.

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. 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. 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.

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, including financial, technical, manufacturing, marketing, sales, supply, human resources, or general experience 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® and XpressCF+® platforms, 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 well-funded biopharmaceutical, biotechnological and therapeutics companies, including large and specialty companies focused on cancer immunotherapies and ADCs, as well as numerous small and mid-cap companies. Moreover, we also compete with current and future therapeutics developed at research-stage biotechnology companies, universities and other research institutions.

We are aware of several companies that are developing ADCs, cytokine derivatives, bispecific antibodies and cancer immunotherapies, including companies developing ADCs directed to the same target as STRO-004. For example, Pfizer has an approved ADC targeting TF, TIVDAK®. In addition, large pharmaceutical companies and smaller biotechnology companies are developing other ADCs, including TF-targeting ADCs; and we anticipate more TF-targeting ADCs and other potential TF-targeting modalities to be evaluated in the clinic in the coming years. Further, other companies may develop ADCs targeting receptors other than TF for the treatment of the same indications for which we are developing STRO-004. 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 therapeutics include a range of biologic modalities with the top selling products by class spanning tumor targeting monoclonal antibodies, to ADCs, to immune checkpoint inhibitors, to T cell-engager immunotherapies, and to CAR-T cell therapies. In addition, numerous compounds are in clinical development for cancer treatment. The clinical development pipeline for cancer includes small molecules, antibodies, vaccines, cell therapies and immunotherapies from a variety of companies and institutions.

Further, 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.

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® 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, particularly in the San Francisco Bay Area, where we are headquartered. Should our competitors recruit our key employees, our level of expertise and ability to execute our business plan would be negatively impacted. Further, 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.

In addition, job candidates and existing employees often consider the value of the stock awards they receive in connection with their employment. If the perceived benefits of our stock awards decline, either because we are a public company or for other reasons, it may harm our ability to recruit and retain highly-skilled employees. Our employees may be more likely to leave us if the shares they own have significantly appreciated in value relative to the original purchase prices of the shares, or if the exercise prices of the options that they hold are significantly below the market price of our common stock, particularly after the expiration of the lock-up agreements described herein.

Moreover, in March 2025, management approved a restructuring plan with an associated reduction in workforce as a result of a review of current strategic priorities, resource allocation, and cost reduction intended to reduce operating costs, streamline operations and extend our cash runway. These reductions in our workforce may also make retention of our current personnel both more important and more challenging. These workforce reductions resulted in the loss of longer-term employees, the loss of institutional knowledge and expertise, and the reallocation and combination of certain roles and responsibilities across the organization, all of which could adversely affect our operations. Given the complexity of our business, we must continue to implement and improve our managerial, operational and financial systems, manage our facilities and continue to recruit and retain qualified personnel.

Further, we recently underwent a leadership transition, which may be viewed negatively by employees, investors and/or our strategic partners. Moreover, any attrition associated with this transition could significantly delay or prevent the achievement of product development and commercialization, and other business objectives, and adversely impact our stock price.

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

As of December 31, 2024, we had 310 full-time employees, prior to our March 2025 restructuring with an associated reduction in workforce, which resulted in a reduction of approximately 50% of our workforce. 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. 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 additional 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 support 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 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 or adoption 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 either the U.S. or foreign markets may adversely 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.

Additionally, 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.

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. Our employees could also inappropriately utilize artificial intelligence, or AI, in connection with their social media communications, introducing another potential source of reputational damage or other potential legal or financial exposure.

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 are increasingly dependent on information technology systems and infrastructure to operate our business. In the ordinary course of our business, we collect, use, store and transmit large amounts of confidential and sensitive information, including intellectual property, proprietary business information and personal information (including health related information). We have established physical, electronic and organizational measures designed to safeguard and secure our systems to prevent a security incident (which may include, for example: data breaches, viruses or other malicious code, coordinated attacks, data loss, phishing attacks, ransomware, distributed 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 information. We have also outsourced elements of our information technology infrastructure, and as a result, a number of third-party vendors have access to our information. Despite the implementation of security measures, 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 breach, breakdown, 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 formal 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 collaborators, CROs, third party vendors, or contractors or consultants or other third parties on which we rely to mitigate a data security incident 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, although we believe that these attempts were detected and neutralized without any compromise to our data and prior to any significant impact to our business. We have also implemented measures to prevent such attacks, but 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, though we believe that such security breaches did not compromise our data or materially impact our business. Such security events, whether impacting our systems directly or impacting those of a third party on which we rely, could cause interruptions in our operations, and 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. Further, if we are unable to generate or maintain access to essential patient samples or data for our research, development, and manufacturing activities for our programs, our business could be materially adversely affected.

Moreover, if a computer security breach affects our systems or results in the unauthorized release of personally information, our reputation could be materially damaged, we may be required to formally notify governmental agencies, the media or individuals pursuant to various federal and state privacy and security laws. We could 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 that may result in regulatory scrutiny, fines, private right of action settlements, and other consequences. Compliance with 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.

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.

Further, some of our employees work remotely from time to time, which presents certain risks to our business. For example, remote work presents significant demands on our information technology resources and systems and can be at risk for phishing and other malicious activity, which can result in an increase to 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.

In our ongoing efforts to innovate and optimize operational efficiency, we have integrated AI into various aspects of our workplace. For example, we have implemented AI machine learning for email behavioral monitoring. While AI presents opportunities for enhanced productivity and innovation, it also introduces inherent risks, including legal and regulatory, that could adversely impact our business and reputation. Proper use of AI can lead to improved decision-making, cost reduction, and competitive advantage. However, improper use, including algorithmic biases, ethical considerations, data privacy issues, unknown or zero-day software vulnerabilities, and potential regulatory non-compliance, could result in reputational damage, legal liabilities, and financial losses. The rapidly evolving regulatory landscape surrounding AI also poses a risk, as new laws and regulations could impose additional compliance burdens, resulting in increased operational costs. We are committed to implementing robust governance and control mechanisms to mitigate these risks, but there can be no assurance that such measures will adequately prevent or mitigate the adverse effects that the integration and use of AI may have on our business, financial condition, and results of operations.

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 generally contract with third parties for the disposal of these materials and wastes. We cannot eliminate the risk of contamination or injury from these materials. We and our third-party contractors 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 and our third-party contractors' 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, including employee and contractor training and procedures regarding safe handling and disposal, the risk of accidental or mistaken 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 and exceed any available insurance. 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 or from other hazards potentially present in our workplaces, such as high voltage electricity, process steam or other hot material, liquid nitrogen or other cold material, materials stored under pressure, laboratory instruments that incorporate powerful lasers or magnets, sonic resonance, heavy machinery, and the like, 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 and existing laws and regulations could become more stringent. Further, we may incur substantial costs to comply with, and substantial fines or penalties if we violate, any of these laws or regulations.

We are subject to certain U.S. and foreign anti-corruption, anti-money laundering, export control, sanctions and other trade laws and regulations. We can face serious consequences for violations.

U.S. and foreign anti-corruption, anti-money laundering, export control, sanctions and other trade laws and regulations prohibit, among other things, companies and their employees, agents, CROs, CMOs, legal counsel, accountants, consultants, contractors and other partners from authorizing, promising, offering, providing, soliciting, or making or receiving directly or indirectly, corrupt or improper payments or anything else of value to or from recipients in the public or private sector. Violations of these laws can result in substantial criminal fines and civil penalties, imprisonment, the loss of trade privileges, debarment, tax reassessments, breach of contract and fraud litigation, reputational harm and other consequences. We have direct or indirect interactions with officials and employees of government agencies or government-affiliated hospitals, universities and other organizations. We also expect our non-U.S. activities to increase over time. We expect to rely on third parties for research, preclinical studies and clinical trials and/or to obtain necessary permits, licenses, patent registrations and other marketing authorizations. We can be held liable for corrupt or other illegal activities of our personnel, agents, or partners, even if we do not explicitly authorize or have prior knowledge of such activities.

Any violations of the laws and regulations described above may result in substantial civil and criminal fines and penalties, imprisonment, the loss of export or import privileges, debarment, tax reassessments, breach of contract and fraud litigation, reputational harm and other consequences.

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, other natural disasters, pandemics, or other catastrophic events 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. Further, many of our employees conduct business outside of our leased or owned facilities and these locations may be subject to additional security risks outside of our control. 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 2017 Tax Act, enacted many significant changes to the U.S. tax laws. Beginning in 2022, the 2017 Tax Act eliminated the option to currently deduct research and development expenditures and instead required taxpayers to capitalize and amortize U.S. based and non-U.S. based research and development expenditures over five and fifteen years, respectively, pursuant to IRC Section 174. Although there have been legislative proposals to repeal the capitalization requirement or limit it to non-U.S. based research, there can be no assurance that the provision will be repealed or otherwise modified. We also cannot predict whether, when, in what form, or with what effective dates, tax laws, regulations and rulings may be enacted, promulgated or issued, which could result in an increase in our or our stockholders' tax liability or require changes in the manner in which we operate in order to minimize or mitigate any adverse effects of changes in tax law. Changes in corporate tax rates, the realization of net deferred tax assets relating to our operations, 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.

Under current law, our net operating loss carryforwards generated in tax years ending on or prior to December 31, 2017, are permitted to be carried forward for 20 years and 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, is limited to 80% of taxable income (without regard to certain deductions).

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 our 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, we experienced ownership change on each of November 20, 2019 and December 31, 2022, which imposed limitations on the use of our net operating losses arising before those dates. In addition, we may have experienced other ownership changes in the past and 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. As a result, our use of federal NOL carryforwards could be further 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 cash and investments could be adversely affected if the financial institutions in which we hold our cash and investments fail.

We regularly maintain cash balances at third-party financial institutions in excess of the FDIC insurance limit and similar regulatory insurance limits outside the United States, and governments may not guarantee all depositors if such financial institutions were to fail, in the event of bank closures and continued instability in the global banking system. Any future adverse developments in the global banking system could directly or indirectly negatively impact our business, financial condition, results of operations and prospects. Further, if we enter into a credit, loan or other similar facility with a financial institution, certain covenants included in such facility may require as security that we keep a significant portion of our cash with the institution providing such facility. If a depository institution where we maintain deposits fails or is subject to adverse conditions in the financial or credit markets, we may not be able to recover all, if any, of our deposits, which could adversely impact our operating liquidity and financial performance.

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 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.

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 licensor'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 that cover our product candidates, methods used to manufacture our product candidates, methods for treating patients using our product candidates, pharmaceutical formulations and dosing regimens, 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. Composition of matter patents for biological and pharmaceutical therapeutic candidates often provide a strong form of intellectual property protection for those types of products, as such patents provide protection without regard to any method of use. We cannot be certain that the claims in our pending patent applications directed to composition of matter of our therapeutic candidates will be considered patentable by the United States Patent and Trademark Office, or USPTO, or by patent offices in foreign countries, or that the claims in any of our issued patents will be considered valid and enforceable by courts in the United States or foreign countries. Method of use patents protect the use of a product for the specified method. This type of patent does not prevent a competitor from making and marketing a product that is identical to our therapeutics for an indication that is outside the scope of the patented method. Moreover, even if competitors do not actively promote their product for our targeted indications, clinicians may prescribe these products "off-label." Although off-label prescriptions may infringe or contribute to the infringement of method of use patents, the practice is common and such infringement is difficult to prevent or prosecute. 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 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 may 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. In addition, the United States federal government retains certain rights in inventions produced with its financial assistance under the Patent and Trademark Law Amendments Act, or the Bayh-Dole Act. The federal government retains a “nonexclusive, nontransferable, irrevocable, paid-up license” for its own benefit. The Bayh-Dole Act also provides federal agencies with “march-in rights.” The government can 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® and XpressCF+® platforms. 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-drug conjugates, or components thereof.

As the field of antibody-drug conjugate 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, or 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, 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.

Geopolitical actions in the United States and in foreign countries could increase the uncertainties and costs surrounding the prosecution or maintenance of patent applications and the maintenance, enforcement or defense of issued patents. For example, the United States and foreign government actions related to Russia’s invasion of Ukraine may limit or prevent filing, prosecution and maintenance of patent applications in Russia. Government actions may also prevent maintenance of issued patents in Russia. These actions could result in abandonment or lapse of patents or patent applications, resulting in partial or complete loss of patent rights in Russia. If such an event were to occur, it could have a material adverse effect on our business. In addition, a decree was adopted by the Russian government in March 2022, allowing Russian companies and individuals to exploit inventions owned by patentees that have citizenship or nationality in, are registered in, or have predominately primary place of business or profit-making activities in the United States and other countries that Russia has deemed unfriendly without consent or compensation. Consequently, we would not be able to prevent third parties from practicing our inventions in Russia or from selling or importing products made using our inventions in and into Russia. Accordingly, our competitive position may be impaired, and our business, financial condition, results of operations and prospects may be adversely affected.

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.

European patent applications now have the option, upon grant of a patent, of becoming a Unitary Patent which will be subject to the jurisdiction of the Unitary Patent Court, or UPC. This will be a significant change in European patent practice. As the UPC is a new court system, there is very limited precedent for the court, increasing the uncertainty of any litigation. As a single court system can invalidate a European patent, we, our licensors or our collaborators, may opt out of the UPC and as such, each European patent would need to be challenged in each individual country. Limited information is available to make judgments about advantages and disadvantages of either opting into or remaining out of UPC jurisdiction; either choice may ultimately prove to have significant implications as to cost, enforceability and scope of protection, among other factors, for applicable European patents.

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.

We may not identify relevant third-party patents or may incorrectly interpret the relevance, scope or expiration of a third-party patent, which might adversely affect our ability to develop and market our therapeutics.

As the biopharmaceutical industry expands and more patents are issued, the risk increases that our product candidates may be subject to claims of infringement of the patent rights of third parties. There can be no assurance that our operations do not, or will not in the future, infringe existing or future third-party patents. Identification of third-party patent rights that may be relevant to our operations is difficult because patent searching is imperfect due to differences in terminology among patents, incomplete databases and the difficulty in assessing the meaning of patent claims. We cannot guarantee that any of our patent searches or analyses, including the identification of relevant patents, the scope of patent claims or the expiration of relevant patents, are complete or thorough, nor can we be certain that we have identified each and every third-party patent and pending application in the United States and abroad that is relevant to or necessary for the commercialization of our therapeutic candidates in any jurisdiction.

Numerous U.S. and foreign patents and pending patent applications exist in our market that are owned by third parties. Our competitors in both the United States and abroad, many of which have substantially greater resources and have made substantial investments in patent portfolios and competing technologies, may have applied for or obtained or may in the future apply for and obtain, patents that will prevent, limit or otherwise interfere with our ability to make, use and sell our therapeutics. We do not always conduct independent reviews of pending patent applications of and patents issued to third parties. Patent applications in the United States and elsewhere are typically 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. Certain U.S. applications that will not be filed outside the U.S. can remain confidential until patents issue. In addition, patent applications in the United States and elsewhere can be pending for many years before issuance, or unintentionally abandoned patents or applications can be revived. Furthermore, pending patent applications that have been published can, subject to certain limitations, be later amended in a manner that could cover our technologies, our therapeutics or the use of our therapeutics. As such, there may be applications of others now pending or recently revived patents of which we are unaware. These patent applications may later result in issued patents, or the revival of previously abandoned patents, that will prevent, limit or otherwise interfere with our ability to make, use or sell our therapeutics.

The scope of a patent claim is determined by an interpretation of the law, the written disclosure in a patent and the patent's prosecution history. Our interpretation of the relevance or the scope of a patent or a pending application may be incorrect. For example, we may incorrectly determine that our therapeutics are not covered by a third-party patent or may incorrectly predict whether a third-party's pending application will issue with claims of relevant scope. Our determination of the expiration date of any patent in the United States or abroad that we consider relevant may be incorrect. Our failure to identify and correctly interpret relevant patents may negatively impact our ability to develop and market our product candidates.

We cannot provide any assurances that third-party patents do not exist which might be enforced against our current technology, including our research programs, product candidates, their respective methods of use, manufacture and formulations thereof, and could result in either an injunction prohibiting our manufacture or future sales, or, with respect to our future sales, an obligation on our part to pay royalties and/or other forms of compensation to third parties, which could be significant.

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 is involved in an opposition proceeding at the European Patent Office, or EPO, and was revoked by the EPO in 2021. In April 2022, an appeal was filed and in 2024, the Opposition Division decided to maintain our European Patent in amended form. Absent our successful appeal, we would not be able to assert 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, linkers, cytotoxins, immunostimulants, or other warheads, or combinations thereof, 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-drug conjugate 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 2031, that relates to strained alkyne reagents that can be used as synthetic precursors for certain of our linker-warheads. We are further aware of an issued patent, expected to expire in 2034, relating to certain conjugates comprising a genus of hemiasterlin derivatives that may be potentially relevant to products incorporating our hemiasterlin-derived linker-warhead. If any of these patents are valid and not yet expired when, and if, we receive marketing approval for STRO-004, as applicable, 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-004 or any other product candidate. 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® and XpressCF+® platforms 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® and XpressCF+® platforms 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. 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 technologies 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 technologies, 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 Supreme Court of the United States held in *Amgen v. Sanofi* (2023) that a functionally claimed genus was invalid for failing to comply with the enablement requirement of the Patent Act. In addition, the Federal circuit issued a decision, *In re Cellect, LLC* (2023) involving the interaction of patent term adjustment (PTA), terminal disclaimers, and obvious-type double patenting which may affect the patent term of any issued patents that rely on any PTA. Depending on future actions by the U.S. Congress, the U.S. courts, the USPTO and the relevant law-making bodies in other countries, 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. Also, 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. For example, the Inflation Reduction Act, or IRA, passed by Congress authorizes the Secretary of the U.S. Department of Health and Human Services, or HHS, to negotiate prices directly with participating manufacturers for selected medicines reimbursed by Medicare Part B or Part D even if these medicines are protected by an existing patent. In addition, we may become subject to claims challenging the inventorship or ownership of our patents and other intellectual property.

We may be subject to claims that former employees, collaborators or other third parties have an interest in our patents or other intellectual property as an inventor or co-inventor. The failure to name the proper inventors on a patent application can result in the patents issuing thereon being unenforceable. Inventorship disputes may arise from conflicting views regarding the contributions of different individuals named as inventors, the effects of foreign laws where foreign nationals are involved in the development of the subject matter of the patent, conflicting obligations of third parties involved in developing our product candidates or as a result of questions regarding co-ownership of potential joint inventions. Litigation may be necessary to resolve these and other claims challenging inventorship or ownership. Alternatively, or additionally, we may enter into agreements to clarify the scope of our rights in such intellectual property. If we fail in defending any such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights, such as exclusive ownership of, or right to use, valuable intellectual property. Such an outcome could have a material adverse effect on our business. Even if we are successful in defending against such claims, litigation could result in substantial costs and be a distraction to management and other employees.

Our current or future licensors may have relied on third-party consultants or collaborators or on funds from third parties, such as the U.S. government, such that our licensors are not the sole and exclusive owners of the patents we in-licensed. If other third parties have ownership rights or other rights to our in-licensed patents, they may be able to license such patents to our competitors, and our competitors could market competing products and technology. This could have a material adverse effect on our competitive position, business, financial conditions, results of operations, and prospects.

In addition, while it is our policy to require our employees and contractors who may be involved in the conception or development of intellectual property to execute agreements assigning such intellectual property to us, we may be unsuccessful in executing such an agreement with each party who, in fact, conceives or develops intellectual property that we regard as our own. The assignment of intellectual property rights may not be self-executing, or the assignment agreements may be breached, and we may be forced to bring claims against third parties, or defend claims that they may bring against us, to determine the ownership of what we regard as our intellectual property. Such claims could have a material adverse effect on our business, financial condition, results of operations, and prospects.

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

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 some of 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 the initial clinical trials, depending upon the type, complexity and novelty of the product candidate and the availability of applicable government resources. 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. For example, the Oncology Center of Excellence within the FDA has advanced Project Optimus, which is an initiative to reform the dose optimization and dose selection paradigm in oncology drug development to emphasize selection of an optimal dose, which is a dose or doses that maximizes not only the efficacy of a drug but the safety and tolerability as well. This shift from the prior approach, which generally determined the maximum tolerated dose, may require sponsors to spend additional time and resources to further explore a product candidate's dose-response relationship to facilitate optimum dose selection in a target population. Other Oncology Center of Excellence initiatives have included Project FrontRunner, an initiative with a goal of developing a framework for identifying candidate drugs for initial clinical development in the earlier advanced setting rather than for treatment of patients who have received numerous prior lines of therapies or have exhausted available treatment options. We are considering these policy changes as they relate to our programs. We may also be affected by ex-US regulatory requirements, given that our trials may be conducted globally; current and unforeseen new EU-specific clinical trial conduct regulations, such as the In Vitro Diagnostic Regulation, or IVDR, and GDPR, may delay, or increase the difficulty and expense of conducting, our clinical studies.

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 expenses. 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 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.

Moreover, 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.

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.

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. Further, three decisions from the U.S. Supreme Court in 2024 may lead to an increase in litigation against regulatory agencies that could create uncertainty and thus negatively impact our business. The first decision overturned established precedent that required courts to defer to regulatory agencies' interpretations of ambiguous statutory language. The second decision overturned regulatory agencies' ability to impose civil penalties in administrative proceedings. The third decision extended the statute of limitations within which entities may challenge agency actions. However, the specific, lasting effects of these decisions, which may vary within different judicial districts and circuits, is unknown. We also cannot predict the extent to which FDA and SEC regulations, policies, and decisions may become subject to increasing legal challenges, delays, and changes. For example, these cases may result in increased litigation by companies against the FDA, and impact the FDA's authority, lead to uncertainties in the industry, and disrupt the FDA's normal operations, which could impact the timely review of any regulatory filings or applications we submit to the FDA.

