# 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**

# Corvus Pharmaceuticals, Inc.
**(Exact name of registrant as specified in its charter)**

| **Delaware** | **001-37719** | **46-4670809** |
|---|---|---|
| (State or other jurisdiction of incorporation) | (Commission File Number) | (IRS Employer Identification Number) |

**901 Gateway Boulevard, Third Floor, South San Francisco, CA 94080**
(Address of principal executive offices, including Zip Code)
Registrant's telephone number, including area code: (650) 900-4520

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

| Title of each class | Trading symbol(s) | Name of each exchange on which registered |
|---|---|---|
| Common Stock, Par Value $0.0001 per share | CRVS | 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 and post 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 ☒

As of June 30, 2024, the aggregate market value of Common Stock held by non-affiliates of the registrant was approximately $69.0 million, computed by reference to the closing price as reported on The Nasdaq Stock Market. As of March 25, 2025, 68,135,796 shares of the registrant's common stock were outstanding.

**DOCUMENTS INCORPORATED BY REFERENCE**

Portions of the registrant's definitive proxy statement to be filed for its 2023 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.

**CORVUS PHARMACEUTICALS, INC.**
**ANNUAL REPORT ON FORM 10-K**
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**Forward-Looking Statements**

This Annual Report on Form 10-K contains forward-looking statements that involve risks and uncertainties. All statements other than statements of historical facts contained in this report are forward-looking statements. In some cases, you can identify forward-looking statements by terminology such as "may," "could," "will," "would," "should," "expect," "plan," "anticipate," "believe," "estimate," "intend," "predict," "seek," "contemplate," "potential" or "continue" or the negative of these terms or other comparable terminology. These forward-looking statements include, but are not limited to, statements about:

- our expectations and beliefs regarding the potential benefits of our product candidates;
- our expectations regarding the clinical effectiveness of our product candidates and utility of our biomarker data;
- the anticipated timing, costs and conduct of our ongoing and planned clinical trials for soquelitinib (formerly CPI-818), ciforadenant and mupadolimab and planned preclinical studies and clinical trials for other product candidates in our development programs, including the anticipated timing of data from such trials and related reports;
- the scope and design of our planned clinical trials, including but not limited to target patient enrollment numbers;
- our ability to develop, acquire and advance product candidates into, and successfully complete, clinical trials;
- the timing of the completion of our ongoing and planned clinical trials of soquelitinib, ciforadenant and mupadolimab and the timing and availability of clinical data from such clinical trials;
- clinical and regulatory development plans with respect to soquelitinib, ciforadenant and mupadolimab, and our other product candidates;
- our strategy to protect, establish and maintain our proprietary technology and intellectual property rights covering our product candidates, including the projected terms of patent protection;
- the potential benefits of strategic collaborations, including our collaboration with Angel Pharmaceuticals, our ongoing business development efforts and our ability to enter into strategic arrangements;
- developments and projections relating to our competitors and our industry, including competing therapies and our beliefs regarding our competitive advantage;
- our estimates regarding the effect of changes in the tax code as a result of recent federal tax legislation and uncertainty as to how some of those changes may be applied; and
- our estimates regarding expenses, future revenue, capital requirements and needs for additional financing, including our forecast of the period of time through which our financial resources will be adequate to support our operations.

Any forward-looking statements in this Annual Report on Form 10-K reflect our current views with respect to future events or to our future financial performance and involve known and unknown risks, uncertainties and other factors that may cause our actual results, performance or achievements to be materially different from any future results, performance or achievements expressed or implied by these forward-looking statements. Factors that may cause actual results to differ materially from current expectations include, among other things, those listed under Part I, Item 1A. Risk Factors and discussed elsewhere in this Annual Report on Form 10-K. Given these uncertainties, you should not place

undue reliance on these forward-looking statements. Except as required by law, we assume no obligation to update or revise these forward-looking statements for any reason, even if new information becomes available in the future.

This Annual Report on Form 10-K also contains estimates, projections and other information concerning our industry, our business and the markets for certain drugs, including data regarding the estimated size of those markets, their projected growth rates and the incidence of certain medical conditions. Information that is based on estimates, forecasts, projections or similar methodologies is inherently subject to uncertainties, and actual events or circumstances may differ materially from events and circumstances reflected in this information. Unless otherwise expressly stated, we obtained this industry, business, market and other data from reports, research surveys, studies and similar data prepared by third parties, industry, medical and general publications, government data and similar sources. In some cases, we do not expressly refer to the sources from which this data is derived. In that regard, when we refer to one or more sources of this type of data in any paragraph, you should assume that other data of this type appearing in the same paragraph is derived from the same sources, unless otherwise expressly stated or the context otherwise requires.

Except where the context otherwise requires, in this Annual Report on Form 10-K, "we," "us," "our" and the "Company" refer to Corvus Pharmaceuticals, 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.

**Risk Factor Summary**

Below is a summary of the principal factors that make an investment in our common stock speculative or risky. This summary does not address all of the risks that we face. Additional discussion of the risks summarized in this risk factor summary, and other risks that we face, can be found below under the heading "Risk Factors" and should be carefully considered, together with other information in this Annual Report on Form 10-K and our other filings with the Securities and Exchange Commission (SEC) before making investment decisions regarding our common stock.

- We have incurred significant operating losses since our inception and expect to incur significant losses for the foreseeable future. We may never generate any revenue or become profitable or, if we achieve profitability, we may not be able to sustain it.

- We will require substantial additional financing to achieve our goals, and a failure to obtain this necessary capital when needed on acceptable terms, or at all, could force us to delay, limit, reduce or terminate our product development, other operations or commercialization efforts.

- Our product candidates are in various stages of development and may fail or suffer delays that materially and adversely affect their commercial viability. If we are unable to advance our product candidates through clinical development, obtain regulatory approval and ultimately commercialize such product candidates, or experience significant delays in doing so, our business will be materially harmed.

- Clinical drug development involves a lengthy and expensive process with an uncertain outcome, and the results of preclinical studies and early clinical trials are not necessarily predictive of future results. Any product candidate we or any of our existing or potential future collaborators advance into clinical trials, including soquelitinib, ciforadenant and mupadolimab, may not have favorable results in later clinical trials, if any, or receive regulatory approval.

- Any termination or suspension of, or delays in the commencement or completion of, our planned clinical trials could result in increased costs to us, delay or limit our ability to generate revenue and adversely affect our commercial prospects.

- Our product candidates are subject to extensive regulation, compliance with which is costly and time consuming, and such regulation may cause unanticipated delays or prevent the receipt of the required approvals to commercialize our product candidates.

- We are conducting and plan to conduct clinical trials for soquelitinib, ciforadenant and mupadolimab, and we and Angel Pharmaceuticals may in the future, conduct additional clinical trials of product candidates at sites outside the United States, and the FDA may not accept data from trials conducted in foreign locations.

- If we encounter difficulties enrolling subjects in our clinical trials, our clinical development activities could be delayed or otherwise adversely affected.