Further, if a prolonged government shutdown occurs, or if global health concerns 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 affect pricing and third-party payments for our product candidates, which could negatively affect our business, financial condition and prospects. 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.

While there have been legislative and judicial efforts to modify, repeal or otherwise invalidate all or certain aspects of the ACA or its implementing regulations, the ACA remains in effect in its current form. It is unclear how any such efforts in the future will impact the ACA or our business.

In addition, other legislative changes have been proposed and adopted in the United States federal and state levels to reduce healthcare expenditures, including the Budget Control Act, which, subject to certain temporary suspension periods, imposed 2% reductions in Medicare payments to providers per fiscal year starting April 1, 2013 and, due to subsequent legislative amendments to the statute, that will remain in effect through 2032, unless additional Congressional action is taken, and the Infrastructure Investment and Jobs Act, which added a requirement for manufacturers of certain single-source drugs (including biologics and biosimilars) separately paid for under Medicare Part B for at least 18 months and marketed in single-dose containers or packages (known as refundable single-dose containers or single-use package drugs) to provide annual refunds for any portions of the dispensed drug that are unused and discarded if those unused or discarded portions exceed an applicable percentage defined by statute or regulation. Further, in November 2020, the 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 this final rule was delayed by the IRA until January 1, 2032. Under the American Rescue Plan Act of 2021, effective January 1, 2024, the statutory cap on Medicaid Drug Rebate Program rebates that manufacturers pay to state Medicaid programs has been eliminated. Elimination of this cap has, in some instances, required pharmaceutical manufacturers to pay more in rebates than they have received on the sale of products.

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. In November 2024, CMS issued a final rule, that decreased Medicare reimbursement for physician services by 2.8%, effective January 1, 2025. 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. CMS bundles the Medicare payments for certain laboratory tests ordered while a patient received services in a hospital outpatient setting and CMS pays 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.

There has been heightened governmental scrutiny over the manner in which manufacturers set prices for their marketed products, which has resulted in several presidential executive orders, 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.

Additionally, several healthcare reform initiatives culminated in the enactment of the IRA in August 2022, which allows, among other things, HHS to directly negotiate the selling price of a statutorily specified number of drugs and biologics each year that CMS reimburses under Medicare Part B and Part D. The negotiated price may not exceed a statutory ceiling price. Only high-expenditure single-source biologics that have been approved for at least 11 years (7 years for single-source small molecule therapeutics) can qualify for negotiations, with the negotiated price taking effect two years after the selection year. For 2026, the first year in which negotiated prices become effective, CMS selected 10 high-cost Medicare Part D products in 2023, negotiations began in 2024, and the negotiated maximum fair price for each product has been announced. These negotiations resulted in significant price reductions for the products from their 2023 list prices, ranging from 38 to 79 percent, with an average price reduction of 59.4 percent. CMS has selected 15 additional Medicare Part D drugs for negotiated maximum fair pricing in 2027. For 2028, an additional 15 drugs, which may be covered under either Medicare Part B or Part D, will be selected, and for 2029 and subsequent years, 20 Part B or Part D drugs will be selected. A drug or biological product that has an orphan drug designation for only one rare disease or condition will be excluded from the IRA's price negotiations requirements, but loses that exclusion if it has designations for more than one rare disease or condition, or if it is approved for an indication that is not within that single designated rare disease or condition, unless such additional designation or such disqualifying approvals are withdrawn by the time CMS evaluates the drug for selection for negotiation. The IRA also imposes rebates on Medicare Part D and Part B drugs whose prices have increased at a rate greater than the rate of inflation, and in November 2024, CMS finalized regulations for the Medicare Part D and Part B inflation rebates. In addition, the law eliminates the "donut hole" under Medicare Part D beginning in 2025 by significantly lowering the enrollee maximum out-of-pocket cost and requiring manufacturers to subsidize, through a newly established manufacturer discount program, 10% of Part D enrollees' prescription costs for brand drugs below the out-of-pocket maximum, and 20% once the out-of-pocket maximum has been reached. The IRA permits the Secretary of HHS to implement many of these provisions through guidance, as opposed to regulation, for the initial years. Manufacturers that fail to comply with the IRA may be subject to various penalties, some significant, including civil monetary penalties. The IRA also extends enhanced subsidies for individuals purchasing health insurance coverage in ACA marketplaces through plan year 2025. These provisions may be subject to legal challenges. For example, the provisions related to the negotiation of selling prices of high-expenditure single-source drugs and biologics have been challenged in multiple lawsuits brought by pharmaceutical manufacturers. Thus, while it is unclear how the IRA will be implemented, it will likely have a significant impact on the pharmaceutical industry and our product candidates.

At the state level, legislatures are increasingly enacting laws 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. For example, the FDA released a final rule in September 2020 providing guidance for states to build and submit importation plans for drugs from Canada, and the FDA authorized the first such plan in January 2024, which has been extended until July 2025. It is unclear how this program will be implemented, including which drugs will be chosen, and whether it will be subject to legal challenges in the United States or Canada. Other states have also submitted proposals that are pending review by the FDA.

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, the IRA and other state or federal 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;

- the Health Insurance Portability and Accountability Act, or 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 the Health Information Technology for Economic and Clinical Health Act, or 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 maintain a quantity of sensitive and confidential information, including confidential business and patient health information in connection with our clinical trials that are subject to US and international laws and regulations governing the privacy and data protection of such information. Each of these laws is subject to varying interpretations and subject to evolving regulations. For example, the EU and United Kingdom, UK respective General Data Protection Regulations, or GDPR, which apply extraterritorially, impose strict requirements for controllers and processors of personal information, which include high standards for obtaining consent from individuals to process their personal information, increased requirements pertaining to the processing of special categories of personal information (such as health information), including in pseudonymized (i.e., key-coded) form, and heightened transfer requirements of personal information from the European Economic Area/UK/Switzerland to countries not deemed to have adequate data protections laws (including the U.S.). Companies that must comply with the GDPR face increased compliance obligations and risk, including more robust regulatory enforcement of data protection requirements and potential fines for noncompliance of up to €20 million (£17.5 million in the UK) or 4 percent of the annual global revenues of the noncompliant company, whichever is greater.

In the United States, in addition to HIPAA, various federal (for example, the Federal Trade Commission) and state regulators have adopted, or are considering adopting, laws and regulations concerning personal information and data security that may conflict or be more stringent or broader in scope, or offer greater individual rights, with respect to personal information than existing federal, international, or other state laws. For example, California enacted the California Consumer Privacy Act, or as amended, the CCPA which grants individual privacy rights for California consumers and places increased privacy and data security obligations on entities handling personal information of consumers or households. Failure to comply with the CCPA may result in significant civil penalties, injunctive relief, or statutory or actual damages. Following California's lead, over a third of U.S. states have adopted comprehensive privacy and security laws and regulations, which govern the privacy, processing and protection of personal information, including certain specific requirements and laws with respect to health-related information. For example, Washington state has passed the My Health My Data Act, which is focused on the collection of consumer health data, has a broader scope than HIPAA and includes a private right of action. In addition, various comprehensive federal privacy bills have been proposed in Congress.

We cannot provide assurance that (i) current or future legislation will not prevent us from generating or maintaining personal information, or (ii) that patients will consent to the use of their personal information (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 addition to government regulation, privacy advocates and industry groups have and may in the future propose self-regulatory standards from time to time. These and other industry standards may legally or contractually apply to us, or we may elect to comply with such standards. It is possible that if our practices are not consistent or viewed as not consistent with legal and regulatory requirements and interpretations, 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.

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. Any failure or perceived failure by us to comply with any applicable federal, state, or similar foreign laws and regulations relating to data privacy and security could result in damage to our reputation, as well as proceedings or litigation by governmental agencies or other third parties, including class action privacy litigation in certain jurisdictions, which would subject us to significant fines, sanctions, awards, injunctions, penalties, or judgments. Any of the foregoing could have a material adverse effect on our business, results of operations, financial condition, 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 a 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 licensure of highly similar and interchangeable biosimilar products was created. The abbreviated regulatory pathway establishes legal authority for the FDA to review and approve a biosimilar biologic, including the possible designation of a biosimilar as interchangeable, based on its similarity to an existing reference product. The BPCIA provides a period of reference product exclusivity for biological products during which an application for a biosimilar product referencing such products cannot be licensed by the FDA until 12 years after the first licensure date of the reference product. Additionally, a biosimilar application referencing such exclusivity-protected biological products may not be submitted for four years after the first licensure date of the reference product.

During this 12-year period of exclusivity, another company may still market a competing version of the reference product if the FDA licenses a full BLA for the competing product containing the sponsor’s own preclinical data and data from adequate and well-controlled clinical trials to demonstrate the safety, purity and potency of their product. The law is complex and is still being interpreted and implemented by the FDA. As a result, its ultimate impact, implementation, and meaning are subject to uncertainty. While it is uncertain when and how such processes intended to implement BPCIA may be fully adopted by the FDA, any such processes could have an adverse effect on the future commercial prospects for our product candidates.

There is a risk that any product candidates we may develop that are licensed as a biological product under a BLA would not qualify for the 12-year period of exclusivity or that this exclusivity could be shortened due to congressional action or otherwise, potentially creating the opportunity for generic competition sooner than anticipated.

Most states have enacted substitution laws that permit substitution of interchangeable biosimilars. The extent to which a biosimilar, once licensed, will be substituted for any one of our reference products that may be approved 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. 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 boxed 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.

If we decide to seek Fast Track Designation by the FDA for any product candidate, even if successful, it may not lead to a faster development or regulatory review or approval process.

As part of our business strategy, we may seek Fast Track Designation for 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, 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 any product candidates if granted Fast Track Designation.

If we decide to seek Orphan Drug Designation for some of our 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.

As part of our business strategy, we may seek Orphan Drug Designation for our 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 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 of the drug to treat 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 condition 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 conditions, we may not be the first to obtain marketing approval of these product candidates for the orphan-designated condition due to the uncertainties associated with developing pharmaceutical products; in such case, no orphan drug exclusivity would be available unless we could demonstrate “clinical superiority.” In addition, exclusive marketing rights in the United States may be limited if we seek approval for an indication broader than the orphan-designated condition 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 not 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 or that our product candidate provides a benefit over available therapy. If standard of care were to evolve or 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 without a showing of benefit over available therapy. 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. Whether any trial is sufficient to receive FDA approval under the accelerated approval pathway will depend on the design and safety and efficacy results of such trial and will only be determined by the FDA upon review of the trial design and a submitted BLA.

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.

Recently, the accelerated approval pathway has come under scrutiny within the FDA and by Congress. The FDA has put increased focus on ensuring that confirmatory studies are conducted with diligence and, ultimately, that such studies confirm the benefit. For example, the FDA has convened its Oncologic Drugs Advisory Committee to review what the FDA has called “dangling” or delinquent accelerated approvals, where confirmatory studies have not been completed or where results did not confirm benefit, but for which marketing approval continues in effect, and some companies have subsequently voluntarily requested withdrawal of approval of their products. In addition, the Oncology Center of Excellence has announced Project Confirm, which is an initiative to promote the transparency of outcomes related to accelerated approvals for oncology indications and provide a framework to foster discussion, research and innovation in approval and post-marketing processes, with the goal to enhance the balance of access and verification of benefit for therapies available to patients with cancer and hematologic malignancies.

Further, the enactment of The Food and Drug Omnibus Reform Act, or FDORA, included provisions related to the accelerated approval pathway. Pursuant to FDORA, the FDA is authorized to require a post-approval study to be underway prior to approval or within a specified time period following approval. FDORA also requires the FDA to specify conditions of any required post-approval study and requires sponsors to submit progress reports for required post-approval studies and any conditions required by the FDA. FDORA enables the FDA to initiate enforcement action for the failure to conduct with due diligence a required post-approval study, including a failure to meet any required conditions specified by the FDA or to submit timely reports.

There is substantial uncertainty regarding the new Administration’s initiatives and how these might impact the FDA, its implementation of laws, regulations, policies and guidance and its personnel. These initiatives could prevent, limit or delay development and regulatory approval, and/or impact commercialization, of our product candidates, which would impact our ability to generate revenue.

FDA-regulated industries, such as ours, face substantial uncertainty regarding the regulatory environment we will face as we proceed with research and development, and possibly in future commercialization, efforts following the inauguration of President Trump in January 2025 (the "Administration"). Some of these efforts have manifested to date in the form of personnel measures that could impact the FDA's ability to hire and retain key personnel, which could result in delays in or limitations on our ability to obtain guidance from the FDA on our product candidates in development and obtaining the requisite regulatory approvals in the future. There remains general uncertainty regarding future activities. The new Administration could issue or promulgate executive orders, regulations, policies or guidance that adversely affect us or create a more challenging or costly environment to pursue the development and sale of new therapeutic products. For example, on January 20, 2025, President Trump announced an executive order establishing the Department of Government Efficiency to maximize government efficiency and productivity. Pressures on and uncertainty surrounding the U.S. federal government's budget and potential changes in budgetary priorities could adversely affect the funding for existing programs and grants and increase the costs to us of conducting clinical trials. Alternatively, state governments may attempt to address or react to changes at the federal level with changes to their own regulatory frameworks in a manner that is adverse to our operations. If we or our collaborators become negatively impacted by future governmental orders, regulations, policies or guidance as a result of the new Administration, there could be a material adverse effect on us and our operating results.

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® and XpressCF+® platforms, our product candidates or future development programs;
- 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;
- the impact of accounting principles and tax laws, including as a result of recent tax law changes;
- epidemics, pandemics or contagious diseases;
- changes in general market and economic conditions; and
- cybersecurity incidents

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 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, or 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 of 1933, as amended, or 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.

The exclusive forum provision in our organizational documents 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, or the underwriters of any offering giving rise to such claim, which may discourage lawsuits with respect to such claims.

Our amended and restated certificate of incorporation provides that, to the fullest extent permitted by law, 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 DGCL, our amended and restated certificate of incorporation or our amended and restated bylaws; or any action asserting a claim against us that is governed by the internal affairs doctrine. This exclusive forum provision does not apply to suits brought to enforce a duty or liability created by the Securities Exchange Act of 1934, as amended, or Exchange Act. It could apply, however, to a suit that falls within one or more of the categories enumerated in the exclusive forum provision.

This choice of forum provision 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, or the underwriters of any offering giving rise to such claims, which may discourage lawsuits with respect to such claims. Alternatively, if a court were to find the choice of forum provisions contained in our amended and restated certificate of incorporation to be inapplicable or unenforceable in an action, we may incur additional costs associated with resolving such action in other jurisdictions, which could harm our business, results of operations and financial condition.

Section 22 of the Securities Act, creates concurrent jurisdiction for federal and state courts over all claims brought to enforce any duty or liability created by the Securities Act or the rules and regulations thereunder. Our amended and restated bylaws provide that the federal district courts of the United States of America will, to the fullest extent permitted by law, be the exclusive forum for resolving any complaint asserting a cause of action arising under the Securities Act, or a Federal Forum Provision, including for all causes of action asserted against any defendant named in such complaint. For the avoidance of doubt, this provision is intended to benefit and may be enforced by us, our officers and directors, the underwriters to any offering giving rise to such complaint and any other professional entity whose profession gives authority to a statement made by that person or entity and who has prepared or certified any part of the documents underlying the offering. Our decision to adopt a Federal Forum Provision followed a decision by the Supreme Court of the State of Delaware holding that such provisions are facially valid under Delaware law. While federal or state courts may not follow the holding of the Delaware Supreme Court or may 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, and our stockholders cannot waive compliance with the federal securities laws and the rules and regulations thereunder.

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.

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;
- general economic uncertainty and capital markets disruptions, including changes in interest rates, a new U.S. presidential administration, rising inflation, changes in tariffs and trade restrictions, potential instability, which have been substantially impacted by regional geopolitical instability due to the impact of geopolitical tensions and the ongoing military conflicts around the world;
- any adverse impact of health pandemics, including on our clinical trials and clinical trial operations;
- 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;
- changes in accounting principles or tax laws;
- terrorist acts, acts of war or periods of widespread civil unrest, including the ongoing armed conflicts around the world;
- natural disasters, epidemics, pandemics or contagious diseases, and other calamities;
- political instability; 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. For example, we are party to a Sales Agreement with Jefferies, pursuant to which, from time to time, we may offer and sell through Jefferies common stock pursuant to one or more "at the market" offerings. Sales of our common stock under the Sales Agreement could be subject to business, economic or competitive uncertainties and contingencies, many of which may be beyond our control, and which could cause actual results from the sale of our common stock to differ materially from expectations. Any future sales of common stock through our "at the market" offering program will result in dilution and may have a negative impact on the 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.

General Risk Factors

Unfavorable global economic conditions could adversely affect our business, financial condition or results of operations.

Our business, financial condition or results of operations could be adversely affected by general conditions in the global economy and in the global financial markets. The global economy, including credit and financial markets, has recently experienced extreme volatility and disruptions, including severely diminished liquidity and credit availability, rising interest and inflation rates, changes in tariffs and trade restrictions, declines in consumer confidence, declines in economic growth, increases in unemployment rates and uncertainty about economic stability. Further, the capital and credit markets may be adversely affected by rising regional geopolitical tensions, and global sanctions imposed in response thereto. Our business and operations may be impacted by the current political instability and military hostilities in multiple geographies including Ukraine, the Middle East and the tensions between China and Taiwan. Moreover, a severe or prolonged economic downturn, such as the global financial crisis, could result in a variety of risks to our business, including, weakened demand for our product candidates and our ability to raise additional capital when needed on acceptable terms, if at all. A weak or declining economy could also strain our suppliers, possibly resulting in supply disruption, or cause our customers to delay making payments for our services. Any of the foregoing could harm our business and we cannot anticipate all of the ways in which the current economic climate and financial market conditions could adversely impact our business.

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. 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 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. 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. Additionally, we may be subject to stockholder activism, which can be costly and time-consuming, disrupting our operations and diverting the attention of management and may lead to additional compliance costs and impact the manner in which we operate our business. 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 have incurred, and will continue to 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 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 became a “smaller reporting company” as of December 31, 2022. We will continue to be a smaller reporting company if either (i) the market value of our stock held by non-affiliates is less than $250.0 million or (ii) our annual revenue is less than $100.0 million during the most recently completed fiscal year and the market value of our stock held by non-affiliates is less than $700.0 million. Specifically, as a smaller reporting company, we may choose to present only the two most recent fiscal years of audited financial statements in our Annual Report on Form 10-K and are eligible to take advantage of certain of the reduced disclosure obligations regarding compensation disclosures. As a smaller reporting company and an “accelerated filer”, we still need to comply with Section 404(a) of the Sarbanes-Oxley Act, which will continue to require substantial management time and expense. Based on our annual revenue for the 2023 fiscal year, and the market value of our non-affiliated common stock, we are an “accelerated filer” and a smaller reporting company as of December 31, 2024. As such, we are required to comply with Section 404(b) of the Sarbanes-Oxley Act for our annual report on Form 10-K for the period ended December 31, 2024.

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 have 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 has been 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 1C. Cybersecurity

Our board recognizes the critical importance of maintaining the trust and confidence of our patients, business partners and employees. Our board is actively involved in oversight of our risk management program, and cybersecurity represents an important component of our overall approach to enterprise risk management, or ERM. Through our ERM program, risks are identified, assessed and managed at the organization level, mission and business process level, and information system level. Our cybersecurity program, policies and procedures are fully integrated into our ERM program and are maintained in accordance with industry good standards. We also have an Information Security program that more specifically addresses cybersecurity risks and is focused on preserving the confidentiality, security and availability of the information that we collect and store by identifying, preventing and mitigating cybersecurity threats and effectively responding to cybersecurity incidents when they occur.

Risk Management and Strategy

As one of the critical elements of our overall ERM approach, our cybersecurity program is focused on the following key areas:

1. Governance: Our board's oversight of cybersecurity risk management is supported by our Audit Committee of our board (the "Audit Committee"), which regularly interacts with our executive leadership, including our Chief Executive Officer, Chief Financial Officer and our General Counsel and other key officers.

2. Collaborative Approach: We have implemented a comprehensive, cross-functional approach to identifying, preventing and mitigating cybersecurity threats and incidents, while also implementing controls and procedures that provide for the prompt escalation of certain cybersecurity incidents so that decisions regarding the public disclosure and reporting of such incidents can be made by management in a timely manner. We also engage security vendors with credentialed security professionals to bolster our cybersecurity risk management, security event monitoring and detection, and incident and crisis response capability.

3. Technical Safeguards: We deploy technical safeguards that are designed to protect our information systems from cybersecurity threats, including mail flow algorithms, firewalls, intrusion prevention and detection systems, malware and antivirus protection, network security protection, cloud console security and single sign-on multi-factor authentication. We also regularly conduct security and patch vulnerability scanning to help safeguard our security infrastructure.