- The occurrence of serious complications or side effects in connection with use of our product candidates, either in clinical trials or post-approval, could lead to discontinuation of our clinical development programs, refusal of regulatory authorities to approve our product candidates or, post-approval, revocation of marketing authorizations or refusal to approve new indications, which could severely harm our business, prospects, operating results and financial condition.

- We may not be successful in our efforts to identify or discover additional product candidates.

- We rely, and expect to continue to rely, on third parties to conduct our clinical trials. If these third parties do not meet our deadlines or otherwise conduct the trials as required, our clinical development programs could be delayed or unsuccessful and we may not be able to obtain regulatory approval for or commercialize our product candidates when expected, or at all.

- We rely on third parties to conduct some or all aspects of our manufacturing, research and preclinical and clinical testing, and these third parties may not perform satisfactorily.

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

- If we are unable to commercialize our product candidates or if we experience significant delays in obtaining regulatory approval for, or commercializing, any or all of our product candidates, our business will be materially and adversely affected.

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

- 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.

- An active, liquid and orderly market for our common stock may not be sustained.

- The trading price of the shares of our common stock could be highly volatile, and investors in our common stock could incur substantial losses.

**Part I**

## Item 1. Business

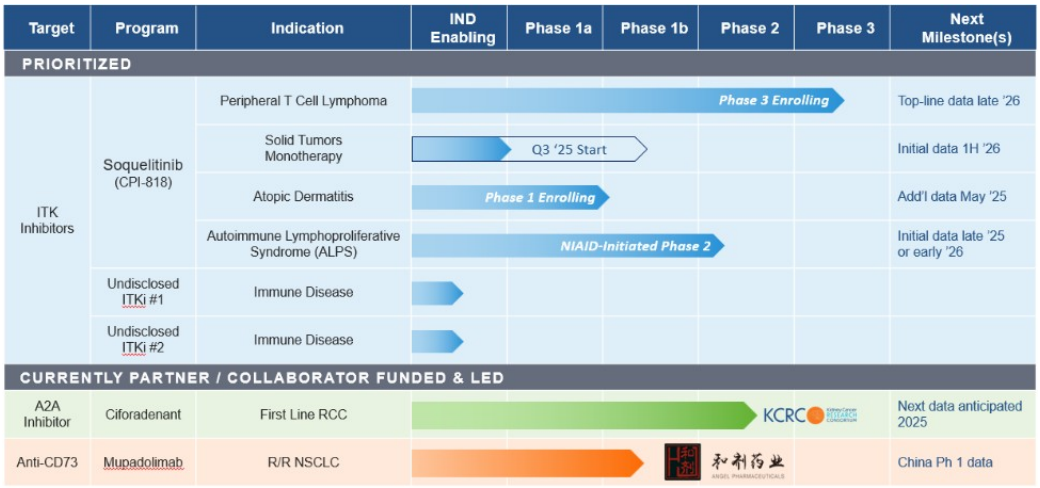
### Overview

We are a clinical stage biopharmaceutical company developing product candidates that precisely target proteins that are critical to immune cell maturation and function. We believe our proprietary product candidates have broad potential to address cancers, immune mediated diseases and inflammatory diseases. Our lead product candidate, soquelitinib (formerly CPI-818), is designed to bind specifically to a protein, interleukin 2 inducible T cell kinase (ITK), involved in T cell activation, T cell receptor signaling and T cell differentiation and function. Based on the proposed mechanism of action, we believe soquelitinib has the potential to be utilized to inhibit the production of a number of inflammatory cytokines involved in diseases such as atopic dermatitis, asthma, psoriasis and fibrotic diseases. In preclinical studies, Soquelitinib has affected T cell differentiation leading to enhanced function of T cells involved in tumor cell killing.

Since the immune cells targeted by our product candidates play a role in many diseases, our strategy is to leverage our research and development capabilities by evaluating our product candidates in clinical trials where there is an understanding of the role of specific T cells in the target indication and where we believe such product candidates have the broadest potential. We believe this strategy has enabled us to move rapidly from preclinical to clinical trials in diverse disease areas, each with large unmet needs. Soquelitinib entered a registrational, Phase 3 clinical trial for relapsed T cell lymphomas and is also being evaluated in a randomized, placebo controlled Phase 1 trial in patients with atopic dermatitis. We have two additional product candidates which are in clinical development for the treatment of various solid tumors, also based on modulation of immune function.

### Product Pipeline

Our product candidate pipeline and anticipated milestones include the following:




***Soquelitinib (CPI-818), ITK Inhibitor.*** Soquelitinib is an investigational selective, orally bioavailable, covalent inhibitor of ITK. ITK, an enzyme that functions in T cell signaling and differentiation, is expressed predominantly in T cells, which are lymphocytes that play a vital role in immune responses. T cell lymphomas are malignancies of T cells that proliferate and spread throughout the body. These lymphomas often have uncontrolled tonic signaling through the T cell receptor pathway, which involves ITK. Inhibition of ITK with soquelitinib could result in blockade of this signaling

pathway and control the growth of the malignancy. In addition, one of the key survival mechanisms of both lymphomas and solid tumors is believed to be the reprogramming of normal T cells to create an environment in the tissues that inhibits an anti-tumor immune response and favors tumor growth. We believe highly selective inhibitors of this enzyme will facilitate induction of normal T cell anti-tumor immunity and may be useful in the treatment of solid tumors as well as lymphomas. A normal functioning immune system maintains balance between inflammation, needed to fight infection or eliminate noxious agents, and suppression of inflammation necessary when the inflammatory signals are eliminated. This balance is restored through the action of T regulatory cells, which dampen inflammatory responses. ITK plays a vital role in the function of these regulatory T cells where it acts to modulate immune responses.

In ITK genetic knockout mice, which completely lack expression of ITK, T cells exhibit defects in T helper cell differentiation and cytokine secretion but retain the ability to differentiate into cytotoxic T cells that secrete IL-2 and interferon gamma ("IFNg"), which are the cells responsible for tumor rejection. We believe that skewing T helper cell differentiation to favor cytotoxic T cells, known as Th1 skewing, may be beneficial in treating T cell lymphomas and many other types of cancer. Mice with genetic knock-out of ITK also demonstrate a reduction in Th2 cells, which produce the cytokines that are often responsible for autoimmunity and allergy such as interleukin (Il) Il-4, Il-5, Il-13, Il-17 and many others.

We have designed and developed soquelitinib to covalently target the cysteine amino acid residue at position 442 in the ITK protein. We believe this irreversible targeting of ITK has the potential to provide a potent, selective and prolonged duration of activity without the need for high systemic exposures and thereby improve the therapeutic window. This approach was previously used by our cofounders to generate ibrutinib. Selective inhibition of ITK can block the production and function of Th2 and Th17 helper T cells, potentially leading to a biasing toward the differentiation of naïve T cells into Th1 helper T cells, a process known as Th1 skewing. Th1 cells lead to the generation of killer T cells that can eliminate tumor cells or viral infected cells. Th1 cells produce interferon gamma and tumor necrosis factor that are cytokines known to destroy cancer cells. We believe, based on our preclinical and Phase 1/1b data from our T cell lymphoma clinical trial, that soquelitinib has the potential to reprogram normal immune responses that also could be beneficial for the treatment of certain autoimmune, inflammatory and allergic diseases. Overactive Th2 and Th17 cells are known to play a role in autoimmune, inflammatory and allergic diseases, which can potentially be ameliorated by selective ITK inhibition by blocking Th2 and Th17 function and their production of inflammatory cytokines such as IL4, IL5, IL13, IL17 and others.