4. Incident Response and Recovery Planning: We have established and maintain comprehensive incident response and recovery plans that fully address our response to a cybersecurity incident, and such plans are periodically evaluated. We utilize an established internal framework designed to assess promptly the severity and materiality of cybersecurity events and incidents based on various predefined quantitative and qualitative criteria, including the impact to potential personally identifiable information and/or patient health information, and to determine the appropriate level of response. Incidents are escalated based on their severity and materiality for prompt response and mitigation. This systematic approach involves preliminary investigations and detailed assessments to determine the severity and materiality of each incident, and there are established communication channels and engagement processes with those involved in this incident response process.

5. Third-Party Risk Management: We maintain a comprehensive, risk-based approach to identifying and overseeing cybersecurity risks presented by third parties, including vendors, service providers and other external users of our systems, as well as the systems of third parties that could adversely impact our business in the event of a cybersecurity incident affecting those third-party systems. We have

implemented communication channels with our key third-party vendors to communicate regarding potential cybersecurity risks and incidents, and generally seek to include appropriate security clauses in our contracts with our vendors, including notification requirements.

6. Education and Awareness: We provide regular, mandatory security awareness training for personnel regarding cybersecurity threats as a means to equip our personnel with effective tools to address cybersecurity threats, and to communicate our evolving information security policies, standards, processes and practices.

We engage in a periodic assessment of our policies, standards, processes and practices that are designed to address cybersecurity threats and incidents at least annually. We evaluate our cybersecurity program's capabilities and processes, and we aim to continuously enhance our program according to our internal and external risk assessments. These efforts include a wide range of activities, including audits, assessments, vulnerability testing and other exercises focused on evaluating the effectiveness of our cybersecurity measures and planning.

We have previously engaged, and may engage in the future, with third parties to perform assessments on our cybersecurity measures, including information security maturity assessments, vulnerability assessments, audits and independent reviews of our information security control environment and operating effectiveness. The results of such assessments, audits and reviews are reported to the Audit Committee and the board, and we adjust our cybersecurity policies, standards, processes and practices as necessary based on the information provided by these assessments, audits and reviews.

Although we are subject to ongoing and evolving cybersecurity threats, we are not aware of any cybersecurity threats that have materially affected or are likely to affect us, including our business strategy, results of operations or financial condition. If we were to experience a material cybersecurity incident in the future, such incident may have a material effect, including on our business strategy, operating results, or financial condition. For more information regarding cybersecurity risks that we face and potential impacts on our business related thereto, see the "Risk Factors" disclosures in Item 1A of this Annual Report on Form 10-K.

Governance

Our board, in coordination with the Audit Committee, oversees our ERM process, including the management of risks arising from cybersecurity threats. Our Audit Committee receives regular presentations and reports on cybersecurity risks, which address a wide range of topics including our information security strategy, ongoing cybersecurity preparedness projects and programs, recent cybersecurity-related developments, changing regulations, evolving standards, vulnerability assessments, third-party and independent reviews, the threat environment, technological trends and information security considerations arising with respect to our peers and third parties. Further, our Information Security Team, consisting of Company IT staff, meets biannually with our Information Security Governance Committee to review our policies, incidents, responses and preventative measures. In addition, our Information Security Team presents a summary of information security key performance indicators quarterly to our Audit Committee.

Our Chief Executive Officer, Chief Financial Officer, General Counsel and other key officers and our Information Security team work collaboratively across the Company to implement and monitor our Information Security Program, which is designed to protect our information systems from cybersecurity threats and to promptly respond to any cybersecurity incidents in accordance with our incident response and recovery plans. Our Information Security team is deployed to address cybersecurity threats and to respond to cybersecurity incidents, including those stemming from any violation of our cybersecurity policies. Further, our Information Security Team monitors the prevention, detection, mitigation and remediation of cybersecurity threats and incidents in real time and reports such threats and incidents to the Audit Committee when appropriate.

Our Information Security team collectively has a combined experience of over 70 years managing and supporting information technology in the biotech industry and oversees our cybersecurity program. They have experience developing and leading cybersecurity programs, including evaluating and implementing tools and technologies that enable defense and response capabilities, and developing critical cybersecurity procedures and training and awareness programs. Our cybersecurity consultant has served in various roles in information technology and information security for approximately 25 years. We also consult with two different service providers who specialize in corporate cybersecurity.

Item 2. *Properties*

Our principal executive office is located in South San Francisco, California, where we lease approximately 115,466 square feet for our corporate headquarters and to conduct, or expand, research and development 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. However, we are currently planning to wind down our manufacturing activities in our San Carlos facility no later than the end of 2025.

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 March 6, 2025, there were approximately 63 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 the 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.

Unregistered Sales of Equity Securities

None.

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 an oncology company developing site-specific and novel-format antibody drug conjugates, or ADCs, enabled by our proprietary integrated cell-free protein synthesis platform, XpressCF®, and our site-specific conjugation platform, XpressCF+®. We aim to design and develop therapeutics using the most relevant and potent modalities, including ADCs, bispecific ADCs, immunostimulatory ADCs, or iADCs, and dual conjugate ADCs, or ADC^{2}s. Our molecules are directed primarily against clinically validated targets where the current standard of care is suboptimal. We believe that our platform allows us to accelerate the discovery and development of potential first-in-class and/or 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 creating 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, or cGMP, compliant manufacturing facility or in the facility of one of our contract development and manufacturing organization, or CDMO, partners. We have the ability to manufacture our proprietary cell-free extract that supports our production of proteins on a large scale using a semi-continuous fermentation process.

Our highest priority wholly-owned preclinical product candidate is STRO-004. This product candidate is a single homogeneous ADC directed against tissue factor, or TF, which we intend to develop for the treatment of solid tumors. We anticipate filing an IND for STRO-004 in the second half of 2025.

We believe STRO-004 has the potential to be a best-in-class ADC targeting TF. Preclinical data suggest that STRO-004 has potent antitumor activity and the potential for a differentiated safety profile. Our other preclinical assets include an ADC targeting Integrinβ6 and ADC^{2}s, and iADCs. We plan to file three INDs over the next three years, including for STRO-004.

Enabled through our proprietary XpressCF® and XpressCF+® platforms, we have entered into multi-target, product-focused collaborations with leading pharmaceutical and biotechnology companies in the field of oncology, with our ongoing relationships that include licensing to Ipsen, on an exclusive basis, the right to research, develop, manufacture and commercialize STRO-003. STRO-003 is intended to be developed for the treatment of solid tumors and we anticipate filing of an IND in connection with this program in 2025. In addition, we have an ongoing iADC collaboration with Astellas.

Our XpressCF® and XpressCF+® platforms have also supported Vaxcyte, focused on discovery and development of vaccines for the treatment and prophylaxis of infectious disease. The lead programs for Vaxcyte are VAX-31 and VAX-24, its 31-valent and 24-valent, respectively, pneumococcal conjugate vaccine candidates. Vaxcyte is responsible for performing all research and development activities, and we provide technical support and supply XtractCF® and other materials to Vaxcyte. In June 2023, we entered into a purchase and sale agreement, or the Purchase Agreement with Blackstone, in which Blackstone acquired the right to receive our 4% royalty, or revenue interest, in the potential future net sales of Vaxcyte products, including Vaxcyte's pneumococcal conjugate vaccine, or PCV, products, such as VAX-24 and VAX-31. Following agreement with Vaxcyte on the Form Definitive Agreement and upon effectiveness of an amendment to the licensing agreement, the revenue interest in the 4% royalty on potential future sales of Vaxcyte products other than Vaxcyte's PCV products reverted to us. Thus, we retain the right to receive a 4% royalty on sales of Vaxcyte's products other than PCV products. In November 2023, Vaxcyte exercised its option to access expanded rights to develop and manufacture cell-free extract for use in development and manufacture of its vaccine products, among certain other rights.

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, Astellas, Vaxcyte, Ipsen, EMD Serono, BioNova, and Tasly, the issuance and sale of redeemable convertible preferred stock, our initial public offering, or IPO, follow-on public and other offerings of common stock, sales of our common stock through our At-the-Market Facility ("ATM Facility") pursuant to our Open Market Sales Agreement℠ dated April 2, 2021 (the "Sales Agreement") with Jefferies LLC ("Jefferies"), debt financing, sale of our holdings of Vaxcyte common stock, and the royalty monetization agreement with Blackstone.

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 $238.5 million and a net loss of $227.5 million for the year ended December 31, 2024, which net loss included the non-operating, realized gain of $32.1 million related to the sale of our holdings of Vaxcyte common stock. We had a loss from operations of $89.3 million and net loss of $106.8 million, which net loss included the non-operating, unrealized gain of $9.9 million related to our holdings of Vaxcyte common stock, for the year ended December 31, 2023. 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, 2024, we had an accumulated deficit of $786.9 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, access, marketing, manufacturing and distribution. We expect a short-term reduction in operating expenses as we strategically reprioritize our resources. However, over the long term, we anticipate an increase in our operating expenses as we advance our product candidates through clinical development, seek regulatory approvals for our product candidates, engage in other research and development activities, expand our pipeline of product candidates, 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. In light of our current resources and the cost of development, we are continuing our process of evaluating our programs and spending. 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.

A discussion and analysis of our financial condition, results of operations, and cash flows for the year ended December 31, 2022 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, 2023 filed with the SEC on March 25, 2024.

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, Astellas, Vaxcyte, Ipsen, EMD Serono, BioNova, and Tasly, and to a lesser extent, from manufacturing, supply and services and materials we provide to the above collaborators.

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 and IT-related costs. We expense both internal and external research and development costs as they are incurred. Nonrefundable 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.

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 indicated periods. 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,	
	2024	2023
	(in thousands)	
Internal costs:		
Research and drug discovery	$ 40,887	$ 34,822
Process and product development	24,440	20,810
Manufacturing	47,864	44,176
Clinical development	15,842	12,601
Total internal costs	129,033	112,409
External Program Costs:		
Research and drug discovery	3,879	3,955
Process and product development	1,936	3,052
Manufacturing	76,718	36,085
Clinical development	40,477	24,924
Total external program costs	123,010	68,016
Total research and development expenses	$ 252,043	$ 180,425

We expect a reduction in research and development expenses as we strategically reprioritize our resources. However, over the longer term, we anticipate such expenses would increase as we advance our product candidates through clinical development, and continue to develop our external manufacturing capabilities.

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 and IT-related costs. Personnel costs include salaries, employee benefits and stock-based compensation. We expect to incur 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 expect a reduction in general and administrative expenses as we strategically reprioritize our resources. However, over the longer term, we anticipate such expenses would increase as we advance our product candidates through clinical development and toward potential commercialization.

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.

Non-cash interest expense related to the sale of future royalties

Non-cash interest expense related to the sale of future Vaxcyte royalties represents the imputed interest expense on our deferred royalty obligation related to the sale of future Vaxcyte royalties pursuant to the Purchase Agreement, using the effective interest method. As further described in the financial statements in Note 9. Deferred Royalty Obligation related to the Sale of Future Royalties, in June 2023, we entered into the Purchase

Agreement with Blackstone, pursuant to which we sold to Blackstone our 4% royalty, or revenue interest, in the potential future net sales of Vaxcyte's PCV products, such as VAX-24 and VAX-31.

Non-cash interest expense will be recognized over the estimated life of the royalty term arrangement using the effective interest method based on the imputed interest rate derived from estimated amounts and timing of potential future royalty payments to be earned and received by Blackstone from Vaxcyte under the 2015 License Agreement.

Interest and Other Income (Expense), Net

Interest expense includes interest incurred on our debt and amortization of debt issuance costs, including accretion of the final payment. Additionally, we identified a financing component under the Astellas Agreement and recorded interest expense associated with the upfront payment. Other income (expense), net, also includes the realized gain on the sale of Vaxcyte common stock.

Income Taxes

We recorded an income tax charge of $2.4 million during the year ended December 31, 2024. The income tax charge was primarily due to prior period tax provision to return adjustment.

We recorded an income tax charge of $18.2 million during the year ended December 31, 2023. The income tax charge was primarily due to unfavorable book-tax differences related to capitalizing and amortizing research and development expenditures under Internal Revenue Code, or IRC, Section 174, the upfront payment from the sale of future royalties, deferred revenue, foreign income tax, and IRC Section 382 limitations imposed on the utilization of our historical tax attributes as a result of cumulative ownership changes that we experienced in prior years.

All other income tax charges and benefits for the years ended December 31, 2024 and 2023 have been immaterial, primarily due to the net loss in each year.

Our deferred assets continue to be subject to full valuation allowance for the tax years ended December 31, 2024 and 2023. A valuation allowance is recorded when it is more likely than not that all or some portion of the deferred income tax assets will not be realized. We regularly assess the need for a valuation allowance against our deferred income tax assets by considering both positive and negative evidence related to whether it is more likely than not that our deferred income tax assets will be realized. In evaluating our ability to recover our deferred income tax assets within the jurisdiction from which they arise, we consider all available positive and negative evidence, including scheduled reversals of deferred income tax liabilities, future tax rates, projected future taxable income, tax-planning strategies, and results of recent operations.

Comparison of the Years Ended December 31, 2024 and 2023

	Year ended December 31,		Change	
	2024	2023	$	%
	(in thousands)			
Revenue	$ 62,043	$ 153,731	$ (91,688)	(60)%
Operating expenses:				
Research and development	252,043	180,425	71,618	40%
General and administrative	48,453	62,584	(14,131)	(23)%
Total operating expenses	300,496	243,009	57,487	24%
Loss from operations	(238,453)	(89,278)	(149,175)	167%
Interest income	18,643	14,510	4,133	28%
Unrealized gain on equity securities	-	9,917	(9,917)	(100)%
Non-cash interest expense related to the sale of future royalties	(31,070)	(12,570)	(18,500)	147%
Interest and other income (expense), net	25,782	(11,180)	36,962	(331)%
Loss before provision for income taxes	(225,098)	(88,601)	(136,497)	154%
Provision for income taxes	2,363	18,192	(15,829)	(87)%
Net loss	$ (227,461)	$ (106,793)	$ (120,668)	113%

Revenue

We have recognized revenue as follows during the indicated periods:

	Year Ended December 31,		Change	
	2024	2023	$	%
	(in thousands)			
Astellas Pharma Inc. (“Astellas”)	$ 52,868	$ 33,992	$ 18,876	56%
Tasly Biopharmaceuticals Co., Ltd. (“Tasly”)	6,021	6,970	(949)	(14)%
Vaxcyte, Inc. ("Vaxcyte")	2,576	101,302	(98,726)	(97)%
Ipsen Pharma SAS (“Ipsen”)	559	-	559	*
Merck Sharp & Dohme Corporation (“Merck”)	19	5,869	(5,850)	(100)%
Bristol Myers Squibb Company (“BMS”)	-	5,590	(5,590)	(100)%
Merck KGaA, Darmstadt, Germany (operating in the United States and Canada under the name “EMD Serono”)	-	8	(8)	(100)%
Total revenue	$ 62,043	$ 153,731	$ (91,688)	(60)%

*Percentage not meaningful

Total revenue decreased by $91.7 million, or 60%, during the year ended December 31, 2024 as compared to the year ended December 31, 2023. This was primarily due to a $98.7 million decrease in Vaxcyte revenue, of which $97.5 million in upfront and option exercise revenue related to the option exercised by Vaxcyte was earned in 2023, and $1.2 million was from a decrease in research and development services and materials supply, a $5.6 million decrease in BMS revenue due to their decision to end clinical development of CC-99712 in 2023, a $5.8 million decrease in Merck revenue, primarily due to a $5.6 million decrease in manufacturing activities supporting clinical trial supply and a $0.2 million decrease in research and development services as a result of Merck's decision to end clinical development of MK-1484 during the third quarter of 2024. Lastly, Tasly revenue decreased by $0.9 million primarily due to a $5.0 million contingent payment earned in 2023 and a $0.9 million decrease in clinical product supply under the 2023 Tasly Supply Agreement, which were partially offset by a $5.0 million contingent payment earned in 2024. These decreases were partially offset by a $18.9 million increase from Astellas, of which $22.9 million was from the ongoing performance related to partially unsatisfied performance obligations, and included a cumulative catch-up adjustment of $17.8 million on the contract modification date from Astellas' decision not to nominate a third target program under the Astellas Agreement and $0.9 million from materials supply, which were partially offset by decreases of $3.5 million from the financing component related to the Astellas Agreement and $1.4 million from research and development services. Additionally, there was a $0.6 million increase in Ipsen revenue from research and development services and materials supply, which commenced in the second quarter of 2024.

Research and Development Expense

Research and development expense increased by $71.6 million, or 40%, during the year ended December 31, 2024 as compared to the year ended December 31, 2023. The overall increase was due primarily to increases of $43.0 million in outside services mainly due to increased CMO-related activities, $12.1 million in preclinical research and clinical development expenses, $11.3 million in facilities expenses and IT-related expenses, $4.3 million in personnel-related expenses due to higher headcount, $2.5 million in equipment and office-related expenses, and $0.2 million in travel-related expenses, partially offset by a decrease of $1.7 million in laboratory supplies.

General and Administrative Expense

General and administrative expense decreased by $14.1 million, or 23%, during the year ended December 31, 2024 as compared to the year ended December 31, 2023. The overall decrease was due primarily to decreases of $10.5 million in IT-related expenses and $5.7 million in personnel-related expenses, partially offset by increases of $0.8 million in outside services, $0.6 million in equipment and office-related expenses, and $0.6 million in allocated facilities-related expenses.

Interest Income

Interest income increased by $4.1 million during the year ended December 31, 2024 as compared to the year ended December 31, 2023, due primarily to higher average investment balances in 2024.

Unrealized Gain on Equity Securities

We sold the remaining shares of Vaxcyte common stock, resulting in no unrealized gain on equity securities during the year ended December 31, 2024, as compared to an unrealized gain of $9.9 million for the year ended December 31, 2023. As of December 31, 2024, we do not hold any shares of Vaxcyte common stock.

Non-cash Interest Expense related to the Sale of Future Royalties

Non-cash interest expense increased by $18.5 million during the year ended December 31, 2024, as compared to the year ended December 31, 2023. Non-cash interest expense was recognized on our deferred royalty obligation related to the June 2023 sale of future Vaxcyte royalties pursuant to the Purchase Agreement, using the effective interest method based on the imputed interest rate derived from estimated amounts and timing of potential future royalty payments to be earned and received by Blackstone from Vaxcyte under the 2015 License Agreement.

Interest and Other Income (Expense), Net

Interest and other income (expense), net, decreased by $37.0 million during the year ended December 31, 2024, as compared to the year ended December 31, 2023, due primarily to a recognized gain of $32.1 million on the sale of Vaxcyte common stock and decreases of $3.6 million from the financing component related to the Astellas Agreement and $1.3 million in interest incurred on our loan which was fully paid in March 2024.

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, debt, sale of shares of Vaxcyte common stock, and a royalty monetization. As of December 31, 2024, we had cash, cash equivalents and marketable securities of $316.9 million, and an accumulated deficit of $786.9 million.

Vaxcyte Equity Ownership

During the year ended December 31, 2024, we sold the remaining 667,780 shares of Vaxcyte common stock for net proceeds of $74.0 million. As of December 31, 2024, we do not hold any shares of Vaxcyte common stock.

Vaxcyte Agreement

In May 2024, Vaxcyte paid us $25.0 million as the second of two installment payments for the Option exercise price under the Vaxcyte Agreement.

Underwritten Offering

In April 2024, we closed an underwritten offering with BofA Securities, Inc., pursuant to which we issued and sold 14,478,764 shares of our common stock at an offering price of $5.18 per share. The gross proceeds from these sales were approximately $75.0 million, before deducting fees and offering expenses.

Ipsen Agreements

In March 2024, we and Ipsen Pharma SAS (“Ipsen”) entered into an Exclusive License Agreement (the “Ipsen License Agreement”) pursuant to which we licensed to Ipsen, on an exclusive basis, the right to research, develop, manufacture and commercialize STRO-003.

In consideration for the rights and licenses granted by us to Ipsen in the Ipsen License Agreement, Ipsen (i) paid us an upfront license fee in the amount of $50.0 million in April 2024 and (ii) Ipsen Biopharmaceuticals, Inc. (USA) (“Ipsen USA”) purchased 4,827,373 shares of our common stock for $25.0 million, at a price of approximately $5.18 per share, in accordance with the terms set forth in a certain investment agreement by and between us and the Ipsen USA dated March 29, 2024 (the “Ipsen Investment Agreement”, and, together with the Ipsen License Agreement, the “Ipsen Agreements”).

We are eligible to receive up to an additional $447.0 million in developmental and regulatory milestones, assuming multiple indications, and up to $360.0 million in sales milestones, as well as tiered royalty payments ranging from low double-digit to mid-teen digit percentages of annual net sales of STRO-003, subject to certain adjustments specified in the Ipsen License Agreement.

The royalty payment obligations under the Ipsen License Agreement expire on a country-by-country basis no earlier than ten years following the first commercial sale of STRO-003 in the applicable country. Ipsen may terminate the Ipsen License Agreement for convenience with sixty calendar days prior written notice or for certain other specified reasons. We may terminate the Ipsen License Agreement if Ipsen or any of its Affiliates challenge the validity of any patents controlled by us that are licensed under the agreement. Both Ipsen and we may terminate the Ipsen License Agreement (i) for material breach by the other party and a failure to cure such breach within the time period specified in the Ipsen License Agreement or (ii) the other party’s bankruptcy event.

Leases

In June 2021, we entered into a third amendment, (the "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, (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 First Amendment, to our manufacturing facility lease, dated March 4, 2015, as amended, by and between 870 Industrial Road LLC, located at 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, we entered into a sublease agreement, (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"). We use the Premises as our corporate headquarters and to conduct (or expand) research and development activities. We 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. We were 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 (the "Landlord"). We commenced using the remaining 29,711 square feet of the Premises, (the "Expansion Premises"), on July 1, 2023 under the sublease agreement. 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, and Expansion Premises of July 1, 2023, 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 us of base rent abatement to be provided by the Sublessor, subject to certain terms contained in the Sublease. The Sublease contains customary provisions requiring us to pay our 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 we fail to remedy a breach of certain of our obligations within specified time periods. Additionally, we posted a security deposit of $0.9 million, which is reflected as restricted cash in non-current assets on our Balance Sheets as of December 31, 2024 and 2023.

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, royalty monetizations, 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 preclinical 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.

In March 2025, we approved a restructuring plan with an associated reduction in workforce as a result of a review of current strategic priorities, resource allocation, and cost reduction intended to reduce operating costs, streamline operations and extend our cash runway. We intend to decommission or otherwise exit our manufacturing facility in San Carlos by the end of 2025 and rely on an external manufacturing strategy where all elements of our product candidates and platform reagents are manufactured by qualified third-party CMOs.

Cash Flows

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

	Year Ended December 31,	
	2024	2023
	(in thousands)	
Cash used in operating activities	$ (191,540)	$ (111,616)
Cash provided by (used in) investing activities	218,508	(3,924)
Cash provided by financing activities	94,054	137,554
Net increase in cash, cash equivalents and restricted cash	$ 121,022	$ 22,014

Cash Flows from Operating Activities

Cash used in operating activities for the year ended December 31, 2024 was $191.5 million. Our net loss of $227.5 million included non-cash amounts of $32.1 million for the realized gain on the sale of Vaxcyte common stock, $31.1 million for non-cash interest expense on our deferred royalty obligation, $24.7 million for stock-based compensation, $9.7 million for the accretion of discount on marketable securities, $7.2 million for depreciation and amortization, and $5.1 million for non-cash lease expense. Cash used in operating activities also reflected a net change in operating assets and liabilities of $8.9 million, due to a decrease of $27.5 million in accounts receivable primarily from receiving $25.0 million from Vaxcyte as the second of two installment payments for the option exercise price under the Vaxcyte Agreement, and an increase of $7.8 million in deferred revenue primarily due to the upfront payment from Ipsen, partially offset by revenue recognized under the Astellas and Tasly Agreements, which were partially offset by an increase of $11.6 million in prepaid expenses and other assets primarily due to increase in CMO-related activities, a decrease of $6.6 million in accounts payable, accrued expenses and other liabilities due to timing of payments, a decrease of $6.4 million in our operating lease liability, and a decrease of $1.8 million in accrued compensation expense.

Cash used in operating activities for the year ended December 31, 2023 was $111.6 million. Our net loss of $106.8 million included non-cash charges of $24.9 million for stock-based compensation, $12.6 million for non-cash interest expense on our deferred royalty obligation, $9.9 million for the unrealized gain on equity securities as a result of the remeasurement of the estimated fair value of our investment in Vaxcyte common stock, $9.1 million for the accretion of discount on our marketable securities, $6.8 million for depreciation and amortization, $3.6 million for noncash lease expenses and $0.6 million in other non-cash charges. Cash used in operating activities also reflected a net change in operating assets and liabilities of $34.4 million, due to a decrease of $32.6 million in our deferred revenue from revenue recognized under our collaboration agreements, an increase of $28.9 million in accounts receivable primarily due to a receivable from Vaxcyte under the Vaxcyte Agreement, and a decrease of $4.6 million in our operating lease liability, which were partially offset by an increase of $30.1 million in accounts payable, accrued expenses and other liabilities mainly due to the tax liability and timing of payments, an increase of $1.5 million in accrued compensation due to increased headcount, and a decrease of $0.1 million in prepaid expenses and other assets.

Cash Flows from Investing Activities

Cash provided by investing activities of $218.5 million for the year ended December 31, 2024 was primarily related to maturities and sales of marketable securities of $609.1 million, and net proceeds from the sale of Vaxcyte common stock of $74.0 million, partially offset by purchases of marketable securities of $461.5 million, and purchases of property and equipment of $3.1 million, principally for laboratory equipment.

Cash used in investing activities of $3.9 million for the year ended December 31, 2023 was primarily related to purchases of marketable securities of $460.3 million and purchases of property and equipment of $4.3 million, principally for laboratory equipment, partially offset by maturities and sales of marketable securities of $460.7 million.

Cash Flows from Financing Activities

Cash provided by financing activities of $94.1 million for the year ended December 31, 2024 was primarily related to $71.5 million of net proceeds from the underwritten common stock offering, $25.0 million of proceeds from Ipsen USA upon the purchase of our common stock under the Ipsen Investment Agreement, $1.8 million of net proceeds received from participants in our employee equity plans, and $0.3 million of proceeds received from the exercise of common stock options, partially offset by debt repayment of $4.1 million and a $0.5 million tax payment related to the net shares settlement of vested restricted stock units.

Cash provided by financing activities of $137.5 million for the year ended December 31, 2023 was primarily related to $136.2 million of net proceeds from the sale of future royalties, $12.0 million of net proceeds from our ATM Facility sales of common stock, $2.0 million of net proceeds received from participants in our employee equity plans and $0.3 million of proceeds received from the exercise of common stock options, partially offset by debt repayment of $12.5 million and a $0.5 million tax payment related to the net share settlement of certain vested restricted stock units.

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, 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 BMS, Merck, Astellas, Vaxcyte, Ipsen, EMD Serono, BioNova, and Tasly, and to a lesser extent, from manufacturing, supply and services and materials we provide to our collaborators.

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.

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. 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. We recognize revenue over time by measuring the 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.

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.

Revenue subject to governmental withholding taxes is recognized on a gross basis with the withholding taxes recorded as a component of income tax expense.

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 measure and recognize compensation expense for all stock-based awards, including restricted stock units, stock options, and the ESPP, to employees, consultants and nonemployee directors based on the estimated fair value of the awards on the grant date. The fair value of stock options and purchase rights under the ESPP are estimated using the Black-Scholes option-pricing model. The Black-Scholes model requires use of assumptions and judgments about the variables used in the calculations, including the expected term, the expected volatility of the underlying stock, the related risk-free interest rate for the expected term of the award and the expected dividends.

Stock-based compensation expense for restricted stock units and stock options is generally recognized on a straight line basis over the requisite service period. Stock-based compensation expense for the ESPP is recognized on a straight-line basis over the offering period. We account for forfeitures of stock-based awards as they occur.

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.

Deferred Royalty Obligation related to the Sale of Future Royalties and Non-cash Interest Expense

We treated the sale of Vaxcyte future royalties to Blackstone as a deferred royalty obligation, as we had ongoing manufacturing obligations under the 2015 License Agreement in the generation of the cash flows. Due to our then ongoing manufacturing obligations, we will account for any royalties earned as non-cash revenue. As royalties are remitted to Blackstone from Vaxcyte, the balance of the deferred royalty obligation will be effectively amortized over the estimated life of the royalty term arrangement. We recorded the proceeds from this transaction as a liability on our Balance Sheets related to the sale of future royalties to be amortized to interest expense using the effective interest rate method over the estimated life of the royalty term arrangement. The liability related to the sale of future royalties and the related interest expense are based on our current estimates of future royalties expected to be earned by Blackstone from Vaxcyte over the estimated life of the royalty term arrangement. We periodically assess the estimated royalties to be earned using forecasts from external sources. To the extent our future estimates of earned royalties are greater or less than previous estimates or the estimated timing of such payments is materially different than our previous estimates, we will prospectively recognize related non-cash interest expense.

Income Taxes

As of December 31, 2024, we had federal net operating loss, or NOL, carryforwards of $149.8 million and federal general business credits from research and development expenses totaling $30.5 million, as well as state NOL carryforwards of $108.0 million and state research and development credits of $32.1 million.If not utilized, the federal NOL carryforwards will expire at various dates beginning in 2027, and the federal credits will expire at various dates beginning in 2032. 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 Section 382 study through December 31, 2022, and concluded that we experienced an ownership change on November 20, 2019, and December 31, 2022. 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 $316.9 million and $333.7 million as of December 31, 2024 and 2023, respectively, which consisted of money market funds, commercial paper, corporate debt securities, asset-backed securities, U.S. government securities, and U.S. agency securities. Such interest earning instruments carry a degree of interest rate risk; however, historical fluctuations in interest income have not been significant.

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.

Item 8. ***Financial Statements and Supplementary Data***

SUTRO BIOPHARMA, INC.

ANNUAL REPORT ON FORM 10-K

INDEX TO AUDITED FINANCIAL STATEMENTS

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, 2024 and 2023, the related statements of operations, comprehensive loss, stockholders' equity and cash flows for each of the three years in the period ended December 31, 2024, 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, 2024 and 2023, and the results of its operations and its cash flows for each of the three years in the period ended December 31, 2024, 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, 2024, 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 March 13, 2025 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 a 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.

	Royalty agreement with Blackstone Life Sciences
Description of the Matter	As discussed in Note 9 to the financial statements, on June 21, 2023, the Company closed a purchase and sale agreement (the "Agreement") with Blackstone Life Sciences ("Blackstone"), pursuant to which the Company sold to Blackstone its 4% royalty in potential net sales of Vaxcyte Inc.'s products and received an upfront payment of $140 million. The Company concluded the Agreement represented a sale of future royalties and accounted for the transaction under Accounting Standards Codification (ASC) 470 as debt. The Company estimated the amount of future royalty payments and expected interest expense using the effective interest rate method

over the life of the agreement. The carrying value of the liability related to the sale of future royalties at December 31, 2024 was $180.8 million and the interest expense for the year ended December 31, 2024 was $31.1 million.

The auditing of the Agreement was complex due to the significant judgment and estimation used by management related to the sale of future royalties and due to the nature and extent of audit effort required to address these matters. The accounting involves significant judgment and inherent uncertainties as it relates to the Company's estimate of future sales for which royalties will be paid, which in turn significantly impacts the calculation of interest expense recognized.

How We Addressed the Matter in Our Audit

We obtained an understanding, evaluated the design and tested the operating effectiveness of the controls over the review of estimation used related to the sale of future royalties and its calculation.

To test the carrying value of the liability related to the sale of future royalties and the amount of interest expense recognized, our audit procedures included, among others, assessing the methodology used, evaluating the reasonableness of the significant estimates discussed above, and testing the completeness and accuracy of the underlying data used by the Company. Specifically, we tested the calculation of the liability balance including the classification of the balance as non-current. In addition, we evaluated the Company’s estimate of future sales, by comparing the estimates to available peer data and market research. We also recalculated the current year interest expense using the effective interest method based on the Company’s estimate of future royalties to be paid.

/s/ Ernst & Young LLP

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

San Mateo, California
March 13, 2025

SUTRO BIOPHARMA, INC.

BALANCE SHEETS

(in thousands, except share and per share data)

	December 31,	
	2024	**2023**
Assets		
Current assets:		
Cash and cash equivalents	$ 190,304	$ 69,268
Marketable securities	126,591	264,413
Investment in equity securities	-	41,937
Accounts receivable	8,616	36,078
Prepaid expenses and other current assets	17,799	9,846
Total current assets	343,310	421,542
Property and equipment, net	18,190	21,940
Operating lease right-of-use assets	17,677	22,815
Other non-current assets	7,172	3,567
Restricted cash	858	872
Total assets	$ 387,207	$ 470,736
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable	$ 10,475	$ 9,440
Accrued compensation	12,905	14,686
Deferred revenue-current	69,783	20,666
Operating lease liability-current	7,480	6,420
Debt-current	-	4,061
Accrued expenses and other current liabilities	31,250	38,473
Total current liabilities	131,893	93,746
Deferred revenue, non-current	12,536	53,379
Operating lease liability-non-current	15,674	23,154
Deferred royalty obligation related to the sale of future royalties	180,809	149,114
Other non-current liabilities	1,694	1,694
Total liabilities	342,606	321,087
Commitments and contingencies (Note 7)		
Stockholders' equity:		
Preferred stock, $0.001 par value — 10,000,000 shares authorized as of December 31, 2024 and 2023; no shares issued and outstanding as of December 31, 2024 and 2023	-	-
Common stock, $0.001 par value — 300,000,000 shares authorized as of December 31, 2024 and 2023; 82,526,430 and 61,009,829 shares issued and outstanding as of December 31, 2024 and 2023, respectively	83	61
Additional paid-in-capital	831,348	708,975
Accumulated other comprehensive income	39	21
Accumulated deficit	(786,869)	(559,408)
Total stockholders' equity	44,601	149,649
Total Liabilities and Stockholders' Equity	$ 387,207	$ 470,736

See accompanying notes to financial statements.

SUTRO BIOPHARMA, INC.

STATEMENTS OF OPERATIONS

(in thousands, except share and per share data)

	Year Ended December 31,		
	2024	2023	2022
Revenue	$ 62,043	$ 153,731	$ 67,772
Operating expenses			
Research and development	252,043	180,425	137,171
General and administrative	48,453	62,584	59,544
Total operating expenses	300,496	243,009	196,715
Loss from operations	(238,453)	(89,278)	(128,943)
Interest income	18,643	14,510	3,455
Unrealized gain on equity securities	-	9,917	12,130
Non-cash interest expense related to the sale of future royalties	(31,070)	(12,570)	-
Interest and other income (expense), net	25,782	(11,180)	(3,346)
Loss before provision for income taxes	(225,098)	(88,601)	(116,704)
Provision for income taxes	2,363	18,192	2,500
Net loss	$ (227,461)	$ (106,793)	$ (119,204)
Net loss per share, basic and diluted	$ (2.96)	$ (1.78)	$ (2.35)
Weighted-average shares used in computing basic and diluted net loss per share	76,829,198	60,163,542	50,739,185

See accompanying notes to financial statements.

SUTRO BIOPHARMA, INC.

STATEMENTS OF COMPREHENSIVE LOSS

(in thousands)

	Year Ended December 31,		
	2024	**2023**	**2022**
Net loss	$ (227,461)	$ (106,793)	$ (119,204)
Other comprehensive income (loss):			
Net unrealized income (loss) on available-for-sale securities	18	639	(304)
Comprehensive loss	$ (227,443)	$ (106,154)	$ (119,508)

See accompanying notes to financial statements.

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

	Common Stock		Additional Paid-In-Capital	Accumulated Other Comprehensive Income (Loss)	Accumulated Deficit	Total Stockholders' Equity
	Shares	Amount				
Balances at December 31, 2021	46,327,131	$ 46	$ 586,243	$ (314)	$ (333,411)	$ 252,564
Exercise of common stock options	49,654	-	268	-	-	268
Issuance of common stock under Employee Stock Purchase Plan	270,516	-	1,613	-	-	1,613
Vesting of restricted stock units	620,647	1	(1)	-	-	-
Stock transaction associated with taxes withheld on restricted stock units	(53,567)	-	(463)	-	-	(463)
Stock-based compensation expense	-	-	26,304	-	-	26,304
Issuance of common stock in connection with At-The-Market sale, net of issuance costs of $2,026	10,285,160	11	56,259	-	-	56,270
Net unrealized loss on available-for-sale securities	-	-	-	(304)	-	(304)
Net Loss	-	-	-	-	(119,204)	(119,204)
Balances at December 31, 2022	57,499,541	$ 58	$ 670,223	$ (618)	$ (452,615)	$ 217,048
Exercise of common stock options	53,060	-	314	-	-	314
Issuance of common stock under Employee Stock Purchase Plan	526,079	-	2,051	-	-	2,051
Vesting of restricted stock units	1,155,644	1	-	-	-	1
Stock transaction associated with taxes withheld on restricted stock units	(81,905)	-	(490)	-	-	(490)
Stock-based compensation expense	-	-	24,908	-	-	24,908
Issuance of common stock in connection with At-The-Market sale, net of issuance costs of $459	1,857,410	2	11,969	-	-	11,971
Net unrealized income on available-for-sale securities	-	-	-	639	-	639
Net Loss	-	-	-	-	(106,793)	(106,793)
Balances at December 31, 2023	61,009,829	$ 61	$ 708,975	$ 21	$ (559,408)	$ 149,649
Exercise of common stock options	63,748	-	271	-	-	271
Issuance of common stock under Employee Stock Purchase Plan	566,247	-	1,848	-	-	1,848
Vesting of restricted stock units	1,695,054	2	(2)	-	-	-
Stock transaction associated with taxes withheld on restricted stock units	(114,585)	-	(509)	-	-	(509)
Stock-based compensation expense	-	-	24,687	-	-	24,687
Issuance of common stock in connection with the underwritten offering, net of issuance costs of $3,474	14,478,764	15	71,512	-	-	71,527
Issuance of common stock to Ipsen Biopharmaceuticals, Inc. (USA) under the Ipsen Investment Agreement	4,827,373	5	24,566	-	-	24,571
Net unrealized income on available-for-sale securities	-	-	-	18	-	18
Net Loss	-	-	-	-	(227,461)	(227,461)
Balances at December 31, 2024	82,526,430	$ 83	$ 831,348	$ 39	$ (786,869)	$ 44,601

See accompanying notes to financial statements.

SUTRO BIOPHARMA, INC.

STATEMENTS OF CASH FLOWS

(in thousands)

	Year Ended December 31,		
	2024	2023	2022
Operating activities			
Net loss	$ (227,461)	$ (106,793)	$ (119,204)
Adjustments to reconcile net loss to net cash (used in) provided by operating activities:			
Depreciation and amortization	7,218	6,816	5,690
Accretion of discount on marketable securities	(9,719)	(9,075)	(364)
Stock-based compensation	24,687	24,908	26,304
Non-cash lease expenses	5,138	3,628	2,598
Realized gain on sale of equity securities	(32,139)	-	(4,074)
Unrealized gain on equity securities	-	(9,917)	(12,130)
Non-cash interest expense on deferred royalty obligation	31,070	12,570	-
Other	766	622	324
Changes in operating assets and liabilities:			
Accounts receivable	27,462	(28,956)	5,341
Prepaid expenses and other assets	(11,558)	109	(3,544)
Accounts payable	706	4,812	(1,225)
Accrued compensation	(1,781)	1,544	1,725
Accrued expenses and other liabilities	(7,354)	25,300	6,562
Deferred revenue	7,845	(32,599)	93,648
Change in operating lease liability	(6,420)	(4,585)	1,898
Net cash (used in) provided by operating activities	(191,540)	(111,616)	3,549
Investing activities			
Purchases of marketable securities	(461,521)	(460,301)	(216,671)
Maturities of marketable securities	538,925	434,966	127,960
Sales of marketable securities	70,155	25,726	32,799
Proceeds from sale of equity securities, net	74,047	-	28,739
Purchases of equipment and leasehold improvements	(3,098)	(4,315)	(7,858)
Proceeds from exercise of options for Vaxcyte shares	-	-	9
Net cash provided by (used in) investing activities	218,508	(3,924)	(35,022)
Financing activities			
Proceeds from sales of common stock, net of issuance costs	71,527	11,971	56,270
Proceeds from sales of common stock to Ipsen Biopharmaceuticals, Inc. (USA)	25,000	-	-
Payments of debt	(4,083)	(12,500)	(9,375)
Proceeds from the sale of future royalties, net of issuance costs	-	136,208	-
Proceeds from exercise of common stock options	271	314	268
Taxes paid related to net share settlement of restricted stock units	(509)	(490)	(463)
Proceeds from employee stock purchase plan	1,848	2,051	1,613
Net cash provided by financing activities	94,054	137,554	48,313
Net increase in cash, cash equivalents and restricted cash	121,022	22,014	16,840
Cash, cash equivalents and restricted cash at beginning of year	70,140	48,126	31,286
Cash, cash equivalents and restricted cash at end of year	$ 191,162	$ 70,140	$ 48,126
Supplemental disclosure of cash flow information			
Cash paid for interest	$ 310	$ 1,126	$ 1,869
Income tax paid	$ 17,520	$ 379	$ -
Supplemental Disclosures of Non-cash Investing and Financing Information			
Purchase of property and equipment included in accounts payable	$ 673	$ 214	$ 280
Value of 167,780 shares of Vaxcyte common stock received under the Vaxcyte Agreement	$ -	$ -	$ 7,500
Financing component associated with program fees	$ 6,289	$ 9,836	$ 5,079
Premium on common stock issued to Ipsen Biopharma, Inc. (USA)	$ 429	$ -	$ -

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 an oncology company developing site-specific and novel-format antibody drug conjugates, or ADCs. The Company was incorporated on April 21, 2003 and is headquartered in South San Francisco, California.

Underwritten Offering

In April 2024, the Company closed an underwritten offering with BofA Securities, Inc., pursuant to which the Company issued and sold 14,478,764 shares of its common stock at an offering price of $5.18 per share. The gross proceeds from these sales were approximately $75.0 million, before deducting fees and offering expenses.

Liquidity

The Company has incurred significant losses and has negative cash flows from operations. As of December 31, 2024, there was an accumulated deficit of $786.9 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, 2024, the Company had unrestricted cash, cash equivalents and marketable securities of $316.9 million which are 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, 2024 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, deferred royalty obligation related to the sale of future royalties and related non-cash interest expense, and certain accrued liabilities. Actual results could differ from such estimates or assumptions.