*Soquelitinib for treatment of T cell lymphomas.*

Soquelitinib is currently being studied both in cancer and in immune mediated disease. A Phase 1/1b clinical trial was conducted in patients with relapsed T cell lymphomas that was designed to select the optimal dose of soquelitinib and evaluate its safety, pharmacokinetics ("PK"), target occupancy, immunologic effects, biomarkers and efficacy. The study is no longer enrolling new patients, however, some of the patients remain on therapy and are continuing to receive follow-up monitoring. The study employs an adaptive, expansion cohort design, with an initial phase that evaluated escalating doses (100, 200, 400 or 600 mg taken twice a day) in successive cohorts of patients, followed by a second phase that was designed to evaluate safety and tumor response to the recommended dose of soquelitinib in disease-specific patient cohorts. The study has enrolled patients from the United States, Australia, China and South Korea with several types of advanced, refractory T cell lymphomas. No dose limiting toxicities were observed in any of the dose levels. As of November 27, 2024, and in a safety population of 75 patients, no hematologic, renal or hepatic treatment-related adverse events were observed and the most common grade 3 to 4 adverse event was pruritus, seen in four patients with lymphoma involving skin. The optimum dose was determined to be 200 mg twice per day based on anti-tumor efficacy and pharmacodynamic studies which revealed full occupancy of the ITK active site by the drug. This dose was also consistent with dose-response effects seen in preclinical experiments both in vitro and in vivo.

Interim data from the Phase 1/1b clinical trial were presented at the American Society of Hematology Annual Meeting ("ASH") in December 2023. At that time, we also announced interim data from the trial as of November 21, 2023 on 21 evaluable patients receiving a dose of 200 mg twice per day ("200 mg BID") and revealed an objective response rate ("ORR") of 33.3% with 3 complete responses ("CRs") and 4 partial responses ("PRs").

As of July 16, 2024, 25 patients (≤ 3 prior therapies) were enrolled in the trial at the 200 mg BID dose,

including 23 evaluable patients. For the 23 evaluable patients, objective responses (CR plus PR) were seen in nine patients (39%), including six CRs (26%) and three PRs. The median progression free survival was 6.2 months. As of November 27, 2024, four of the responding patients remained on therapy; 3 with CRs and one with a PR.

In August 2023, we completed an End-of-Phase/Pre-Phase 3 meeting with the Food and Drug Administration ("FDA") regarding our plans to conduct a potentially registrational Phase 3 clinical trial of soquelitinib in relapsed peripheral T cell lymphoma ("PTCL"). The FDA provided feedback on our proposed registration trial, including the proposed endpoints. We initiated this clinical trial in the third quarter of 2024. The clinical trial is designed to enroll a total of 150 patients with relapsed PTCL that have received ≥ 1 prior therapy and≤3 prior therapies. Patients are being randomized 1:1 to soquelitinib 200 mg two-times a day or one of the standard of care chemotherapies. The standard of care agent is selected based on the physician's choice of either belinostat or pralatrexate. The primary endpoint is progression-free survival. Secondary endpoints include objective response rate, overall survival and duration of response. Leading academic and private medical centers with significant experience in lymphoma research are participating in the trial, including investigators who have conducted other Phase 3 clinical trials in T cell lymphoma and authored many peer-reviewed articles on lymphomas. There are currently no FDA fully approved agents for the treatment of relapsed PTCL. In July 2024, soquelitinib received Fast Track designation for treatment of adult patients with relapsed or refractory peripheral T cell lymphoma after at least 2 lines of systemic therapy.

As reported at the International Conference of Malignant Lymphoma in June 2023, preclinical data suggest that ITK inhibition with soquelitinib has the potential to treat solid and hematological cancers based on its novel proposed mechanism of action. Tumor immune responses were enhanced by the modulation of T cell differentiation resulting in increased T cell cytolytic capacity, increased migration of T cells into the tumor and reduced T cell exhaustion. Highlights of the presentation included:

- monotherapy provided statistically significant inhibition of tumor growth in established tumors in the following cancer models: EL4 TCL (T cell lymphoma), A20 B cell lymphoma and CT26 colon cancer.

- In the EL4 TCL model, treatment with soquelitinib led to increased infiltration of normal CD8+ T cells into the tumor. In addition, these CD8+ T cells had higher expression of perforin, an effector molecule produced by killer T cells that is involved in killing cancer cells.

- In the CT26 colon cancer model, the depletion of normal CD8 cells reduced the activity observed for soquelitinib treatment, suggesting that its potential mechanism of action involves the production of normal CD8+ T cells.

- In the CT26 colon cancer model, treatment with soquelitinib reduced the expression of T cell exhaustion markers. T cell exhaustion is a phenomenon seen in tumors and chronic infections where prolonged exposure to antigens results in exhausted or ineffective T cell function and inability to eliminate tumors or infections.

- In other murine studies using antigen primed T cells that were repeatedly stimulated, soquelitinib reduced the development of T cell exhaustion and reversed it in already exhausted T cells. These reinvigorated T cells regained their cancer cell killing capacity.

We believe these findings suggest that the inhibition of ITK by soquelitinib produced changes in the tumor microenvironment that enhanced anti-tumor immunity creating a less favorable environment for tumor growth and provides the rationale for clinical investigation in a monotherapy trial of soquelitinib in solid tumors. We are planning a Phase 1b/2 clinical trial, in collaboration with the Kidney Cancer Research Consortium, of soquelitinib in solid tumors in patients with renal cell cancer who have failed checkpoint inhibitor therapy.

In December 2024, we and our academic collaborators published results describing the chemistry, enzymology and preclinical anti-tumor activity of soquelitinib in the journal npj Drug Discovery. Key results from the publication include that soquelitinib:

- Selectively bound to and inhibited ITK function while sparing other closely related kinases, including resting lymphocyte kinase.

- Inhibited Th2 T cell function and the production of various Th2 cytokines leading to Th1 skewing and production of interferon gamma and tumor necrosis factor, which are important cytokines in tumor rejection. Th2 cytokines have been previously implicated in promoting tumor growth and are also involved in autoimmune and allergic diseases.

- Activated cytotoxic killer cells and increases infiltration of these cells into tumors.

- Reduced and reversed T cell exhaustion resulting in a more potent and prolonged immune response. T cell exhaustion is often a major reason for resistance to immune checkpoint therapy.

- Led to in vivo anti-tumor activity in several mouse tumor models, including colon, renal, melanoma, B cell and T cell tumor.