Recently Adopted Accounting Pronouncements

In November 2023, the Financial Accounting Standards Board (FASB) issued ASU 2023-07, Segment Reporting (Topic 280): Improvements to Reportable Segment Disclosures, which enhances the disclosures required for operating segments in the Company's annual and interim financial statements. ASU 2023-07 is effective for the Company in the Company's annual reporting for fiscal 2024 and for interim period reporting beginning in fiscal 2025 on a retrospective basis. The Company adopted the new standard effective beginning fiscal year 2024. The Company presented the effects of the adoption of ASU 2023-07 in Note 10. Segment Reporting.

Recent Accounting Pronouncements Not Yet Adopted

In December 2023, the FASB issued ASU No. 2023-09, Income Taxes (Topic 740): Improvements to Income Tax Disclosures (“ASU 2023-09”). This new guidance is designed to enhance the transparency and decision usefulness of income tax disclosures. The amendments of this update are related to the rate reconciliation and income taxes paid. ASU 2023-09 is effective for fiscal years beginning after December 15, 2024. Early adoption is permitted. The Company is currently assessing the impact that adopting this new accounting standard will have on its financial statements.

In November 2024, the FASB issued ASU 2024-03, Income Statement - Reporting Comprehensive Income - Expense Disaggregation Disclosures (Subtopic 220-40): Disaggregation of Income Statement Expenses, which is intended to enhance transparency into the nature and function of expenses, primarily through additional disclosures on certain cost and expenses. ASU 2024-03 should be applied on a prospective basis, and retrospective application is permitted. ASU 2024-03 is effective for annual periods beginning after December 15, 2026, and interim reporting periods beginning after December 15, 2027. Early adoption is permitted. The Company is in the process of evaluating the impact of this new guidance on its disclosures.

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 income (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 income (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, U.S. government securities, U.S. agency securities and supranational debt 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. As of both December 31, 2024 and 2023, restricted cash related to such agreements was $0.9 million.

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:

	December 31,		
	2024	2023	2022
	(in thousands)		
Cash and cash equivalents	$ 190,304	$ 69,268	$ 47,254
Restricted cash	858	872	872
Total cash, cash equivalents and restricted cash shown in the Statements of Cash Flows	$ 191,162	$ 70,140	$ 48,126

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.

Investment in Equity Securities

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 realized or 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 at 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, 2024, 2023 and 2022. As of December 31, 2024 and 2023, 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 Right-of-Use (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.

Deferred Royalty Obligation related to the Sale of Future Royalties and Non-cash Interest Expense

In June 2023, the Company entered into a purchase and sale agreement (the “Purchase Agreement”) with Blackstone, pursuant to which the Company sold to Blackstone its 4% royalty, or revenue interest, in the potential future net sales of Vaxcyte products, including Vaxcyte’s pneumococcal conjugate vaccine, or PCV, products such as VAX-24 and its second-generation PCV product, VAX-31, (the “Purchased Interest”) under that certain Amended and Restated SutroVax Agreement, dated October 12, 2015, by and between the Company and Vaxcyte, as amended (the “2015 License Agreement”). In June 2023, Blackstone made an upfront payment of $140.0 million to the Company and will also pay up to an additional $250.0 million upon the achievement of various return thresholds as set forth in the Purchase Agreement. The net proceeds from the upfront payment received by the Company from the sale of future royalties from Vaxcyte are recorded as deferred royalty obligation related to the sale of future royalties on the Company's Balance Sheets. As royalties are earned and remitted pursuant to the 2015 License Agreement, the balance of the deferred royalty obligation will be amortized over the estimated life of the royalty term arrangement, and non-cash interest expense related to the sale of future royalties is recorded using the effective interest method. To determine the amortization of the deferred royalty obligation, the Company is required to estimate the total amount of future royalties to be earned under the 2015 License Agreement. There are a number of factors that could materially affect the amount and timing of royalty payments earned, most of which are not within the Company's control. The Company periodically assesses the amount of royalty payments expected to be earned which are subject to the Purchase Agreement and, to the extent that the amount or timing of such earned royalties is materially different than the Company's original estimates, the Company will prospectively adjust the imputed interest rate and the related amortization of the deferred royalty obligation. As described in Note 5. Collaboration and License Agreements and Supply Agreements, Vaxcyte Agreement, following agreement with Vaxcyte on the Form Definitive Agreement and upon effectiveness of the amendment No. 3 to the 2015 License Agreement, the revenue interest in the 4% royalty on potential future net sales of Vaxcyte products other than Vaxcyte's PCV products reverted to the Company.

Issuance fees and costs directly related to the Purchase Agreement were offset against the initial carrying value of the deferred royalty obligation and are being amortized using the effective interest method over the estimated life of the royalty term arrangement.

Revenue Recognition

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 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 Company satisfies a performance obligation. 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 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. 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 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.

Revenue subject to governmental withholding taxes is recognized on a gross basis with the withholding taxes recorded as a component of income tax expense.

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.

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 to nonemployees. The Company also maintains an employee stock purchase plan.

The Company measures and recognizes compensation expense for all stock-based awards, including restricted stock units, stock options, and the ESPP, to employees, consultants and nonemployee directors based on the estimated fair value of the awards on the grant date. The fair value of stock options and purchase rights under the ESPP are estimated using 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, the expected volatility of the underlying stock over the expected term of the award, the related risk-free interest rate for the expected term of the award and the expected dividends.

Stock-based compensation expense for restricted stock units and stock options is generally recognized on a straight line basis over the requisite service period. Stock-based compensation expense for the ESPP is recognized on a straight-line basis over the offering period. The Company accounts for forfeitures of stock-based awards as they occur.

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

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 carrying value of the deferred royalty obligation related to the sale of future royalties under the 2015 License Agreement with Vaxcyte approximates its fair value as of December 31, 2024, and is based on the Company's current estimates of future royalties expected to be earned over the estimated life of the royalty term arrangement. See Note 9. Deferred Royalty Obligation Related to the Sale of Future Royalties for a description of the Level 3 inputs used to estimate the fair value of the liability.

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:

	December 31, 2024			
	Total	Level 1	Level 2	Level 3
	(in thousands)			
Assets:				
Money market funds	$ 68,474	$ 68,474	$ -	$ -
Commercial paper	50,932	-	50,932	-
Corporate debt securities	94,257	-	94,257	-
Asset-backed securities	40,522	-	40,522	-
U.S. government securities	49,644	49,644	-	-
U.S. agency securities	9,582	-	9,582	-
Total	$ 313,411	$ 118,118	$ 195,293	$ -

	December 31, 2023			
	Total	Level 1	Level 2	Level 3
	(in thousands)			
Assets:				
Money market funds	$ 56,397	$ 56,397	$ -	$ -
Commercial paper	82,152	-	82,152	-
Corporate debt securities	61,894	-	61,894	-
Equity securities	41,937	41,937	-	-
Asset-backed securities	10,505	-	10,505	-
U.S. government securities	113,652	113,652	-	-
U.S. agency securities	4,961	-	4,961	-
Total	$ 371,498	$ 211,986	$ 159,512	$ -

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, and 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 U.S. agency 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, 2024 and 2023, the deferred royalty obligation related to the sale of future Vaxcyte royalties was classified as Level 3 within the valuation hierarchy. Refer to Note 9 below for information relating to the Purchase Agreement between the Company and Blackstone, pursuant to which the Company sold to Blackstone its 4% royalty, or revenue interest, in potential future net sales of Vaxcyte's pneumococcal conjugate vaccine, or PCV, products, including VAX-24 and VAX-31.

Investments in Equity Securities

During the year ended December 31, 2024, the Company sold 667,780 shares of Vaxcyte common stock it held at their fair market value of approximately $74.0 million, net of transaction cost and recognized a gain of $32.1 million which is recorded under interest and other income (expense), net, in the Statements of Operations. No shares of Vaxcyte common stock were sold during the year ended December 31, 2023.

The Company recognized an unrealized gain of $9.9 million and $12.1 million on equity securities during the years ended December 31, 2023, and 2022, respectively.

As of December 31, 2024, the Company did not hold any shares of Vaxcyte common stock. As of December 31, 2023, the Company held 667,780 shares of Vaxcyte common stock with an estimated fair value of $41.9 million.

4. Cash Equivalents and Marketable Securities

Cash equivalents and marketable securities consisted of the following:

	December 31, 2024			
	Amortized Cost Basis	Unrealized Gains	Unrealized Losses	Fair Value
	(in thousands)			
Money market funds	$ 68,474	$ -	$ -	$ 68,474
Commercial paper	50,933	3	(4)	50,932
Corporate debt securities	94,248	13	(4)	94,257
Asset-based securities	40,521	2	(1)	40,522
U.S. government securities	49,619	25	-	49,644
U.S. agency securities	9,577	5	-	9,582
Total	313,372	48	(9)	313,411
Less: amounts classified as cash equivalents	(186,818)	(9)	7	(186,820)
Total marketable securities	$ 126,554	$ 39	$ (2)	$ 126,591

	December 31, 2023			
	Amortized Cost Basis	Unrealized Gains	Unrealized Losses	Fair Value
	(in thousands)			
Money market funds	$ 56,397	$ -	$ -	$ 56,397
Commercial paper	82,179	1	(28)	82,152
Corporate debt securities	61,887	12	(5)	61,894
Asset-based securities	10,505	-	-	10,505
U.S. government securities	113,612	40	-	113,652
U.S. agency securities	4,960	1	-	4,961
Total	329,540	54	(33)	329,561
Less: amounts classified as cash equivalents	(65,144)	(4)	-	(65,148)
Total marketable securities	$ 264,396	$ 50	$ (33)	$ 264,413

No marketable securities had maturities of more than one year as of December 31, 2024 and 2023.

There were $69.9 million and $110.9 million of investments in an unrealized loss position of $9,000 and $33,000 as of December 31, 2024 and 2023, respectively. During the years ended December 31, 2024, 2023 and 2022, 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 and losses on the portfolio after December 31, 2024, 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, 2024. 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 marketable securities as of December 31, 2024 and as a result, the Company did not reclassify any amounts out of accumulated other comprehensive income (loss) 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 losses from its accounts receivable and, therefore, has not recorded a reserve for estimated credit losses as of December 31, 2024 and 2023.

In accordance with the collaboration, license, and supply agreements, the Company recognized revenue as follows:

	Year Ended December 31,		
	2024	**2023**	**2022**
		(in thousands)	
Astellas Pharma Inc. ("Astellas")	$ 52,868	$ 33,992	$ 10,897
Tasly Biopharmaceuticals Co., Ltd. ("Tasly")	6,021	6,970	25,000
Vaxcyte, Inc. ("Vaxcyte")	2,576	101,302	3,828
Ipsen Pharma SAS ("Ipsen")	559	-	-
Merck Sharp & Dohme Corporation ("Merck")	19	5,869	11,600
Bristol Myers Squibb Company ("BMS")	-	5,590	9,752
Merck KGaA, Darmstadt, Germany (operating in the United States and Canada under the name "EMD Serono")	-	8	2,695
BioNova Pharmaceuticals, Ltd. ("BioNova")	-	-	4,000
Total revenue	$ 62,043	$ 153,731	$ 67,772

The following table presents the changes in the Company's deferred revenue balance from the agreements during the year ended December 31, 2024:

	Year ended December 31, 2024
	(in thousands)
Deferred revenue—December 31, 2023	$ 74,045
Additions to deferred revenue	53,173
Recognition of revenue in current period	(44,899)
Deferred revenue—December 31, 2024	$ 82,319

The Company's balance of deferred revenue contains upfront and contingent payments for obligations from our agreements which remain partially unsatisfied. The Company expects to recognize approximately $69.8 million of the deferred revenue over the next twelve months.

Astellas License and Collaboration Agreement

In June 2022, the Company entered into a License and Collaboration Agreement (the “Astellas Agreement”) with Astellas for the development of immunostimulatory antibody-drug conjugates for up to three biological targets, to be identified by Astellas. The Company will conduct research and preclinical development of any compound (as designated by Astellas) in each of the three programs in accordance with the terms of a research plan between the Company and Astellas. Astellas will have an exclusive worldwide license to develop and commercialize any such designated compound, subject to the Company’s rights to participate in cost and profit sharing in the United States, as described below.

Pursuant to the Astellas Agreement, the Company received from Astellas a one-time, nonrefundable, non-creditable, upfront payment of $90.0 million during the year ended December 31, 2022. Under ASC 808 and ASC 606, the Company determined that both parties are active participants in the activities and are exposed to significant risks and rewards dependent on the success of the development program, and identified four performance obligations under the Astellas Agreement as: (1) performance of services related to the first target program; (2) performance of services related to the second target program; (3) performance of services related to the third target program; and (4) the Company’s estimated future services on the collaboration JSC. The transaction price of $90.0 million was allocated among the performance obligations using the Company’s best estimate of the standalone selling price, or SSP, for each of the associated performance obligations. Revenue allocated to the three target programs, which totaled $89.1 million, was being recognized on a proportional performance basis, using FTE cost as the basis of measurement, with such performance expected to occur over an estimated service period of four years for each target program. For the JSC performance obligation, revenue allocated to such performance obligation was $0.9 million, and was being recognized on a proportional performance basis using FTE cost as the basis of measurement, and such effort is expected to be incurred on a relatively consistent basis throughout the term of the Astellas Agreement.

Additionally, under ASC 606, the Company determined a financing component associated with the $90.0 million upfront payment and has calculated $24.7 million as of December 31, 2024 on the unearned revenue portion beyond one year from the effective date of the agreement, which amount is being recognized as interest expense and revenue over the estimated service period for the target programs.

The Company is also eligible to receive up to $422.5 million in development, regulatory and commercial milestones for each product candidate, and tiered royalties ranging from low double-digit to mid-teen percentages on worldwide sales of any commercial products that may result from the collaboration, subject to customary deductions under certain circumstances. The Company can also elect to convert any product candidate into a cost and profit-sharing arrangement, for the United States only. In the event the Company makes such election, it will share commercialization costs and profits relating to such product candidate equally with Astellas in the United States, and no royalties will be due from Astellas for net sales of such product candidates in the United States.

In June 2024, Astellas notified the Company that it would not be nominating a third target program. This decision was based on Astellas' strategic portfolio considerations. Pursuant to ASC 606, Astellas' decision to not elect a third target program is a change in the scope of the original contract and thus represents a contract modification. At the date of the modification, the Company determined that the remaining research and development activities related to the first target program and the second target program to be undertaken by the Company after the notice of termination were not distinct from the related activities performed on each target prior to the modification. Accordingly, after re-allocation of the updated transaction price, the Company updated the cost-based input measure of progress for the remaining performance obligations and recorded a cumulative catch-up adjustment to revenue of $17.8 million on the modification date relating to the ongoing unsatisfied performance obligations. For the JSC performance obligation, as the remaining services were determined to be distinct from those already provided, the Company determined that the contract modification should be treated as a termination of the existing contract and the creation of a new contract, to be accounted for prospectively.

Revenues under the Astellas Agreement were as follows:

	Year ended December 31,		
	2024	2023	2022
		(in thousands)	
Ongoing performance related to unsatisfied performance obligations	$ 39,900	$ 17,015	$ 3,940
Research and development services	5,200	6,584	1,878
Financing component on unearned revenue	6,289	9,836	5,079
Materials supply	1,479	557	-
Total revenue	$ 52,868	$ 33,992	$ 10,897

As of December 31, 2024 and 2023, there was $29.1 million and $69.0 million of deferred revenue, respectively, related to the upfront payment received by the Company under the Astellas Agreement.

Collaboration with Tasly

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, or luveltamab tazevibulin, or luvelta, in Greater China (the "Tasly License Agreement"). Tasly will pursue the clinical development, regulatory approval, and commercialization of luvelta 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 luvelta globally outside of Greater China, including the United States.

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 luvelta 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 accounted for it in accordance with ASC 606. 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, 2024 and 2023, the Company did not recognize any material reduction of research and development expenses under the Tasly License Agreement.

In April 2022, the Company entered into amendment No. 1 (the “Tasly Amendment”) to the Tasly License Agreement with Tasly. Pursuant to the Tasly Amendment, the initial nonrefundable upfront payment due by Tasly was amended to $25.0 million, and a $15.0 million payment will become payable to the Company upon the achievement of certain regulatory milestones. The Tasly Amendment also added an additional regulatory milestone payment to the Tasly License Agreement, providing additional potential payments totaling up to $350.0 million related to development, regulatory and commercialization milestones, beyond the payments described above, and made certain other ministerial edits.

During the year ended December 31, 2022, the Company recognized the $25.0 million upfront payment as revenue after the payment, net of a withholding tax, was received by the Company from Tasly. The withholding tax of $2.5 million was recorded as an income tax charge related to the upfront payment.

During the year ended December 31, 2023, the Company recognized a $5.0 million contingent payment as revenue, net of withholding tax, after Tasly received its first IND clearance by National Medical Products Administration, or NMPA, in Greater China. The withholding tax of $0.5 million was recorded as an income tax charge related to the contingent payment.

During the year ended December 31, 2024, the Company recognized a $5.0 million contingent payment as revenue, net of withholding tax, after the Company announced the selected dose from the dose-optimization portion (Part 1) of REFRaME-O1 for luvelta.

2023 Tasly Supply Agreement

In June 2023, the Company entered into a Master Development and Clinical Supply Agreement (the “2023 Tasly Supply Agreement”) with Tasly, wherein Tasly requested the Company to provide development, manufacturing and supply chain management services, including clinical product supply.

Revenues under the Tasly agreements were as follows:

	Year ended December 31,		
	2024	2023	2022
		(in thousands)	
Upfront payment	$ -	$ -	$ 25,000
Contingent payment	5,000	5,000	-
Research and development services	70	92	-
Materials supply	951	1,878	-
Total revenue	$ 6,021	$ 6,970	$ 25,000

Agreements with Vaxcyte

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 manufacturing organizations, or CMOs, to conduct process transfers to allow for such CMOs to manufacture and supply extract and custom reagents for Vaxcyte. As part of the agreement with Vaxcyte, should the Company decide to purchase extract from the extract CMO, the Company would be required to reimburse Vaxcyte for a portion of all incurred process transfer costs. As of December 31, 2024 and 2023, there was $12.4 million and $6.9 million in such accruals related to the Vaxcyte Supply Agreement.

For the years ended December 31, 2024, 2023 and 2022, the agreed-upon reimbursements by Vaxcyte of the costs associated with such arrangements, principally for pass-through costs from the CMOs, were $9.0 million, $8.6 million and $12.4 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.

Vaxcyte Agreement

In December 2022, the Company entered into a letter agreement (the "Vaxcyte Agreement") with Vaxcyte under which the Company granted to Vaxcyte (i) authorization to enter into an agreement with an independent alternate CMO to source cell-free extract solely for the products it licensed from the Company, allowing Vaxcyte to have direct oversight over financial and operational aspects of the relationship with the CMO ("CMO Relationship Rights"), and (ii) a right, but not an obligation, to obtain certain exclusive rights to internally manufacture and/or source extract from certain CMOs and the right to independently develop and make improvements to extract for use in connection with the exploitation of certain vaccine compositions (the "Option").

In November 2023 (the "Exercise Date"), Vaxcyte exercised the Option by submitting written notice thereof to the Company and concurrently paid the Company $50.0 million in cash as the first of two installment payments for the Option exercise price. In May 2024, Vaxcyte paid the Company an additional $25.0 million in cash as the second of two installment payments for the Option exercise price under the Vaxcyte Agreement. Also, the Company received a one-time, nonrefundable, non-creditable, upfront payment of $10.0 million in cash, and 167,780 shares of Vaxcyte common stock with a fair value of $7.5 million in December 2022.

Upon the occurrence of certain regulatory milestones, Vaxcyte would be obligated to pay the Company certain additional payments totaling up to $60.0 million in cash. In the event that Vaxcyte undergoes a change of control, certain rights and payments may be accelerated. These contingent payments were considered constrained variable consideration or otherwise not eligible for revenue recognition at inception and as of December 31, 2024.

Revenues under the Vaxcyte agreements were as follows:

	Year ended December 31,		
	2024	2023	2022
		(in thousands)	
Upfront payments	$ -	$ 97,500	$ -
Research and development services	2,287	2,435	2,356
Materials supply	289	1,367	1,472
Total revenue	$ 2,576	$ 101,302	$ 3,828

Refer to Note 9 below for information relating to the Purchase Agreement between the Company and Blackstone, pursuant to which the Company sold to Blackstone its 4% royalty, or revenue interest, in potential future net sales of Vaxcyte products, including VAX-24 and VAX-31.

Ipsen Agreements

In March 2024, the Company and Ipsen Pharma SAS ("Ipsen") entered into an Exclusive License Agreement (the "Ipsen License Agreement") pursuant to which the Company licensed to Ipsen, on an exclusive basis, the right to research, develop, manufacture and commercialize STRO-003.

In consideration for the rights and licenses granted by the Company to Ipsen in the Ipsen License Agreement, (i) Ipsen paid the Company an upfront license fee in the amount of $50.0 million in April 2024 and (ii) Ipsen Biopharmaceuticals, Inc. (USA) ("Ipsen USA"), a fully-owned Affiliate of Ipsen, purchased 4,827,373 shares of the Company's common stock for $25.0 million, at a price of approximately $5.18 per share, in accordance with the terms set forth in a certain investment agreement by and between the Company and Ipsen USA dated March 29, 2024 (the "Ipsen Investment Agreement", and, together with the Ipsen License Agreement, the "Ipsen Agreements"). The fair market value of the common stock issued to Ipsen USA in April 2024 was $24.6 million, based on the stock price on the date of issuance, resulting in a $0.4 million premium on the Ipsen Investment Agreement.