In November 2023, we announced the posting of preclinical data on soquelitinib in bioRxiv that demonstrated that ITK's selective inhibition produced therapeutic benefits in several autoimmune and allergy preclinical models, including psoriasis, asthma, pulmonary fibrosis, scleroderma and graft versus host disease. The mechanism of action involves the inhibition of Th2 and Th17 cells and their subsequent production of cytokines such as IL-4, IL-5, IL-17 and other cytokines involved in these diseases. The novel mechanism is a result of ITK inhibition and blockade of formation of Th2 and Th17 cells.

The FDA has granted Fast Track Designation to soquelitinib for the treatment of adult patients with relapsed or refractory peripheral T cell lymphoma (PTCL) after at least two lines of systemic therapy. In addition to Fast Track Designation, soquelitinib has also been granted FDA Orphan Drug Designation for the treatment of T cell lymphoma.

*Soquelitinib for treatment of atopic dermatitis.*

In April 2024, we initiated a randomized, double-blind, placebo-controlled Phase 1 clinical trial with soquelitinib in patients with moderate to severe atopic dermatitis that previously failed one prior topical or systemic therapy. The clinical trial is planned to enroll 64 patients into one of four dosing cohorts in a 3:1 ratio (12 active and 4 placebo) to receive either soquelitinib or placebo. The cohorts are sequentially enrolled and will examine 100 mg oral twice per day, 200 mg oral once per day, 200 mg oral twice per day and 400 mg oral once per day. Patients are treated for 28 days and are then followed for an additional 30 days with no therapy. The primary endpoints include safety and tolerability, and efficacy, measured by improvement in Eczema Area and Severity Index ("EASI") score, Investigator Global Assessment ("IGA"), reduction in itch and various cytokine biomarkers. EASI scores are also evaluated by the percent of patients that achieve a specified percent reduction in EASI score – EASI 50 for patients that achieved a 50% reduction; EASI 75 for a 75% reduction; and EASI 90 for a 90% reduction. Corvus and a data monitoring committee will be able to monitor the data from the trial as the trial progresses.

On January 13, 2025, we reported top-line results from 16 patients in Cohort 1 (12 patients in the soquelitinib group receiving 100 mg orally twice per day vs. four receiving placebo) and 10 patients in Cohort 2 (seven patients in the soquelitinib group receiving 200 mg orally once per day vs. three receiving placebo) for which 28 days of treatment had been completed. For those 19 patients in the soquelitinib group, 26% achieved IGA 0 or 1 and 37% achieved EASI 75; and of the seven in the placebo group, none achieved IGA 0 or 1 or EASI 75.

No significant safety issues were observed and no clinically significant laboratory abnormalities were seen. All 10 patients from Cohort 2 completed 28 days of dosing at the full dose of 200 mg orally once per day. Cohort 2 of the trial is fully enrolled (N=16) and we are nearing completion of enrollment in the third cohort. We plan to report topline results from Cohorts 1, 2 and 3 in May 2025. To date, over 100 patients have been treated with soquelitinib on our lymphoma and atopic dermatitis clinical trials. Some of the lymphoma patients received continuous therapy for up to two years.

Beyond our current and planned clinical trials for soquelitinib, we also continue to advance our next-generation ITK inhibitor preclinical product candidates, which were designed to deliver precise T-cell modulation that is optimized for specific immunology indications. The next-generation ITK inhibitor candidates are part of our ongoing business development efforts to maximize the potential of our ITK inhibitor programs and other programs.

We have issued patents covering composition of matter and uses of our ITK inhibitors and hold exclusive worldwide rights (except for greater China) for all indications.

***Ciforadenant Adenosine A2A Receptor Antagonist.*** Our second product candidate, ciforadenant, is an oral, small molecule antagonist of the A2A receptor for adenosine designed to disable a tumor's ability to subvert attack by the immune system by blocking the binding of immunosuppressive adenosine in the tumor microenvironment to the A2A receptor. In 2018, we published preclinical findings in animal tumor models demonstrating that treatment with anti-CTLA4 antibody combined with ciforadenant provided synergistic anti-tumor activity based on a novel proposed mechanism of action. We are collaborating with the Kidney Cancer Research Consortium to evaluate ciforadenant in an open label Phase 1b/2 clinical trial as a first line therapy for metastatic RCC in combination with ipilimumab (anti-CTLA-4) and nivolumab (anti-PD-1). The efficacy endpoints for the trial are deep response rate, defined as CR plus PRs of greater than 50% tumor volume reduction as well as progression free survival. The clinical trial is planned to enroll up to 60 patients. The protocol defined pre-specified statistical threshold for efficacy is a 50% increase above the 32% deep response rate seen with previous ipilimumab/nivolumab combination trials in RCC conducted by investigators at the Kidney Cancer Research Consortium. An interim analysis performed on May 31, 2024 of the clinical trial has met the interim threshold for efficacy and therefore enrollment continued. Enrollment in the clinical trial now has been completed and patients are being followed.

***Mupadolimab, B Cell Activating Anti-CD73 Antibody.*** Our third product candidate is mupadolimab, a humanized monoclonal antibody that is designed to react with a specific site on CD73. In both preclinical and in vivo studies, mupadolimab has demonstrated binding to various immune cells and the enhancement of immune responses by activating B cells. While we believe mupadolimab has the potential to be an important new therapeutic agent with a novel mechanism of action for the treatment of a broad range of cancers and infectious diseases, we are waiting to initiate a potential Phase 2 randomized clinical trial in order to prioritize the development of our other two lead product candidates. Angel Pharmaceuticals is continuing the development of mupadolimab in China.

**Manufacturing**

We do not own or operate, and currently have no plans to establish any manufacturing facilities. We currently rely, and expect to continue to rely, on third parties for the manufacture of our product candidates for clinical testing, as well as for manufacture of any products that we may commercialize. We are able to internally produce small quantities of our product candidates required for relatively short preclinical animal studies. We believe that this allows us to accelerate the drug development process by not having to rely on third parties for all of our research and development needs. However, we currently rely, and expect to continue to rely, on a number of contract manufacturers to produce sufficient quantities of our product candidates for use in more lengthy preclinical development and clinical trials and in relation to any future commercialization of our product candidates. Additional contract manufacturers are used to fill, label, package and distribute investigational drug products. This strategy allows us to maintain a more efficient infrastructure, avoid depending on our own manufacturing facility and equipment while simultaneously enabling us to focus our expertise on developing our products. Although we believe we have multiple potential sources for the manufacturing of our product candidates, we currently rely on several different manufacturers who supply different components of the soquelitinib and ciforadenant molecules, on one manufacturer for mupadolimab drug substance and other third-party manufacturers to produce our other product candidates.

**Competition**

The pharmaceutical and biotechnology industries are characterized by intense competition and rely heavily on the ability to move quickly, adapt to changing medical and market needs, and develop and maintain strong intellectual property positions. We believe that the development experience of our scientific and management teams, as well as the strength and promise of our product candidates, provides us with a competitive advantage; nevertheless, we face

potential competition from myriad sources, including pharmaceutical and biotechnology companies, academic institutions, governmental agencies and public and private research institutions.

Soquelitinib is an investigational oral therapy in development for the treatment of immune diseases and cancer. Soquelitinib is designed to precisely inhibit ITK, a critical signaling pathway in the immune system, and is currently in Phase 3 for relapsed and refractory PTCL (R/R PTCL) as well as Phase 1 for atopic dermatitis (AD). If approved for use in patients with AD, we will potentially face branded competition from dupilumab, a biologic approved in 2017, as well as biologics tralokinumab, nemolizumab, and lebrikizumab. In addition, there are several companies developing treatments that may be approved for AD including large pharmaceutical and biotechnology companies such as Pfizer, Sanofi, Amgen, GSK, Lilly, AbbVie, and Incyte.

Currently approved treatments for R/R PTCL include belinostat and pralatrexate, both under accelerated approval. In addition, brentuximab vedotin (BV), is approved for CD30-positive PTCL patients, including front line as well as a subset of previously treated patients. There are also several companies developing treatments for PTCL including, but not limited to, valemetostat (approved in Japan), duvelisib, linperlisib, and golidocitinib (approved in China).

Ciforadenant is an investigational A2A receptor antagonist intended to treat solid tumors. Arcus Biosciences is developing an A2A receptor antagonist for cancer. Mupadolimab is a humanized monoclonal antibody designed to react with a specific site on CD73 and is intended to treat solid tumors. AstraZeneca (AZ) has reported positive results in a Phase 2 clinical trial in Stage 3 NSCLC with the combination of durvalumab and their anti CD73 antibody, oleclumab, and is currently conducting a Phase 3 trial with durvalumab and olecumab.

Many of the companies against which we may compete have significantly greater financial resources and expertise in research and development, manufacturing, preclinical testing, conducting clinical trials, obtaining regulatory approvals and marketing approved products than we do. Smaller or early-stage companies may also prove to be significant competitors, particularly through collaborative arrangements with large and established companies. These competitors also compete with us in recruiting and retaining qualified scientific and management personnel and establishing clinical trials sites and patient registration for clinical trials, as well as in acquiring technologies complementary to, or necessary for, our programs.

**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 our collaborators or other third parties. Our policy is to seek to protect our proprietary position by, among other methods, filing patent applications in the United States and in jurisdictions outside of the United States covering our proprietary technology, inventions, improvements and product candidates that are important to the development and implementation of our business. We also rely on trade secrets and know-how relating to our proprietary technology and product candidates, continuing innovation, and in-licensing opportunities to develop, strengthen and maintain our proprietary position in the field of immuno-oncology. We also plan to rely on data exclusivity, market exclusivity, and patent term extensions when available. Our commercial success will 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 obtain and maintain licenses to use intellectual property owned by third parties; to defend and enforce our proprietary rights, including any patents that we may own in the future; and to operate without infringing on the valid and enforceable patents and other proprietary rights of third parties.

We have in licensed patents and patent applications directed to certain of our product candidates and related uses thereof. We also possess and in license substantial know how and trade secrets relating to the development and commercialization of our product candidates, including related manufacturing processes and technology. As of February 6, 2025, our owned and licensed patent portfolio consisted of fourteen licensed U.S. issued patents, thirteen owned U.S. issued patents, six owned U.S. pending patent applications, four owned pending Patent Cooperation Treaty (“PCT”) applications, and one owned U.S. provisional patent applications directed to soquelitinib, ciforadenant and

mupadolimab, and certain of our other proprietary technology, inventions, improvements or other potential product candidates. In addition, our owned and licensed patent portfolio included forty licensed patents, four licensed patent applications, forty-one owned patents, and thirty owned patent applications pending in jurisdictions outside of the United States that are foreign counterparts to one or more of the foregoing U.S. patents and patent applications. The patents and patent applications outside of the United States in our portfolio are held primarily in Europe, Canada, Japan, South Korea, Australia and China.

With respect to the immuno-oncology product candidates and processes we intend to develop and commercialize in the normal course of business, we intend to pursue patent protection covering, when possible, compositions, methods of use, dosing and formulations. We may also pursue patent protection with respect to manufacturing and drug development processes and technologies.

Issued patents can provide protection for varying periods of time, depending upon the date of filing of the patent application, the date of patent issuance, and the legal term of patents in the countries in which they are obtained. In general, patents issued for applications filed in the United States can provide exclusionary rights for 20 years from the earliest effective filing date. In addition, in certain instances, the term of an issued United States patent that covers or claims an FDA approved product can be extended to recapture a portion of the term effectively lost as a result of the FDA regulatory review period, which is called patent term extension. The restoration period cannot be longer than five years and the total patent term, including the restoration period, must not exceed 14 years following FDA approval. The term of patents outside of the United States varies in accordance with the laws of the foreign jurisdiction, but typically is also 20 years from the earliest effective filing date. The issued United States patents we license from Vernalis directed to the composition of matter of ciforadenant and its method of use for treating disorders treatable by purine receptor blocking are expected to expire around June 2029, excluding any patent term extension that may be available. The granted U.S. and foreign patents, pending U.S. and foreign patent applications, and PCT International patent application, if granted as patents, that we own directed to the methods of treatment for ciforadenant are expected to expire between December 2036 and April 2045, excluding any patent term extension that may be available. The granted U.S. and foreign patents and pending U.S. and foreign patent applications, if granted as patents, that we own directed to the composition of matter and methods of treatment for mupadolimab are expected to expire between December 2036 and May 2042, excluding any patent term extension that may be available. The granted U.S. and foreign patents, pending U.S. and foreign patent applications, PCT International patent application, and US provisional applications, if granted as patents, that we own directed to the composition of matter and methods of treatment for soquelitinib are expected to expire between November 2037 and December 2044, excluding any patent term extension that may be available. 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 immuno-oncology has emerged in the United States. The relevant patent laws and their interpretation outside of the United States is also uncertain. Changes in either the patent laws or their interpretation in the United States and other countries may diminish our ability to protect our technology or product candidates and enforce the patent rights that we license, and could affect the value of such intellectual property. In particular, our ability to stop third parties from making, using, selling, offering to sell, or importing products that infringe our intellectual property will depend in part on our success in obtaining and enforcing patent claims that cover our technology, inventions, and improvements. With respect to both licensed and company-owned intellectual property, we cannot guarantee that patents will be granted with respect to any of our pending patent applications or with respect to any patent applications we may file in the future, nor can we be sure that any patents that may be granted to us in the future will be commercially useful in protecting our products, the methods of use or manufacture of those products. Moreover, even the issued patents that we license do not guarantee us the right to practice our technology in relation to the commercialization of our products. Patent and other intellectual property rights in the pharmaceutical and biotechnology space are evolving and involve many risks and uncertainties. For example, third parties may have blocking patents that could be used to prevent us from commercializing our product candidates and practicing our proprietary technology, and the issued patents that we in-license 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 products or could limit the term of patent protection that otherwise may exist for our product candidates. In

addition, the scope of 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 that are outside the scope of the rights granted under any issued patents that we own or exclusively in-license. For these reasons, we may face competition with respect to our 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 patent protection for such product may expire or remain in force for only a short period following commercialization, thereby reducing the commercial advantage the patent provides.