The Company is eligible to receive up to an additional $447.0 million in developmental and regulatory milestones, assuming multiple indications, and up to $360.0 million in sales milestones, as well as tiered royalty payments ranging from low double-digit to mid-teen digit percentages of annual net sales of STRO-003, subject to certain adjustments specified in the Ipsen License Agreement.

The royalty payment obligations under the Ipsen License Agreement expire on a country-by-country basis no earlier than ten years following the first commercial sale of STRO-003 in the applicable country. Ipsen may terminate the Ipsen License Agreement for convenience with sixty calendar days prior written notice or for certain other specified reasons. The Company may terminate the Ipsen License Agreement if Ipsen or any of its Affiliates challenge the validity of any patents controlled by the Company that are licensed under the agreement. Both Ipsen and the Company may terminate the Ipsen License Agreement (i) for material breach by the other party and a failure to cure such breach within the time period specified in the Ipsen License Agreement or (ii) the other party’s bankruptcy event.

The Company concluded that the Ipsen License Agreement contains three promised goods and services consisting of the STRO-003 license, technology transfer, and IND-enabling activities. The Company concluded that these promised goods and services are not distinct from each other, and all play an integral role in allowing Ipsen to file an IND and begin its development of STRO-003. As such, the STRO-003 license, technology transfer, and IND-enabling activities are accounted for as one single performance obligation.

The Ipsen License Agreement and the Ipsen Investment Agreement are being accounted for as one arrangement because they were entered into at or near the same time and negotiated in contemplation of one another. The Company determined that the total transaction price of the Ipsen License Agreement was $50.4 million, comprised of the one-time, nonrefundable, non-creditable upfront payment of $50.0 million paid by Ipsen under the Ipsen License Agreement, and a $0.4 million premium from the Ipsen Investment Agreement.

Revenue for the performance obligation will be recognized at a point in time when the Company has completed all its deliverables, i.e., STRO-003 license, technology transfer, and IND-enabling activities, at which time Ipsen would have what it needs from the Company to file an IND for STRO-003.

Ipsen Transition Services Agreement ("TSA"), Material Transfer Agreement ("MTA") and Manufacturing and Supply Agreement (“MSA”)

In July 2024, the Company executed the Transition Services Agreement (“TSA”) with Ipsen. The TSA outlines the terms and conditions for transition services requested by Ipsen as part of the Ipsen License Agreement. Further, as part of the transition activities under the TSA, Ipsen and the Company executed a Material Transfer Agreement ("MTA") to govern the transfer of certain materials from the Company to Ipsen for research and development purposes. The pricing for the services and material supply is outlined in the TSA and MTA.

In December 2024, the Company executed the Manufacturing and Supply Agreement (“MSA”) with Ipsen. The MSA outlines the terms and conditions for certain manufacturing services, manufacturing transition activities and transfer of the manufacturing technology as part of the Ipsen License Agreement. The pricing is based on an agreed upon cost-plus arrangement.

Revenues under the Ipsen agreements were as follows:

	Year ended December 31,		
	2024	2023	2022
		(in thousands)	
Research and development services	$ 174	$ -	$ -
Materials supply	385	-	-
Total revenue	$ 559	$ -	-

As of December 31, 2024, there was $53.2 million of deferred revenue related to the Ipsen Agreements.

Collaboration with Merck

In August 2024, Merck informed the Company of its decision to discontinue the clinical trial of MK-1484 in patients. Merck stated that the decision was based on strategic portfolio considerations.

6. Property and Equipment, Net

Property and equipment, net, consists of the following:

	December 31, 2024	December 31, 2023
	(in thousands)	
Computer equipment and software	$ 1,623	$ 1,750
Furniture and office equipment	244	244
Laboratory equipment	40,251	38,006
Leasehold improvements	24,205	23,606
Construction in progress	497	497
Total	66,820	64,103
Less accumulated depreciation and amortization	(48,630)	(42,163)
Total property and equipment, net	$ 18,190	$ 21,940

Depreciation and amortization expense amounted to $7.2 million, $6.8 million and $5.7 million for the years ended December 31, 2024, 2023 and 2022, respectively.

7. 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 March 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 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 Company commenced using the remaining 29,711 square feet of the Premises, or the Expansion Premises on July 1, 2023 under the sublease agreement. 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, and Expansion Premises of July 1, 2023, 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 Sheets as of December 31, 2024 and 2023.

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:

	Year ended December 31,		
	2024	2023	2022
		(in thousands)	
Operating lease cost	$ 7,936	$ 7,039	$ 6,154
Short-term lease cost	195	274	82
Variable lease cost	2,882	2,047	1,610
Total lease cost	$ 11,013	$ 9,360	$ 7,846

During the years ended December 31, 2024, 2023 and 2022, the Company recorded operating lease expense of $7.9 million, $7.0 million and $6.2 million, respectively, and paid $9.2 million, $8.0 million, and $1.7 million, respectively, 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, 2024 and 2023, the weighted-average remaining lease term was 2.8 years and 3.8 years, respectively, and the weighted-average discount rate used to determine the operating lease liability was 10.8% for both years.

As of December 31, 2024, the maturities of the Company's operating lease liabilities were as follows:

Year Ending December 31,	**Amount**
	(in thousands)
2025	9,533
2026	8,994
2027	8,289
Total lease payments	26,816
Less: imputed interest	(3,662)
Operating lease liabilities	23,154
Less: current portion	(7,480)
Total lease liabilities, non-current	$ 15,674

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.

8. Accrued Expenses and Other Current Liabilities

Accrued expenses and other current liabilities consist of the following:

	December 31,	
	2024	2023
	(in thousands)	
Vaxcyte-related accrual under Vaxcyte Supply Agreement	$ 12,435	$ 6,933
CMO-related accrual	8,525	8,195
Clinical trials-related accrual	6,263	4,283
Tax and related expenses	18	15,165
Other	4,009	3,897
Total accrued expenses and other current liabilities	$ 31,250	$ 38,473

9. Deferred Royalty Obligation related to the Sale of Future Royalties

In June 2023, the Company entered into the Purchase Agreement with Blackstone, pursuant to which the Company sold to Blackstone its 4% royalty, or revenue interest, in the potential future net sales of Vaxcyte products, including the Purchased Interest under the 2015 License Agreement. As described in Note 5. Collaboration and License Agreements and Supply Agreements, Vaxcyte Agreement, following agreement with Vaxcyte on the Form Definitive Agreement and upon effectiveness of the amendment No. 3 to the 2015 License Agreement, the revenue interest in the 4% royalty on potential future net sales of Vaxcyte products other than Vaxcyte's PCV products reverted to the Company. The Company retains 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.

In June 2023, Blackstone made an upfront payment of $140.0 million to the Company and will also pay up to an additional $250.0 million upon the achievement of various return thresholds as set forth in the Purchase Agreement.

Under the Purchase Agreement, and in connection with its sale of the Purchased Interest, the Company has agreed to certain covenants with respect to the exercise of its rights under the 2015 License Agreement, including with respect to the Company's right to amend, assign and terminate the 2015 License Agreement. The Purchase Agreement contains other customary terms and conditions, including representations and warranties, covenants, and indemnification obligations in favor of each party.

The Company recorded the $140.0 million upfront payment from Blackstone as a deferred royalty obligation related to the sale of future royalties on the Company's Balance Sheets. Due to the Company's then ongoing manufacturing obligations under the 2015 License Agreement, the Company accounted for the proceeds as imputed debt and, therefore, will recognize future non-cash royalty revenues. Non-cash interest expense will be recognized over the estimated life of the royalty term arrangement using the effective interest method based on the imputed interest rate derived from estimated amounts and timing of potential future royalty payments to be received from Vaxcyte. As part of the sale, the Company incurred approximately $3.8 million in transaction costs, which are being amortized over the estimated life of the royalty term arrangement using the effective interest method. As future royalties are earned from Vaxcyte by Blackstone, the balance of the deferred royalty obligation will be amortized over the estimated life of the royalty term arrangement.

There are a number of factors that could materially affect the fair value of the deferred royalty obligation. Such factors include, but are not limited to, the amount and timing of potential future royalty payments to be earned and received by Blackstone from Vaxcyte under the 2015 License Agreement, changing standards of care, the introduction of competing products, manufacturing or other delays, intellectual property matters, adverse events that result in governmental health authority imposed restrictions on the use of the vaccine products, and other events or circumstances that could result in reduced royalty payments from Vaxcyte to Blackstone, which are not within the Company's control, and all of which would result in a reduction of non-cash royalty revenues and the non-cash interest expense over the estimated life of the royalty term arrangement. The Company periodically assesses the estimated royalty payments to be earned by Blackstone from Vaxcyte and, to the extent that the amount or timing of such payments is materially different than our original estimates, the Company will prospectively adjust the imputed interest rate and the related amortization of the deferred royalty obligation. As of December 31, 2024, the Company's effective interest rate used to amortize the liability is 19.8%.

During the year ended December 31, 2024, the Company recognized approximately $31.1 million of non-cash interest expense on the deferred royalty obligation, which amount will increase such balance. As of December 31, 2024, Blackstone has not received any royalty payment from Vaxcyte and, therefore, the deferred royalty obligation has not begun to be amortized.

The following table shows the activity of the deferred royalty obligation for the years ended December 31, 2024 and 2023:

	December 31, 2024	December 31, 2023
	(in thousands)	
Liability related to sale of future Vaxcyte royalties - beginning balance	$ 149,114	$ -
Proceeds from the sale of future Vaxcyte royalties	-	140,000
Issuance costs	-	(3,792)
Non-cash interest expense associated with the sale of future Vaxcyte royalties	31,070	12,570
Amortization of issuance costs	625	336
Liability related to the sale of future Vaxcyte royalties - ending balance	$ 180,809	$ 149,114

10. Segment Reporting

The Company operates in one business segment that focuses on developing site-specific and novel-format ADCs. The Company's Chief Executive Officer, as the chief operating decision-maker, reviews financial information on an aggregate basis for the purposes of allocating resources and evaluating financial performance. Consistent with this decision-making process, the Chief Executive Officer uses loss from operations to monitor budget versus actual results for purposes of evaluating performance and to make decisions about the allocation of resources.

Summary of the segment net loss, including significant segment expenses were as follows:

	Year Ended December 31, 2024	2023	2022
		(in thousands)	
Revenue	$ 62,043	$ 153,731	$ 67,772
Less:			
Personnel-related expenses	(107,916)	(108,772)	(95,793)
Outside services	(105,056)	(61,233)	(40,508)
Preclinical research and clinical development expenses	(35,217)	(23,131)	(14,805)
Laboratory supplies	(15,547)	(17,251)	(19,115)
Facility and maintenance expenses	(16,030)	(14,169)	(11,762)
Equipment and office-related expenses	(19,216)	(17,439)	(13,945)
Travel-related expenses	(1,514)	(1,014)	(787)
Operating expenses	(300,496)	(243,009)	(196,715)
Loss from operations	(238,453)	(89,278)	(128,943)
Non-cash interest expense related to the sale of future royalties	(31,070)	(12,570)	-
Interest income	18,643	14,510	3,455
Interest and other (income) expense, net	25,782	(1,263)	8,784
Non-operating income	13,355	677	12,239
Loss before provision for income taxes	(225,098)	(88,601)	(116,704)
Income tax expense	(2,363)	(18,192)	(2,500)
Segment net loss	$ (227,461)	$ (106,793)	$ (119,204)
Reconciliation of profit or loss			
Adjustments and reconciling items	-	-	-
Net loss	$ (227,461)	$ (106,793)	$ (119,204)

All of the Company's long-lived assets are maintained in the United States.

11. 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.

The Company has reserved common stock, on an if-converted basis, for issuance as follows:

	December 31,	
	2024	2023
Common stock options issued and outstanding	8,671,883	7,905,032
Common stock awards issued and outstanding	5,955,109	5,244,873
Remaining shares reserved for issuance under 2018 Equity Incentive Plan and 2021 Equity Inducement Plan	1,626,268	1,777,919
Shares reserved for issuance under 2018 Employee Stock Purchase Plan	1,213,418	914,911
Warrants to purchase common stock	127,616	127,616
Total	17,594,294	15,970,351

Preferred Stock

As of December 31, 2024 and 2023, the Company had 10,000,000 shares of preferred stock authorized with a par value of $0.001 per share. No shares of preferred stock were outstanding as of December 31, 2024 and 2023.

12. Equity Incentive Plans, Equity Inducement Plans, Employee Stock Purchase Plan and Stock-Based Compensation

2004 Equity Incentive Plan, 2018 Equity Incentive Plan, 2021 Equity Inducement Plan, and Amended and Restated 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 last day of the preceding year (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 3,050,491 shares on January 1, 2024.

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.

In August 2022, the Company amended and restated the 2021 Plan (the "Amended and Restated 2021 Plan") and reserved an additional 750,000 shares of common stock available for issuance under the Amended and Restated 2021 Plan to be granted by the Company to certain employees as a material inducement to their acceptance of employment with the Company in accordance with Nasdaq Listing Rule 5635(c)(4).

Additionally, in February 2023, the Company amended and restated the Amended and Restated 2021 Plan and reserved an additional 500,000 shares of common stock available for issuance under the Amended and Restated 2021 Plan to be granted by the Company to certain employees as a material inducement to their acceptance of employment with the Company in accordance with Nasdaq Listing Rule 5635(c)(4). The total number of shares reserved for issuance pursuant to the Amended and Restated 2021 Plan is 2,000,000 shares.

As of December 31, 2024, the Company had 1,626,268 shares available for grant under the 2018 Plan and the 2021 Plan.

The following table summarizes option activity under the Company's 2004 Plan, 2018 Plan and 2021 Plan:

	Shares	Weighted-Average Exercise Price	Weighted-Average Remaining Contract Term (Years)	Aggregate Intrinsic Value (in thousands)
Stock options outstanding at December 31, 2023	7,905,032	$ 11.24	6.02	$ 180
Granted	1,627,209	4.09		
Exercised	(63,748)	4.24		
Canceled and forfeited	(796,610)	11.83		
Stock options outstanding at December 31, 2024	8,671,883	$ 9.89	5.89	$ -
Stock options exercisable at December 31, 2024	6,374,481	$ 11.54	4.96	$ -

The aggregate intrinsic value in the table above represents the total intrinsic value (the difference between our closing stock price on the last trading day of fiscal 2024 and the exercise prices, multiplied by the number of in-the-money stock options) that would have been received by the stock option holders had all stock option holders exercised their stock options on December 31, 2024. For the years ended December 31, 2024, 2023 and 2022, the aggregate intrinsic value of stock options exercised was immaterial, 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,		
	2024	2023	2022
Expected term (in years)	6.0-6.1	5.3-6.1	5.3-6.1
Expected volatility	86.4%-89.2%	80.7%-84.1%	81.8%-83.5%
Risk-free interest rate	3.5%-4.7%	3.6%-4.7%	1.7%-4.2%
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 term 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, 2024, 2023 and 2022 was $3.07, $3.84 and $5.03 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, 2024 is as follows:

	Number of Shares	Weighted Average Grant-Date Fair Value
Non-vested December 31, 2023	5,244,873	$ 8.31
Granted	2,889,530	4.30
Released	(1,695,054)	9.57
Canceled	(484,240)	7.75
Non-vested December 31, 2024	5,955,109	$ 6.05

2018 Employee Stock Purchase Plan

In September 2018, the Company adopted the 2018 Employee Stock Purchase Plan ("ESPP"), which became effective on September 26, 2018, 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 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 1% of the total number of shares of the Company's capital stock outstanding on the last day of the preceding year (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 ESPP was increased by 114,754 shares on January 1, 2024. 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.

At the Company's annual stockholder meeting in June 2024, the Company amended the ESPP (the "Amended ESPP") to increase the overall limit on the number of shares that may be issued under the Amended ESPP throughout its ten-year term from 2,300,000 shares to 3,050,0000 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, 2024, 2023 and 2022, the fair value of ESPP shares was estimated using the following assumptions:

	Year Ended December 31,		
	2024	2023	2022
Expected term (in years)	0.5	0.5	0.5
Expected volatility	88.4-93.7%	79.6-89.9%	65.9-88.1%
Risk-free interest rate	4.6%-5.5%	3.8%-5.5%	0.1%-3.8%
Expected dividend	-	-	-

During the years ended December 31, 2024, 2023 and 2022, 566,247, 526,079, and 270,516 shares, respectively, had been purchased. As of December 31, 2024, 1,213,418 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,		
	2024	2023	2022
		(in thousands)	
Research and development expense:			
Stock options	$ 1,898	$ 2,183	$ 2,287
Restricted stock units	9,813	8,885	7,227
ESPP	792	764	592
Subtotal	12,503	11,832	10,106
General and administrative expense:			
Stock options	5,494	6,066	10,261
Restricted stock units	6,517	6,796	5,781
ESPP	173	214	156
Subtotal	12,184	13,076	16,198
Total	$ 24,687	$ 24,908	$ 26,304

As of December 31, 2024, unrecognized stock-based compensation expense related to the unvested stock options and RSUs granted was $7.8 million and $24.0 million, respectively. The remaining unrecognized compensation cost is expected to be recognized over a weighted-average period of 2.1 years and 2.3 years, respectively. As of December 31, 2024, there is $0.2 million of unrecognized stock-based compensation expense related to the ESPP.

13. Income Taxes

Current provision for income taxes consists of the following:

	Year Ended December 31,		
	2024	2023	2022
		(in thousands)	
Federal	$ 2,238	$ 16,646	$ -
State	125	603	-
Foreign	-	943	2,500
Total current provision for income taxes	$ 2,363	$ 18,192	$ 2,500

For the year ended December 31, 2024, the Company recognized an income tax expense of $2.4 million. This was primarily due to prior period tax provision to return adjustment. The effective tax rates for the year ended December 31, 2024 vary from the U.S. federal statutory tax rate of 21% primarily due to the Company's inability to recognize the benefit from its net deferred tax assets, which are offset by a valuation allowance. 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.

For the year ended December 31, 2023, the Company recognized an income tax expense of $18.2 million. The income tax charge for the year ended December 31, 2023, was primarily due to unfavorable book-tax differences related to capitalizing and amortizing research and development expenditures under Internal Revenue Code, or IRC, Section 174, the upfront payment from the sale of future royalties, deferred revenue, foreign income tax, and IRC Section 382 limitations imposed on the utilization of the Company's historical tax attributes as a result of cumulative ownership changes that the Company experienced in prior years.

The Company recorded a foreign income tax charge of $2.5 million during the year ended December 31, 2022, due to a withholding tax in China on its license revenue from Tasly.

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,		
	2024	**2023**	**2022**
Federal statutory rate	21.0%	21.0%	21.0%
State tax	(0.1)	(0.6)	-
Change in valuation allowance	(26.7)	(41.2)	(26.2)
Tax credits	5.8	3.1	7.9
Stock compensation	(1.1)	(3.1)	(3.2)
Foreign-Derived Intangible Income deduction	-	1.4	-
Foreign withholding	-	(1.1)	(2.1)
Other	-	(0.1)	0.5
Total	(1.1)%	(20.6)%	(2.1)%

The components of the Company's deferred tax assets consist of the following:

	December 31	
	2024	**2023**
	(in thousands)	
Deferred tax assets:		
Net operating loss carryforwards	$ 39,662	$ 37,231
Research and development credits	46,739	32,800
Capitalized research and development expenditure	77,845	46,260
Deferred royalty obligation	38,639	31,944
Deferred revenue	16,620	15,274
Operating lease liability	4,948	6,335
Stock based compensation	5,824	5,613
Accruals and other	1,376	5,309
Total deferred tax assets	231,653	180,766
Less: valuation allowance	(227,831)	(167,693)
Gross deferred tax assets	3,822	13,073
Deferred tax liabilities:		
Operating lease right-of-use asset	(3,778)	(4,887)
Fixed asset basis	(10)	(809)
Vaxcyte investment	-	(7,377)
Other	(34)	-
Total deferred tax liabilities	(3,822)	(13,073)
Total net deferred tax assets	$ -	$ -

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 realization 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 years ended December 31, 2024, 2023 and 2022, the net increase in the valuation allowance was $60.1 million, $36.5 million and $30.6 million, respectively.

As of December 31, 2024, the Company had federal net operating loss carryforwards of $149.8 million and federal general business credits from research and development expenses totaling $30.5 million, as well as state net operating loss carryforwards of $108.0 million and state research and development credits of $32.1 million.

The federal net operating loss carryforwards will expire at various dates beginning in 2027, and the federal credits will expire at various dates beginning in 2032, 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. Under the Internal Revenue Code and similar state provisions, certain substantial changes in the Company's ownership could result in an annual limitation on the amount of net operating loss and credit carryforwards that can be utilized in future years to offset future taxable income. The annual limitation may result in the expiration of net operating losses and credit carryforwards before utilization. The Company completed Section 382 analysis through December 31, 2022, and concluded that the Company experienced an ownership change on November 20, 2019, and December 31, 2022. 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 2023 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 $12.1 million, $8.7 million and $8.6 million as of December 31, 2024, 2023 and 2022, 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 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:

	December 31		
	2024	**2023**	**2022**
		(in thousands)	
Gross unrecognized tax benefit at January 1	$ 8,730	$ 8,649	$ 6,409
Additions for tax positions taken in the current year	3,511	2,631	2,255
Additions / (Reductions) for tax positions of prior years	(184)	(2,550)	(15)
Gross unrecognized tax benefit at December 31	$ 12,057	$ 8,730	$ 8,649

The Company is subject to taxation in the United States and various state jurisdictions. All tax years remain subject to examination for U.S. federal and state purposes. All net operating losses generated to date are subject to adjustment for U.S. federal and state purposes. The Company is not currently under examination in federal or state jurisdictions.

14. Net Loss Per Share

The following table sets forth the computation of the Company's basic and diluted net loss per share.

	Year Ended December 31,		
	2024	2023	2022
	(in thousands, except share and per share amounts)		
Numerator:			
Net loss	$ (227,461)	$ (106,793)	$ (119,204)
Denominator:			
Shares used in computing net loss per share	76,829,198	60,163,542	50,739,185
Net loss per share, basic and diluted	$ (2.96)	$ (1.78)	$ (2.35)

The following common stock equivalents were excluded from the computation of diluted net loss per share for the years ended December 31, 2024, 2023 and 2022 because including them would have been antidilutive:

	Year Ended December 31,		
	2024	2023	2022
Common stock options issued and outstanding	8,671,883	7,905,032	7,310,611
Restricted stock units issued and outstanding	5,955,109	5,244,873	3,958,478
Warrants to purchase common stock	127,616	127,616	127,616
Shares to be issued under ESPP	440,170	226,490	150,532
Total	15,194,778	13,504,011	11,547,237

15. Subsequent Event

Restructuring

On March 13, 2025, the Company announced the completion of a strategic portfolio review resulting in the prioritization of the Company's three wholly-owned preclinical programs in the Company's next-generation ADC pipeline. The Company also announced that the Company is deprioritizing additional investment into development of luvelta across all indications and is reducing headcount by nearly 50 percent. Further, given the Company's significant progress in fully externalizing the cell-free manufacturing to scale, the Company intends to exit its internal GMP manufacturing facility by year-end. The Company is currently evaluating the accounting impact on the 2025 financial statements.

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, 2024, 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, 2024, 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, 2024. 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, 2024, 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, 2024 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, 2024 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, 2024, 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. (the Company) maintained, in all material respects, effective internal control over financial reporting as of December 31, 2024, 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 the Company as of December 31, 2024 and 2023, the related statements of operations, comprehensive loss, stockholders' equity and cash flows for each of the three years in the period ended December 31, 2024, and the related notes and our report dated March 13, 2025 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 Annual 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
San Mateo, California
March 13, 2025

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 2025 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 filled with the Securities and Exchange Commission within 120 days after our fiscal year end and is incorporated herein by reference.

3/13/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.

		Incorporated by Reference				
Exhibit Number	Exhibit Description	Form	Number	Exhibit	Date	Filed Herewith
3.1	Amended and Restated Certificate of Incorporation of Sutro Biopharma, Inc.	10-Q	001-38662	3.1	11/13/2023	
3.2	Amended and Restated Bylaws of Sutro Biopharma, Inc.	8-K	001-38662	3.1	2/24/2023	
4.2	Description of Registrant's Securities.	10-K	001-38662	4.2	3/25/2024	
4.3	Form of Warrant to Purchase Shares of Common Stock.	S-1	333-227103	4.3	8/29/2018	
4.6	Form of Warrant to Oxford Finance LLC pursuant to the Loan and Security Agreement.	10-K	001-38662	10.21	3/16/2020	
4.7	Form of Warrant to Silicon Valley Bank pursuant to the Loan and Security Agreement.	10-K	001-38662	10.22	3/16/2020	
10.1	Form of Indemnity Agreement by and between the Registrant and its directors and officers.	S-1/A	333-227103	10.1	9/17/2018	
10.2‡	2018 Equity Incentive Plan and form of award agreements thereunder.	S-1/A	333-227103	10.4	9/17/2018	
10.3‡	Amended Form of Restricted Stock Unit Agreement under the 2018 Equity Incentive Plan.	10-Q	001-38662	10.1	11/8/2019	
10.4‡	Amended Form of Performance Stock Unit Agreement under the 2018 Equity Incentive Plan.	10-Q	001-38662	10.2	11/8/2019	
10.6‡	2018 Employee Stock Purchase Plan and form of award agreements thereunder.	S-1/A	333-227103	10.5	9/17/2018	
10.7‡	2004 Stock Plan, as amended, and forms of award agreements.	S-1	333-227103	10.2	8/29/2018	

10.9†	Exclusive Patent License and Research Collaboration Agreement, dated July 23, 2018, by and between the Registrant and Merck Sharp & Dohme Corp., a subsidiary of Merck & Co., Inc., Kenilworth, NJ.	S-1/A	333-227103	10.15	9/17/2018
10.12‡	Offer Letter, dated December 29, 2008, by and between the Registrant and William J. Newell, as amended.	S-1	333-227103	10.6	8/29/2018
10.14‡	Offer Letter, dated December 11, 2012, by and between the Registrant and Edward C. Albini.	10-K	001-38662	10.11	2/28/2022
10.16	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.	S-1	333-227103	10.10	8/29/2018
10.19†	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.	S-1/A	333-227103	10.13	9/17/2018
10.23	Sublease Agreement, dated September 3, 2020, by and between the Company and Five Prime Therapeutics, Inc.	10-Q	001-38662	10.1	11/5/2020
10.24‡	Severance and Change in Control Plan of the Company	10-K	001-38662	10.24	3/25/2024
10.25	Third Amendment to Lease 888-894 Industrial Road, San Carlos, CA.	10-Q	001-38662	10.2	8/9/2021
10.27	Second Amendment to the Exclusive Patent License and Research Collaboration Agreement.	10-Q	001-38662	10.2	11/10/2021
10.29	License Agreement, dated December 24, 2021, by and between the Registrant and Tasly Biopharmaceuticals Co., Ltd.	10-K	001-38662	10.29	2/28/2022
10.31†	First Amendment to the Tasly License Agreement dated April 18, 2022.	10-Q	001-38662	10.1	8/8/2022
10.32†^	License and Collaboration Agreement, dated June 27, 2022, by and between the Registrant and Astellas Pharma Inc.	10-Q	001-38662	10.2	8/8/2022
10.33	Offer Letter, dated May 23, 2021, by and between the Registrant and Jane Chung.	10-K	001-38662	10.30	2/28/2022

10.34‡	Amended and Restated 2021 Equity Inducement Plan and forms of award agreements thereunder.	10-K	001-38662	10.34	3/25/2024	
10.35	Letter Agreement, dated December 19, 2022, by and between the Registrant and Vaxcyte, Inc.	10-K	001-38662	10.35	3/30/2023	
10.41†^	Purchase Agreement, dated June 21, 2023, between the Registrant and an affiliate of Blackstone Life Sciences.	10-Q	001-38662	10.1	8/10/2023	
10.42	Third Amendment to the Vaxcyte License Agreement between the Registrant and Vaxcyte, Inc.	10-K	001-38662	10.1	11/13/2023	
10.43	Manufacturing Rights Agreement between the Registrant and Vaxcyte, Inc.	10-K	001-38662	10.43	3/25/2024	
10.44†^	Exclusive License Agreement between the Registrant and Ipsen Pharma SAS.	10-Q	001-38662	10.1	5/13/2024	
10.45‡	Amended 2018 Employee Stock Purchase Plan	10-Q	001-38662	10.1	8/13/2024	
19.1	Insider Trading Policy					X
21.1	Subsidiaries of the Registrant.	S-1	333-227103	21.1	8/29/2018	
23.1	Consent of independent registered public accounting firm.					X
24.1	Power of Attorney. Reference is made to the signature page hereto.					X
31.1	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.					X
31.2	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.					X
32.1**	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.					X
32.2**	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.					X

97.1	Compensation Recovery Policy	10-K	001-38662	97.1	3/25/2024	
101.INS	Inline XBRL Instance Document					X
101.SCH	Inline XBRL Taxonomy Extension Schema 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.

† Registrant has omitted portions of the exhibit as permitted under Item 601(b)(10) of Regulations S-K.

^ Registrant has omitted schedules and exhibits pursuant to Item 601(a)(5) of Regulation S-K. The Registrant agrees to furnish supplementally a copy of the omitted schedules and exhibits to the SEC upon request.

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: March 13, 2025	By:	/s/ William J. Newell
	Name:	William J. Newell
	Title:	Chief Executive Officer
Date: March 13, 2025	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	President, Chief Executive Officer and Director	March 13, 2025
William J. Newell	*(Principal Executive Officer)*	
/s/ Edward C. Albini	Chief Financial Officer and Corporate Secretary	March 13, 2025
Edward C. Albini	*(Principal Financial and Accounting Officer)*	
/s/ Michael Dybbs, Ph.D.	Director	March 13, 2025
Michael Dybbs, Ph.D.		
/s/ John G. Freund, M.D.	Director	March 13, 2025
John G. Freund, M.D.		
/s/ Heidi Hunter	Director	March 13, 2025
Heidi Hunter		
/s/ Sukhi Jagpal	Director	March 13, 2025
Sukhi Jagpal		
/s/ Joseph M. Lobacki	Director	March 13, 2025
Joseph M. Lobacki		
/s/ Connie Matsui	Director	March 13, 2025
Connie Matsui		
/s/ James Panek	Director	March 13, 2025
James Panek		
/s/ Daniel H. Petree	Director	March 13, 2025
Daniel H. Petree		
/s/ Jon M. Wigginton, M.D.	Director	March 13, 2025
Jon M. Wigginton, M.D.		

I. PURPOSE

Sutro Biopharma, Inc. (collectively with its subsidiaries, the "***Company***") is committed to promoting high standards of honest and ethical business conduct and compliance with laws, rules and regulations. As part of this commitment, the Company has adopted this Insider Trading Policy (as adopted and amended from time to time by the Board, this "***Policy***") governing the purchase, sale and other dispositions of the Company's securities by the individuals and entities covered by this policy to promote compliance with insider trading laws, rules and regulations, as well as applicable stock exchange listing standards. Under this Policy, every employee, contractor and consultant and member of the Board is prohibited from trading in Company securities while in possession of material nonpublic information (defined in Appendix A) about the Company, and is prohibited from giving material nonpublic information about the Company or others to anyone who might trade on the basis of that information.

You should also read the FAQs about this Policy in Appendix A to this Policy. The FAQs are part of this Policy and the rules articulated in the FAQs must be followed as well.

Neither the Company nor the Compliance Officer (as defined below) is liable for any act made under this Policy. Neither the Company nor the Compliance Officer is responsible for any failure to approve a trade or for imposing any Blackout Period (as defined below).

II. DEFINITIONS

"***10b5-1 Plan***" means a written plan for selling or purchasing a predetermined number of shares of the Company that is entered into while a Covered Person is not in possession of material nonpublic information (MNPI) as contemplated in Rule 10b5-1.

"***Blackout Period***" means any trading blackout period specifically designated by the Compliance Officer. It may apply to particular individuals or groups of persons (including all Covered Persons), and last for such time as the Compliance Officer determines. No Covered Person may trade in Company securities during any such applicable Blackout Periods.

"***Board***" means the Company's Board of Directors.

"***Compliance Officer***" means the Company's General Counsel; *provided that*, in the event that the General Counsel is unavailable, the Company's Chief Financial Officer or Chief Executive Officer will be authorized to serve as the Compliance Officer in the interim or to designate another person as the Compliance Officer.

"***Covered Persons***" refers to (a) all employees, contractors, consultants, advisors, and Board members of the Company, (b) the members of such persons' immediate families (as defined below) residing with such persons, any other person in such persons' households, any other family members whose transactions in Company securities are directed by such persons or subject to such persons' influence or control and (c) venture capital funds and other entities (such as partnerships, trusts private equity, and corporations) that are affiliated or associated with such persons. An affiliate is someone who directly or indirectly controls or is controlled by, or is under common control with such person. An associate of a Covered Person is (x) a corporation or organization (other than the Company or a majority-owned subsidiary of the Company) of which such person is an officer or partner or is directly or indirectly the beneficial owner of 10% or more of any class of equity securities or (y) any trust in which such person has a substantial beneficial interest or as to which such person serves as trustee or in a similar capacity.

"***Exchange Act***" means the Securities Exchange Act of 1934, as amended.

The term "***immediate families***" includes, but is not limited to, a Covered Person's spouse, parents, children and siblings (whether biological, by marriage or adopted), or mothers and fathers-in-law, sons and daughters-in-law, brothers and sisters-in-law or anyone residing in such Covered Person's home. Any question regarding whether a relationship qualifies as "immediate family" should be addressed to the Compliance Officer.

"***Pre-clearance Persons***" means persons, other than Section 16 Insiders, who have been designated by the Company as having regular access to material nonpublic information about the Company in the normal course of their duties. Special provisions of this Policy, such as pre-approval of any trades, apply to Pre-clearance Persons. The Pre-clearance Persons are listed on Appendix B to this Policy. The Compliance Officer may update and amend this list from time to time.

"***SEC***" means the U.S. Securities and Exchange Commission.

"***Section 16 Insiders***" means the Company's officers (as defined in Rule 16a-1(f) of the Exchange Act) and directors, including the Company's principal accounting officer (if separate from the Company's principal financial officer). Special provisions of this Policy, such as pre-approval of any trades, and special SEC reporting requirements, apply to Section 16 Insiders.

"***Securities Act***" means the Securities Act of 1933, as amended.

III. SCOPE

This Policy covers all Covered Persons. All employees, contractors, consultants, advisors, and Board members of the Company are responsible for ensuring compliance with this Policy by members of their immediate families and other persons sharing their households, and by entities with which they are affiliated or associated.

This Policy applies to all transactions in Company securities, including shares of Company common stock, restricted stock units and options to purchase common stock, however acquired, and any other type of securities that the Company may issue, such as preferred stock, convertible notes, warrants or other derivative securities. Additionally, the Company will not transact in Company securities unless in compliance with U.S. securities laws.

The Company may impose sanctions for violation of this Policy and may issue stop-transfer orders to the Company's transfer agent to implement this Policy. Sanctions for individuals may include any disciplinary action, including termination of employment with the Company, where applicable. Directors, Section 16 Insiders and/or Pre-clearance Persons may be required to certify compliance with this Policy on an annual basis. Notifications and approvals required under this Policy may be provided by email.

IV. STATEMENT OF COMPANY POLICY

Prohibited Activities

- No Section 16 Insider, and no Pre-clearance Person, may trade in Company securities unless the trade has been approved in advance by the Compliance Officer in accordance with this Policy.

- No Covered Person may trade in Company securities while possessing material nonpublic information about the Company. It does not matter if the personal decision to trade was made before coming into possession of material nonpublic information; once a Covered Person comes into possession of the material nonpublic information, such Covered Person cannot trade (other than pursuant to a 10b5-1 Plan permitted under this Policy).

- No Covered Person may trade in, or make a gift or other transfer without consideration of, Company securities during any Blackout Period designated by the Compliance Officer.

- No Covered Person may disclose material nonpublic information about the Company to any outside person, unless required to do so as part of that Covered Person's regular duties for the Company or authorized by the Compliance Officer.

- No Covered Person may give trading advice of any kind about the Company to anyone while possessing material nonpublic information about the Company, except that Covered Persons should advise others not to trade if doing so might violate this Policy or the law. The Company strongly discourages Covered Persons from giving trading advice concerning the Company to third parties even when the Covered Persons do not possess material nonpublic information about the Company.

- No Covered Person may engage in transactions involving options or other derivative securities on Company securities, such as puts and calls, whether on an exchange or in any other market; provided however that a Covered Person may exercise compensatory equity awards issued by the Company as described in the FAQs, but may not sell the underlying securities.

- No Covered Person may engage in hedging or monetization transactions involving Company securities, such as zero-cost collars and forward sale contracts, or contribute Company securities to exchange funds that could be interpreted as having the effect of hedging in Company securities.

- No Covered Person may engage in short sales of Company securities, including short sales "against the box."

- No Covered Person may use or pledge Company securities as collateral in a margin account or as collateral for a loan unless the pledge has been approved by the Compliance Officer.

- No Covered Person may engage in any of the above activities for securities he or she owns in any other company if he or she has material nonpublic information about that company obtained in the course of his or her service to the Company.

Section 16 Insiders and Pre-clearance Persons Require Prior Approval of Trades

The Section 16 Insiders and Pre-clearance Persons (as listed on Appendix B to this Policy), prior to trading the Company's securities other than pursuant to a 10b5-1 Plan, must obtain prior approval of all trades in Company securities from the Compliance Officer by: (a) providing written notification of the amount and nature of the proposed trade, (b) certifying no earlier than two business days prior to the proposed trade that they have no material nonpublic information and, to their knowledge, will have no material nonpublic information as of the proposed trade date, and (c) receiving email confirmation from the Compliance Officer approving the trade, which approval can be granted or denied at the Compliance Officer's discretion. Section 16 Insiders and Pre-clearance Persons may satisfy (a) and (b) by emailing the required information and certification to the Compliance Officer and must notify the Compliance Officer promptly via email of any changes to the certification in (b) prior to the proposed trade date. In addition, Section 16 Insiders must obtain approval by the Compliance Officer prior to any gifts or other transfers of Company securities.

We recommend Section 16 Insiders trade in the Company's securities pursuant to a 10b5-1 Plan entered into in accordance with this policy.

Blackout Periods

- **No Trading During Blackout Periods**. The Compliance Officer may designate special trading Blackout Periods that apply to particular individuals or groups of persons (including all Covered Persons), for such time, and with respect to such persons, as the Compliance Officer determines in the Compliance Officer's discretion. No Covered Person subject to such Blackout Periods may trade in Company securities during any such applicable Blackout Periods. No Covered Person who learns of such a Blackout Period may disclose to any other person that a Blackout Period has been designated or that one was previously in place. The fact of the Blackout Period is confidential and cannot be disclosed internally or externally. The failure of the Compliance Officer to subject a person to a Blackout Period does not relieve that person of the obligation not to trade while in possession of material nonpublic information.

Permitted Trades Under 10b5-1 Plans

Sales, purchases and other transfers of Company securities otherwise prohibited by this Policy may be permitted by a Covered Person if they are effected pursuant to a 10b5-1 Plan that meets the following requirements:

- the 10b5-1 Plan complies with the requirements of Rule 10b5-1 under the Exchange Act;
- the 10b5-1 Plan is not entered into during any Blackout Period;

- the Compliance Officer has approved the 10b5-1 Plan and the first trade under the 10b5-1 Plan occurs 30 days after entry into the 10b5-1 Plan;

- the person establishing the 10b5-1 Plan has certified to the Compliance Officer in writing (which may be by email), no earlier than two business days prior to the date that the 10b5-1 Plan is formally established (and shall not have withdrawn such certification prior to such adoption), as of such date and as of the adoption date of the 10b5-1 Plan, that (i) such person is not, and, to such person's knowledge will not be, in possession of material nonpublic information concerning the Company, (ii) all such trades to be made pursuant to the 10b5-1 Plan will be in accordance with applicable SEC rules, (iii) such person is adopting the 10b5-1 Plan in good faith and not as part of a plan or scheme to evade the prohibitions of Section 10(b) of the Exchange Act and Rule 10b-5 of the Exchange Act, and (iv) such person will act in good faith with respect to the 10b5-1 Plan throughout its duration. This certification may be made in an email to the Compliance Officer. The person establishing the 10b5-1 Plan must notify the Compliance Officer promptly via email and withdraw the certification if any changes of circumstances prior to the adoption date of the 10b5-1 Plan have or will render such certification to be inaccurate as of that time.

- The first trade under the 10b5-1 Plan does not occur (i) for a Section 16 Insider: until the later of (A) ninety (90) days after adoption of the 10b5-1 Plan and (B) two (2) business days following the disclosure of the Company's financial results in a Form 10-Q or Form 10-K for the completed fiscal quarter in which the 10b5-1 Plan was adopted that discloses the Company's financial results (but not to exceed 120 days following the adoption of the 10b5-1 Plan); and (ii) for persons other than Section 16 Insiders: thirty (30) days after the adoption of the 10b5-1 Plan, in each case, following the Compliance Officer's approval of the 10b5-1 Plan. These waiting periods are collectively referred to as the "***Cooling-Off Period***."

- The 10b5-1 Plan is not a single-trade 10b5-1 Plan adopted during the 12-month period immediately following the person's adoption of another single-trade 10b5-1 Plan, subject to the exceptions noted in Rule 10b5-1, which are provided in Appendix C.

- A person may have no more than one 10b5-1 Plan adopted at any point in time (i.e., multiple concurrent or overlapping plans are prohibited), subject to the exceptions noted in Rule 10b5-1, which are provided to in Appendix C. One of these exceptions is for plans authorizing certain "sell-to-cover" transactions.

Approval of a 10b5-1 Plan by the Compliance Officer and/or an acknowledgement of a 10b5-1 Plan by the Company shall not be considered a determination by the Company or the Compliance Officer that the 10b5-1 Plan satisfies the requirements of Rule 10b5-1.

Once a person has an approved 10b5-1 Plan in place, such person will need approval from the Compliance Officer to make certain changes to it. Modifying or changing the amount, price, or timing of the purchase or sale of the Company's securities underlying the 10b5-1 Plan (or a modification or change to a written formula or algorithm, or computer program that affects the amount, price, or timing of the purchase or sale of such securities) (any such modification or change, a "***Plan Modification***") will be deemed to be the same as terminating such person's existing 10b5-1 Plan and entering into a new 10b5-1 Plan. As a result, the approval process for a Plan Modification is the same as the approval process for initially adopting a 10b5-1 Plan, including being subject to a new Cooling-Off Period. Making multiple Plan Modifications is discouraged by the Company, as that may give the appearance that a person is trading on material nonpublic information under the guise of that plan. Plan Modifications can not be made during any Blackout Period and only when a person not in possession of material nonpublic information. For other modifications to a 10b5-1 Plan, a person must notify the Compliance Officer of such modification in writing at least two business days prior to the modification and such modification must be approved by the Compliance Officer.