**Licenses and Collaborations**

***Vernalis Licensing Agreement***

In February 2015, we entered into a license agreement with Vernalis, pursuant to which we were granted an exclusive, worldwide license under certain patent rights and know-how, including a limited right to grant sublicenses, for all fields of use to develop, manufacture and commercialize products containing certain adenosine receptor antagonists, including ciforadenant. The issued U.S. patents that we in-licensed from Vernalis pursuant to this agreement are directed to the composition of matter of ciforadenant and its method of use for treating disorders treatable by purine receptor blocking and are expected to expire between September 2028 and July 2029, excluding any patent term extension that may be available. Vernalis has the first right to prosecute and maintain the licensed patent rights worldwide, subject to our right with respect to certain of the licensed patents to continue prosecution and maintenance if Vernalis elects not to do so. We also have the right to prosecute and maintain any patent rights that we may own that cover the licensed compounds that do not fall within the licensed patent rights. Pursuant to this agreement, we are required to use commercially reasonable efforts to conduct certain activities to obtain marketing authorizations for licensed products and to conduct certain preclinical and clinical studies for ciforadenant. We also must use commercially reasonable efforts to conduct certain preclinical and clinical studies to support the use of ciforadenant as an immunotherapeutic agent for cancer studies, and to meet certain specified development, regulatory and commercial milestones within specified time periods.

Pursuant to this agreement, we made a one-time cash payment to Vernalis in the amount of $1.0 million upon entering into the agreement. We are also required to make cash milestone payments to Vernalis upon the successful completion of clinical and regulatory milestones for licensed products depending on the indications for which such licensed products are developed and upon achievement of certain sales milestones. In February 2017, we made a milestone payment of $3 million to Vernalis following the expansion of a cohort of patients with renal cell cancer treated with single-agent ciforadenant in our Phase 1/1b clinical trial. During the year ended December 31, 2023, no clinical or regulatory milestones were completed or paid to Vernalis and the aggregate potential milestone payments were approximately $220 million for all indications as of December 31, 2024.

We have also agreed to pay Vernalis tiered incremental royalties based on the annual net sales of licensed products containing ciforadenant on a product-by-product and country-by-country basis, subject to certain offsets and reductions. The tiered royalty rates for products containing ciforadenant range from the mid-single digits up to the low-double digits on a country-by-country net sales basis. The royalties on other licensed products that do not include ciforadenant also increase with the amount of net sales on a product-by-product and country-by-country basis and range from the low-single digits up to the mid-single digits on a country-by-country net sales basis.

The agreement will expire on a product-by-product and country-by-country basis upon the expiration of our payment obligations to Vernalis in respect of a particular product and country. Both parties have the right to terminate the agreement in the event of an uncured material breach by the other party. We may also terminate the agreement at our convenience by providing 90 days written notice, provided that we have not received notice of our own default under the agreement at the time we exercise such termination right. Vernalis may also terminate the agreement if we challenge a licensed patent or undergo a bankruptcy event.

***Scripps Licensing Agreement***

In December 2014, we entered into a license agreement with Scripps, pursuant to which we were granted a non-exclusive, world-wide license for all fields of use under Scripps' rights in certain know-how and technology related to a mouse hybridoma clone expressing an anti-human CD73 antibody, and to progeny, mutants or unmodified derivatives of such hybridoma and any antibodies expressed by such hybridoma, from which we developed mupadolimab. Scripps also granted us the right to grant sublicenses in conjunction with other proprietary rights we hold, or to others collaborating with or performing services for us. Under this license agreement, Scripps has agreed not to grant any additional commercial licenses with respect to such materials, other than march-in rights granted to the U.S. government.

Upon execution of the agreement, we made a one-time cash payment to Scripps of $10,000 and are also obligated to pay a minimum annual fee to Scripps of $25,000. The first minimum annual fee payment is due on the first anniversary of the effective date of the agreement and will be due on each subsequent anniversary of the effective date for the term of the agreement. We are also required to make performance-based cash payments upon successful completion of clinical and sales milestones. The aggregate potential milestone payments are $2.6 million. We are also required to pay royalties on net sales of licensed products (including mupadolimab) sold by us, our affiliates and our sublicensees at a rate in the low-single digits. In addition, should we sublicense the rights licensed under the agreement, we have agreed to pay a percentage of sublicense revenue received at single digit percentages based on the achievement of development milestones.

Our license agreement with Scripps will terminate upon expiration of our obligation to pay royalties to Scripps under the license agreement. The license agreement is terminable by the consent of the parties, at will by us or upon providing 90 days written notice to Scripps, or by Scripps for certain material breaches by us, or if we undergo a bankruptcy event. In addition, Scripps may terminate our license on a product-by-product basis, or the entire agreement, if we fail to meet specified diligence obligations related to the development and commercialization of licensed products. Scripps may also terminate the agreement after the third anniversary of the effective date of the agreement if it reasonably believes, based on reports we provide to Scripps, that we have not used commercially reasonable efforts as required under the agreement, subject to a specified notice and cure period.

***Monash License Agreement***

In April 2017, we entered into a license agreement with Monash University ("Monash"), pursuant to which we were granted an exclusive, sublicensable worldwide license under certain know-how, patent rights and other intellectual property rights controlled by Monash to research, develop, and commercialize certain antibodies directed to CXCR2 for the treatment of human diseases.

Upon execution of the agreement, we made a one-time cash payment to Monash of $275,000 and reimbursed Monash for certain patent prosecution costs incurred prior to execution of the agreement. We are also obligated to pay an annual license maintenance fee to Monash of $25,000 until a certain development milestone is met with respect to the licensed product, after which no further maintenance fee will be due. We are also required to make development and sales milestone payments to Monash with respect to the licensed products. During the year ended December 31, 2024, no development or sales milestones were completed or paid to Monash and the aggregate potential milestones were $45.1 million as of December 31, 2024. We are also required to pay to Monash tiered royalties on net sales of licensed products sold by us, our affiliates and our sublicensees at a rate ranging in the low-single digits. In addition, should we sublicense our rights under the agreement, we have agreed to pay a percentage of sublicense revenue received at specified rates that are currently at low double digit percentages and decrease to single digit percentages based on the achievement of development milestones.

The term of our agreement with Monash continues until the expiration of our obligation to pay royalties to Monash thereunder. The license agreement is terminable at will by us upon providing 30 days written notice to Monash, or by either party for material breaches by the other party. In addition, Monash may terminate the entire agreement or convert the license to a non-exclusive license if we have materially breached our obligation to use commercially reasonable efforts to develop and commercialize a licensed product, subject to a specified notice and cure mechanism.