Once a 10b5-1 Plan is approved and in place, a person will need approval from the Compliance Officer to terminate it.

Unless otherwise approved by the Compliance Officer, all 10b5-1 Plans must be implemented through a broker approved by the Compliance Officer.

Priority of Statutory or Regulatory Trading Restrictions

The trading prohibitions and restrictions of this Policy are also subject to prohibitions or restrictions prescribed by contract or by federal and state securities laws and regulations (e.g., contractual restrictions on the resale of securities, short-swing trading by Section 16 Insiders or compliance with Rule 144 under the Securities Act). Any Covered Person who is uncertain whether other prohibitions or restrictions apply should ask the Compliance Officer.

Exceptions to Prohibited Activities

The trading restrictions of this Policy do not apply to the following:

- *401(k) Plan*. Investing 401(k) plan contributions in a company stock fund in accordance with the terms of our 401(k) plan. However, any changes in your investment election regarding the Company's securities are subject to trading restrictions under this Policy.

- *ESPP*. Purchasing the Company's stock through periodic, automatic payroll contributions, or making election changes, under the Company's Employee Stock Purchase Plan, if established. However, any sales of stock acquired under the ESPP are subject to trading restrictions under this Policy.

- *Options*. Exercising stock options granted under the Company's equity incentive plans for cash or by delivering to the Company previously owned Company stock or through a net exercise of a stock option that is permitted by the Company's equity incentive plans and that does not involve a sale of shares in the open market. Payment of taxes in connection with exercising stock options granted under our equity incentive plans pursuant to net withholding arrangements approved by the Company for the payment of taxes upon the exercise of stock options and that does not involve a sale of shares in the open market. However, the sale of any shares issued on the exercise of Company-granted stock options, as well as any cashless exercise of Company-granted stock options in which stock is sold on the open market to pay the exercise price or taxes (i.e., "same-day sales") are subject to trading restrictions under this Policy.

- *RSUs*. The settlement of RSUs pursuant to a net settlement or a "sale to cover" for non-discretionary, automatic tax withholdings initiated and approved by the Company for the payment of taxes upon the vesting of RSUs.

V. REPORTING VIOLATIONS; INQUIRIES

The Compliance Officer (or the Compliance Officer designee(s)) will review, and either approve or prohibit, any proposed trades in Company securities by Section 16 Insiders and Pre-clearance Persons. The Compliance Officer will administer and interpret this Policy, and enforce compliance as needed. The Compliance Officer may consult with the Company's outside legal counsel as needed. The Compliance Officer may designate one or more individuals who may perform the Compliance Officer's duties in the event that the Compliance Officer is unable or unavailable to perform such duties.

Any Covered Person who violates this Policy or any federal or state laws governing insider trading or tipping, or knows of any such violation by any other Covered Person, must report the violation immediately to the Compliance Officer.

Please direct all inquiries about this Policy to the Compliance Officer.

VI. POLICY HISTORY

The effective date of this Policy is February 23, 2023. The amendments to this Policy would not apply to any existing 10b5-1 Plan that was entered into prior to February 27, 2023, except to the extent that a Plan Modification is made to such plan after February 27, 2023.

VII. ADDITIONAL INFORMATION

Not applicable to this policy.

APPENDIX A

Frequently Asked Questions

What is "material nonpublic information?"

Information is "material" if it would be expected to affect the investment or voting decisions of a reasonable investor, or if the disclosure of the information would be expected to alter significantly the total mix of the information in the marketplace about the Company. In simple terms, material information is any type of information that could reasonably be expected to affect the market price of Company securities. Both positive and negative information may be material.

The following types of information about the Company (among others) would often be considered material:

- status of the Company's progress toward achieving significant developmental milestones;
- results of preclinical studies and clinical trials, including interim data;
- communications and filings with regulatory authorities regarding the Company's product candidates;
- entry into a new strategic relationship or partnership, and termination of existing strategic relationships or partnerships;
- financial performance, especially quarterly and year-end revenues and earnings, and significant changes in financial performance or liquidity;
- financial and operational forecasts, including projections of future expenses, cash burn or other earnings guidance;
- significant cybersecurity incidents or data breaches;
- product and market strategies and shifts;
- potential tender offers, joint ventures, mergers, acquisitions or material sales of Company assets or subsidiaries or other strategic transactions;
- significant developments regarding vendors, suppliers or partners;
- public or private securities or debt offerings and stock splits;
- significant changes in senior management or the Board;
- significant developments in the Company's business operations;
- initiation or resolution of significant litigation or regulatory proceedings;

- potential defaults under the Company's credit agreements; and
- potential restatements of the Company's financial statements, changes in the Company's auditor or notification that the Company may no longer rely on an auditor's report.

The SEC has stated there is no fixed quantitative threshold amount for determining materiality, and that even very small quantitative changes can be qualitatively material if they would result in a movement in the price of the Company's securities.

Information is "nonpublic" if it has not been widely disseminated to the public (e.g. through major newswire services, national news services, Forms 8-K and other filings with the SEC, webcasts or financial news services). For the purposes of this Policy, information will be considered public (i.e. no longer "nonpublic") only after the open of trading on the second full trading day following the Company's widespread public release of the information.

Covered Persons who are unsure whether the information that they possess is material or nonpublic are encouraged to consult the Compliance Officer for guidance.

What are the penalties for failing to comply with the Policy?

The consequences of prohibited insider trading or tipping can be severe. People who violate insider trading or tipping laws may be required to disgorge profits made or losses avoided by trading, pay the loss suffered by the persons who purchased securities from or sold securities to the insider tipper, pay civil penalties of up to three times the profit made or loss avoided, pay a criminal penalty of up to $5 million and serve a prison term of up to 20 years. The Company and/or the supervisors of the person violating the rules may also be required to pay major civil or criminal penalties and could under certain circumstances be subject to private lawsuits by contemporaneous traders for damages suffered as a result of illegal insider trading or tipping by persons under the Company's control.

Violation of this Policy, or federal or state securities laws governing insider trading, may subject the violator to disciplinary action by the Company up to and including termination of employment for cause (in the case of an employee or further service in the case of a contractor) or removal (in the case of a Board member). A violation of this Policy is not necessarily the same as a violation of law. In fact, for the reasons indicated above, this Policy is intended to be broader than the law. The Company reserves the right to determine, in its own discretion and on the basis of the information available to it, whether this Policy has been violated. The Company may determine that specific conduct violates this Policy, whether or not the conduct also violates the law. It is not necessary for the Company to await the filing or conclusion of a civil or criminal action against the alleged violator before taking disciplinary action.

Are these FAQs part of the Insider Trading Policy?

Yes, these FAQs are part of the Policy, and you must comply with their provisions.

How does the Policy apply to trades under the Company's Equity Award Plans and Employee Stock Purchase Plan?

The trading prohibitions and restrictions of this Policy do not apply to:

- the exercise of a stock option with cash that is not accompanied by a sale; or
- the settlement of a restricted stock unit pursuant to a net settlement for non-discretionary, automatic tax withholdings initiated and approved by the Company for the payment of taxes upon the vesting of such restricted stock units.

The trading prohibitions and restrictions of this Policy do apply to:

- the use of outstanding Company securities to serve as all or a portion of the exercise price of any stock option; and
- the use of outstanding Company securities to perform a cashless exercise of an option, which is accomplished by a broker-assisted sale of a portion of the shares issued upon exercise of an option.

Sales of Company securities acquired under such plans are subject to this Policy.

The trading prohibitions and restrictions set forth in this Policy also do not apply to periodic wage withholding contributions by the Company or employees to the Company's 2018 Employee Stock Purchase Plan or any successor employee stock purchase plan that are used to purchase Company securities pursuant to the employees' advance instructions. Any sale of securities acquired under such plan is subject to the prohibitions and restrictions of this Policy. Covered Persons may make changes in elections under the ESPP during a Blackout Period.

Can I still exercise a stock option during a Blackout Period if I am not going to sell any shares?

Yes. For clarity, the exercise of a vested stock option which is not accompanied by a sale is not considered a "trade" under this Policy.

How does the Policy apply to tax withholding arrangements?

The trading prohibitions and restrictions of this Policy do apply to any elective tax withholding right made (i.e. pursuant to which an election has been made in advance, outside of a Blackout Period, to have the Company withhold shares subject to such awards to satisfy tax withholding requirements), as well as to any sales of Company common stock, including as part of a broker-assisted cashless exercise of an option, or any other market sale (e.g., a "sell to cover" sale) for the purpose of generating the cash needed to pay the exercise price of an option or satisfy tax withholding requirements. The trading prohibitions and restrictions of this Policy do not apply to any automatic tax withholding (i.e., pursuant to which the withholding method has been determined in advance of the tax withholding event).

What are the procedures for obtaining approval of a proposed trade in compliance with the Policy?

No Section 16 Insider or Pre-clearance Person may trade in Company securities until the following steps are completed:

- The person trading has notified the Compliance Officer in writing (which may be by email) of the amount and nature of the proposed trade and that (i) such person is not in possession of material nonpublic information concerning the Company, and to such person's knowledge, such person will have no material nonpublic information as of the proposed trade date; (ii) the proposed trade does not violate the trading restrictions of Section 16 of the Exchange Act, Rule 144 of the Securities Act (if applicable) or any other securities laws. The form of email that should be sent to the Compliance Officer, David Pauling @dpauling@sutrobio.com and can be found on the Company's t-drive, under Company Information. To initiate this process please email The Compliance Officer and obtain approval for the trade in writing (which may be by email). The Compliance Officer is not obligated to approve any trades requested by any person.

- The Compliance Officer has approved the trade in writing (which may be by email). The Compliance Officer is not obligated to approve any trades requested by any person.

Which of my family members are covered by this Policy?

Family members of a Covered Person that are subject to this Policy include the members of such Covered Person's immediate family residing with such Covered Person, any other person in such Covered Person's household and any other family members whose transactions in Company securities are directed by such Covered Person or subject to such Covered Person's influence or control.

Is a gift of Company stock covered by the Policy?

Yes. A Covered Person may not make a gift, charitable contribution or other transfer without consideration, of Company securities during a period when that Covered Person is not permitted to trade. In addition, Section 16 Insiders must notify the Compliance Officer of any such gifts or transfers.

Is a distribution of Company stock to the limited partners of a partnership covered by the Policy?

Yes. An entity over which a Covered Person has or shares voting or investment control may not distribute Company securities to its limited partners, general partners or stockholders during a period when the Covered Person is not permitted to trade, unless the limited partners, general partners or stockholders of that entity have agreed in writing to hold the securities until the next time such Covered Person can trade under this Policy.

Is a purchase of Company stock considered a "trade" under the Policy? Or only sales of Company stock?

Both purchases and sales of Company stock are considered "trades" under the Policy.

Are transactions in derivative securities covered by the Policy?

Yes. No Covered Person may acquire, sell, trade or participate in any interest or position relating to the future price of Company securities, such as a put option, a call option, or a short sale (including a short sale "against the box," as further described below).

What is a short sale, and what is a short sale "against the box?"

A short sale is a sale of securities that you do not own (i.e., borrowed securities). A short sale "against the box" is a sale of securities you own, but with delayed delivery.

Are standing and limit orders covered by the Policy?

Unless part of a 10b5-1 Plan, standing or limit orders should be used only for a very brief period of time, if at all. A standing order placed with a broker to sell or purchase Company stock at a specified minimum or maximum price leaves you with no control over the timing of the transaction. The limit order could be executed by the broker when you are aware of material nonpublic information, which would result in unlawful insider trading. Irrespective, for Section 16 Insiders and Pre-clearance Persons, they cannot extend beyond the pre-clearance period approved by the Compliance Officer.

Can I hold Company securities in a margin account?

No. Securities held in a margin account or pledged as collateral for a loan may be sold without your consent, either by the broker if you fail to meet a margin call or by the lender in foreclosure if you default on the loan. Because a margin or foreclosure sale may occur at a time when you are aware of material nonpublic information or otherwise are not permitted to trade in Company securities, you are prohibited from holding Company securities in a margin account or pledging Company securities as collateral for a loan.

Under what circumstances can I pledge Company securities as collateral for a loan?

An exception to the prohibition on using Company securities as collateral for a loan (not including margin debt) may be granted by the Compliance Officer where you have clearly demonstrated the financial capacity to repay the loan without resort to the pledged securities. If you wish to pledge Company securities as collateral for a loan, you must submit a request for approval to the Compliance Officer at least two weeks prior to the proposed execution of documents evidencing the proposed pledge.

I have a hardship or other urgent need to sell Company shares, or exercise a stock option so I can sell some Company shares. Is that okay?

No. It does not matter that there may exist a justifiable reason for a purchase or sale apart from the nonpublic information; if a Covered Person has material nonpublic information, the prohibition still applies.

I know that disclosures of material nonpublic information are prohibited under the Policy; is it okay if I monitor or participate in a chat room?

No. A Covered Person may not participate, in any manner other than passive observation, in any investment or stock-related Internet "chat" rooms, blogs, social media sites, message boards or other similar online forums relating to the Company without the prior approval of the Compliance Officer and in compliance with the Company's Corporate Communications and Social Media Policies and any other applicable policy.

What are the procedures for trading under a 10b5-1 Plan?

Any person seeking to trade under a 10b5-1 Plan must put in place such a plan that complies with the requirements of Rule 10b5-1. The establishment and implementation of any 10b5-1 Plan will be the sole responsibility of the person seeking to establish such a plan. Compliance Officer approval of a 10b5-1 Plan will not be considered a determination by the Company or the Compliance Officer that the 10b5-1 Plan satisfies the requirements of Rule 10b5-1. The Company reserves the right to prevent any transactions in Company securities, even those pursuant to a 10b5-1 Plan, in the sole discretion of the Compliance Officer.

No trades will be treated as having been made pursuant to a 10b5-1 Plan under this Policy unless it complies with all requirements set forth in Section IV Statement of Company Policy—Permitted Trades under 10b5-1 Plans, above.

What are my obligations once I am no longer providing services to the Company?

If you are aware of material nonpublic information when your employment or service relationship terminates, you may not trade in Company securities until that information has become public or is no longer material.

How does the Policy apply to trades by the Compliance Officer?

The Compliance Officer may not trade in Company securities unless the trade has been approved by the Company's Chief Executive Officer in accordance with this Policy.

What additional duties does the Compliance Officer have?

In addition to the duties of the Compliance Officer specified in the Policy, the Compliance Officer or its designee, will:

- Respond to inquiries relating to this Policy and its procedures.

- Designate and announce special trading Blackout Periods during which Covered Persons may not trade in Company securities.

- Revise this Policy as necessary to reflect changes in federal or state laws and regulations, subject to approval by the Board or a duly authorized committee thereof.

- Maintain (with the assistance of his or her designees) as Company records, originals or copies of all documents required by the provisions of this Policy or the procedures set forth herein, and copies of all required SEC reports relating to insider trading, including without limitation Forms 3, 4, 5 and 144 and Schedules 13D and 13G.

APPENDIX B

Section 16 Insiders

ROLE / FUNCTION
Chief Executive Officer
Chief Financial Officer
Chief Technical Operations Officer
Chief Scientific Officer
Chief Medical Officer
Chief Business Development Officer
Chief People & Communications Officer
President & Chief Operating Officer
All Members of the Board of Directors

Pre-clearance Persons

ROLE / FUNCTION
General Counsel
All Senior Vice Presidents, Vice Presidents, and Executive Directors
Senior Strategic Advisor
Science Advisory Board Member
All Investor Relations and Commercial Employees, Contractors and Consultants
All Clinical Sciences Employees, Contractors, and Consultants
All Accounting & Finance Employees, Contractors and Consultants
All Legal Employees, Contractors and Consultants
All Business Development Employees, Contractors and Consultants
All Alliance Management / Global Program Management Employees, Contractors and Consultants
All Information Technology Employees, Contractors and Consultants
All Executive Assistant(s) / Assistant (s) to Senior Management Team

APPENDIX C

Exceptions to the Multiple, Overlapping 10b5-1 Plan Restriction

Such exceptions are:

- An eligible "sell-to-cover" 10b5-1 Plan where such plan authorizes an agent to sell only such securities as are necessary to satisfy tax withholding obligations arising exclusively from the vesting of a compensatory award, such as restricted stock or stock appreciation rights, and the Insider does not otherwise exercise control over the timing of such sales. For the avoidance of doubt, this exception does not extend to sales incident to the exercise of option awards.

- A series of separate contracts with different broker-dealers or other agents acting on behalf of the person (other than the Company) to execute trades thereunder may be treated as a single 10b5-1 Plan, provided that the individual constituent contracts with each broker-dealer or other agent, when taken together as a whole, meet all of the applicable conditions of and remain collectively subject to the provisions of Rule 10b5-1, including that a modification of any individual contract acts as modification of the whole 10b5-1 Plan, as defined in Rule 10b5-1(c)(1)(iv). The substitution of a broker-dealer or other agent acting on behalf of the person (other than the Company) for another broker-dealer that is executing trades pursuant to a 10b5-1 Plan shall not be a "Plan Modification" as long as the purchase or sales instructions applicable to the substitute and substituted broker are identical with respect to the prices of securities to be purchased or sold, dates of the purchases or sales to be executed, and amount of securities to be purchased or sold.

- One later-commencing 10b5-1 Plan for purchases or sales of any securities of the Company on the open market under which trading is not authorized to begin until after all trades under the earlier-commencing 10b5-1 Plan are completed or expired without execution. However, the first trade under such later-commencing 10b5-1 Plan must be scheduled after the "Effective Cooling-Off Period," or the Cooling-Off Period that would be applicable to the later-commencing 10b5-1 Plan if the date of adoption of the later-commencing 10b5-1 Plan were deemed to be the date of termination of the earlier-commencing 10b5-1 Plan.

Exceptions to the Single-Trade 10b5-1 Plan Restriction

There is an exception for eligible "sell-to-cover" 10b5-1 Plans where the plan authorizes an agent to sell only such securities as are necessary to satisfy tax withholding obligations arising exclusively from the vesting of a compensatory award, such as restricted stock or stock appreciation rights, and the Insider does not otherwise exercise control over the timing of such sales.

Exhibit 23.1

CONSENT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

We consent to the incorporation by reference in the following Registration Statements:

1. Registration Statement on Form S-3 (No. 333-275525),
2. Registration Statement on Form S-8 (No. 333-227551) pertaining to the 2018 Equity Incentive Plan, 2018 Employee Stock Purchase Plan, and 2004 Stock Plan of Sutro Biopharma, Inc.,
3. Registration Statement on Form S-8 (No. 333-230641) pertaining to the 2018 Equity Incentive Plan and 2018 Employee Stock Purchase Plan of Sutro Biopharma, Inc.,
4. Registration Statement on Form S-8 (No. 333-237202) pertaining to the 2018 Equity Incentive Plan and 2018 Employee Stock Purchase Plan of Sutro Biopharma, Inc.,
5. Registration Statement on Form S-8 (No. 333-254456) pertaining to the 2018 Equity Incentive Plan and 2018 Employee Stock Purchase Plan of Sutro Biopharma, Inc.,
6. Registration Statement on Form S-8 (No. 333-258603) pertaining to the 2021 Equity Inducement Plan of Sutro Biopharma, Inc.,
7. Registration Statement on Form S-8 (No. 333-263113) pertaining to the 2018 Equity Incentive Plan and 2018 Employee Stock Purchase Plan of Sutro Biopharma, Inc.,
8. Registration Statement on Form S-8 (No. 333-267194) pertaining to the Amended and Restated 2021 Equity Inducement Plan of Sutro Biopharma, Inc.,
9. Registration Statement on Form S-8 (No. 333-270055) pertaining to the 2018 Equity Incentive Plan, 2018 Employee Stock Purchase Plan and Amended and Restated 2021 Equity Inducement Plan of Sutro Biopharma, Inc.,
10. Registration Statement on Form S-8 (No. 333-277404) pertaining to the 2018 Equity Incentive Plan and 2018 Employee Stock Purchase Plan of Sutro Biopharma, Inc., and
11. Registration Statement on Form S-8 (No. 333-285346) pertaining to the 2018 Equity Incentive Plan and 2018 Employee Stock Purchase Plan of Sutro Biopharma, Inc.

of our reports dated March 13, 2025, 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, 2024.

/s/ Ernst & Young LLP

San Mateo, California
March 13, 2025

Exhibit 31.1

**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: March 13, 2025

/s/ William J. Newell

William J. Newell

Chief Executive Officer

(Principal Executive Officer)

Exhibit 31.2

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: March 13, 2025

/s/ Edward C. Albini
Edward C. Albini
Chief Financial Officer
(Principal Accounting Officer and Principal Financial Officer)

Exhibit 32.1

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, 2024 (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: March 13, 2025

/s/ William J. Newell
William J. Newell
Chief Executive Officer
(Principal Executive Officer)

Exhibit 32.2

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, 2024 (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: March 13, 2025

/s/ Edward C. Albini
Edward C. Albini
Chief Financial Officer
(Principal Financial Officer and Principal Accounting Officer)

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