**Regulation**

Government authorities in the United States, at the federal, state and local level, and other countries extensively regulate, among other things, the research, development, testing, manufacture, quality control, approval, labeling, packaging, storage, record-keeping, promotion, advertising, distribution, marketing and export and import of products such as those we are developing. A new drug must be approved by the FDA through the New Drug Application ("NDA") process and a new biologic must be approved by the FDA through the Biologics License Application ("BLA") process before it may be legally marketed in the United States.

***United States Drug Development Process***

In the United States, the FDA regulates drugs under the federal Food, Drug, and Cosmetic Act ("FDCA"), and in the case of biologics, also under the Public Health Service Act ("PHSA"), and their implementing regulations. The process of obtaining regulatory approvals and the subsequent compliance with appropriate federal, state, local and foreign statutes and regulations require the expenditure of substantial time and financial resources. Failure to comply with the applicable U.S. requirements at any time during the product development process, approval process or after approval may subject an applicant to administrative or judicial sanctions. These sanctions could include the FDA's refusal to approve pending applications, withdrawal of an approval, a clinical hold, warning letters, product recalls, product seizures, total or partial suspension of production or distribution, injunctions, fines, refusals of government contracts, restitution, disgorgement or civil or criminal penalties. Any agency or judicial enforcement action could have a material adverse effect on us.

The process required by the FDA before a drug or biologic may be marketed in the United States generally involves the following:

- completion of certain preclinical laboratory tests, animal studies and formulation studies in accordance with Good Laboratory Practice ("GLP") regulations and other applicable regulations;
- submission to the FDA of an IND, which must become effective before human clinical trials may begin;
- approval by an institutional review board ("IRB") or ethics committee at each clinical site before the trial is commenced;
- performance of adequate and well-controlled human clinical trials in accordance with Good Clinical Practice ("GCP") regulations to establish the safety and efficacy of the proposed drug, or safety, purity and potency of the proposed biologic for its intended use;
- submission to the FDA of an NDA or BLA;
- satisfactory completion of an FDA Advisory Committee review, if applicable;
- a determination by the FDA within 60 days of its receipt of an NDA or BLA to file the application for review;
- satisfactory completion of an FDA inspection of the manufacturing facility or facilities at which the drug is produced to assess compliance with current Good Manufacturing Practice ("cGMP") requirements to assure that the facilities, methods and controls are adequate to preserve the drug's identity, strength, quality and purity;
- satisfaction of selected clinical investigation sites to assess compliance with GCP; and
- FDA review and approval of the NDA or BLA to permit commercial marketing of the product for particular indications for use in the United States.

Once a pharmaceutical candidate is identified for development, it enters the preclinical testing stage. Preclinical tests include laboratory evaluations of product chemistry, toxicity and formulation, as well as animal studies. An IND sponsor must submit the results of the preclinical tests, together with manufacturing information and analytical data, to the FDA as part of the IND. The sponsor will also include a protocol detailing, among other things, the objectives of the clinical trial, the parameters to be used in monitoring safety, and the effectiveness criteria to be evaluated, if the clinical trial lends itself to an efficacy evaluation. Some preclinical testing may continue even after the IND is submitted. The IND automatically becomes effective 30 days after receipt by the FDA, unless the FDA, within the 30 day time period, places the clinical trial on a clinical hold. In such a case, the IND sponsor and the FDA must resolve any outstanding concerns before the clinical trial can begin. Clinical holds also may be imposed by the FDA at any time before or during clinical trials due to safety concerns about on-going or proposed clinical trials or non compliance with specific FDA requirements, and the trials may not begin or continue until the FDA notifies the sponsor that the hold has been lifted.

While the IND is active, each protocol or protocol amendment must be submitted to the FDA as part of the IND and progress reports summarizing the results of the clinical trials and nonclinical studies performed since the last progress report, among other information, must be submitted at least annually to the FDA, and written IND safety reports must be submitted to the FDA and investigators for serious and unexpected suspected adverse events, findings from other studies suggesting a significant risk to humans exposed to the same or similar drugs, findings from animal or in vitro testing suggesting a significant risk to humans, and any clinically important increased incidence of a serious suspected adverse reaction compared to that listed in the protocol or investigator brochure.

All clinical trials must be conducted under the supervision of one or more qualified investigators in accordance with GCP regulations. Furthermore, an IRB at each institution participating in the clinical trial must review and approve each protocol before a clinical trial commences at that institution and must also approve the information regarding the trial and the consent form that must be provided to each trial subject or his or her legal representative, monitor the study until completed and otherwise comply with IRB regulations. The FDA or the sponsor may suspend a clinical trial at any time on various grounds, including a finding that the research subjects or patients are being exposed to an unacceptable health risk. Similarly, an IRB can suspend or terminate approval of a clinical trial at its institution if the clinical trial is not being conducted in accordance with the IRB's requirements or if the drug has been associated with unexpected serious harm to patients. In addition, some clinical trials are overseen by an independent group of qualified experts organized by the sponsor, known as a data safety monitoring board or committee. Depending on its charter, this group may determine whether a trial may move forward at designated check points based on access to certain data from the trial.

Human clinical trials are typically conducted in three sequential phases that may overlap or be combined:

- **Phase 1**: The product candidate is initially introduced into healthy human subjects and tested for safety, dosage tolerance, absorption, metabolism, distribution and excretion. In the case of some products for severe or life-threatening diseases, such as cancer, especially when the product may be too inherently toxic to ethically administer to healthy volunteers, the initial human testing is often conducted in patients.

- **Phase 2**: The product candidate is evaluated in a limited patient population to identify possible adverse effects and safety risks, to preliminarily evaluate the efficacy of the product for specific targeted diseases and to determine dosage tolerance and appropriate dosage.

- **Phase 3**: The product candidate is administered to an expanded patient population to provide statistically significant evidence of clinical efficacy and further test for safety, generally at geographically dispersed clinical study sites. These clinical trials are intended to establish the overall risk-benefit ratio of the product candidate and provide an adequate basis for product labeling.

Post-approval trials, sometimes referred to as Phase 4 studies, may be conducted after initial marketing approval. These trials are used to gain additional experience from the treatment of patients in the approved therapeutic indication. In certain instances, the FDA may mandate the performance of Phase 4 clinical trials as a condition of approval of an NDA or BLA.

The FDA or the sponsor may suspend a clinical trial at any time on various grounds, including a finding that the research subjects or patients are being exposed to an unacceptable health risk. Similarly, an IRB can suspend or terminate approval of a clinical trial at its institution if the clinical trial is not being conducted in accordance with the IRB's requirements or if the drug has been associated with unexpected serious harm to patients.

During the development of a new drug or biologic, sponsors are given opportunities to meet with the FDA at certain points. These points may be prior to submission of an IND, at the end of Phase 2, and before an NDA or BLA is submitted. Meetings at other times may be requested. These meetings can provide an opportunity for the sponsor to share information about the data gathered to date, for the FDA to provide advice, and for the sponsor and the FDA to reach agreement on the next phase of development.

Concurrent with clinical trials, companies usually complete additional animal studies and must also develop additional information about the chemistry and physical characteristics of the drug and finalize a process for manufacturing the product in commercial quantities in accordance with cGMP requirements. The manufacturing process must be capable of consistently producing quality batches of the product candidate and, among other things, the manufacturer must develop methods for testing the identity, strength, quality and purity of the final drug. In addition, appropriate packaging must be selected and tested and stability studies must be conducted to demonstrate that the product candidate does not undergo unacceptable deterioration over its shelf life.

There are also requirements governing the reporting of ongoing clinical trials and completed trial results to public registries. Sponsors of certain clinical trials of FDA-regulated products are required to register and disclose specified clinical trial information, which is publicly available at www.clinicaltrials.gov.

***United States Review and Approval Process***

Assuming successful completion of all required testing in accordance with all applicable regulatory requirements, the results of product development, preclinical and other non-clinical studies and clinical trials, along with descriptions of the manufacturing process, analytical tests conducted on the chemistry of the drug, proposed labeling and other relevant information are submitted to the FDA as part of an NDA or BLA requesting approval to market the product. The submission of an NDA or BLA is subject to the payment of user fees; a waiver of such fees may be obtained under certain limited circumstances.

In addition, the Pediatric Research Equity Act ("PREA"), which requires a sponsor to conduct pediatric clinical trials for most drugs and biologics, for a new active ingredient, new indication, new dosage form, new dosing regimen or new route of administration. Under PREA, original NDAs, BLAs and supplements thereto must contain a pediatric assessment unless the sponsor has received a deferral or waiver. The required assessment must evaluate the safety and effectiveness of the product for the claimed indications in all relevant pediatric subpopulations and support dosing and administration for each pediatric subpopulation for which the product is deemed to be safe and effective. The sponsor or FDA may request a deferral of pediatric clinical trials for some or all of the pediatric subpopulations. A deferral may be granted for several reasons, including a finding that the drug or biologic is ready for approval for use in adults before pediatric clinical trials are complete or that additional safety or effectiveness data needs to be collected before the pediatric clinical trials begin. The FDA must send a non compliance letter to any sponsor that fails to submit the required assessment, keep a deferral current or fails to submit a request for approval of a pediatric formulation.

Within 60 days following submission of the application, the FDA reviews all NDAs and BLAs submitted to ensure that they are sufficiently complete for substantive review before it accepts them for filing. The FDA may request additional information rather than accept an NDA or BLA for filing. In this event, the NDA or BLA must be resubmitted with the additional information. The resubmitted application also is subject to review before the FDA accepts it for filing.

Once the submission is accepted for filing, the FDA begins an in depth substantive review. The FDA reviews an NDA to determine, among other things, whether a product is safe and effective for its intended use and whether its manufacturing is cGMP compliant to assure and preserve the product's identity, strength, quality and purity. The FDA reviews a BLA to determine, among other things whether the product is safe, pure and potent and the facility in which it

is manufactured, processed, packed or held meets standards designed to assure the product's continued safety, purity and potency. Under the Prescription Drug User Fee Act guidelines that are currently in effect, the FDA has a goal to complete a standard review of an NDA for a new molecular entity or an original BLA within ten months after the filing date, or, if the application qualifies for priority review, within six months after the filing date.

Before approving an NDA or BLA, the FDA will inspect the facility or facilities where the product is manufactured. The FDA may refer the NDA or BLA to an advisory committee for review, evaluation and recommendation as to whether the application should be approved and under what conditions. The FDA is not bound by the recommendation of an advisory committee, but it generally follows such recommendations.

After the FDA evaluates an NDA or BLA and conducts any required inspections, it will issue an approval letter or a Complete Response Letter. An approval letter authorizes commercial marketing of the drug with prescribing information for specific indications. A Complete Response Letter indicates that the review cycle of the application is complete and the application will not be approved in its present form. A Complete Response Letter usually describes the specific deficiencies in the NDA or BLA identified by the FDA and may require additional clinical data, such as an additional clinical trial or other significant and time consuming requirements related to clinical trials, nonclinical studies or manufacturing. If a Complete Response Letter is issued, the sponsor must resubmit the NDA or BLA, addressing all of the deficiencies identified in the letter, or withdraw the application. Even if such data and information are submitted, the FDA may decide that the NDA or BLA does not satisfy the criteria for approval.

If a product receives regulatory approval, the approval may be significantly limited to specific diseases and dosages or the indications for use may otherwise be limited, which could restrict the commercial value of the product. In addition, the FDA may require a sponsor to conduct Phase 4 testing, which involves clinical trials designed to further assess a drug's safety and effectiveness after NDA or BLA approval, and may require other clinical or non-clinical testing and surveillance programs to monitor the safety of approved products which have been commercialized. The FDA may also place other conditions on approval including the requirement for a risk evaluation and mitigation strategy ("REMS") to assure the safe use of the drug. If the FDA concludes a REMS is needed, the sponsor of the NDA must submit a proposed REMS. The FDA will not approve the NDA without an approved REMS, if required. A REMS could include medication guides, physician communication plans or elements to assure safe use, such as restricted distribution methods, patient registries and other risk minimization tools. Any of these limitations on approval or marketing could restrict the commercial promotion, distribution, prescription or dispensing of products.

***Orphan Drug Designation***

Under the Orphan Drug Act, the FDA may grant orphan designation to a drug or biologic intended to treat a rare disease or condition, which is a disease or condition that affects fewer than 200,000 individuals in the United States or, if it affects more than 200,000 individuals in the United States, there is no reasonable expectation that the cost of developing and making a drug or biologic product available in the United States for this type of disease or condition will be recovered from sales of the product. Orphan designation must be requested before submitting an NDA or BLA. After the FDA grants orphan designation, the identity of the therapeutic agent and its potential orphan use are disclosed publicly by the FDA. Orphan designation does not convey any advantage in or shorten the duration of the regulatory review and approval process.

If a product that has orphan designation subsequently receives the first FDA approval for the disease or condition for which it has such designation, the product is entitled to orphan product exclusivity, which means that the FDA may not approve any other applications to market the same drug or biological product for the same disease or condition for seven years, except in limited circumstances, such as a showing of clinical superiority to the product with orphan exclusivity or inability to manufacture the product in sufficient quantities. The designation of such drug or biologic also entitles a party to financial incentives such as opportunities for grant funding towards clinical trial costs, tax advantages and user fee waivers. However, competitors may receive approval of different products for the disease or condition for which the orphan product has exclusivity or obtain approval for the same product but for a different disease or condition for which the orphan product has exclusivity. Orphan exclusivity also could block the approval of a product candidate for seven years if a competitor obtains approval of the same drug or biologic as defined by the FDA or if such product candidate is determined to be contained within the competitor's product for the same condition or disease. If an

orphan designated product receives marketing approval for a disease or condition broader than what is designated, it may not be entitled to orphan exclusivity.

***Expedited Development and Review Programs***

The FDA has a Fast Track program that is intended to expedite or facilitate the process for reviewing product candidates that meet certain criteria. Specifically, drugs and biologics are eligible for Fast Track designation if they are intended to treat a serious or life-threatening disease or condition and nonclinical or clinical data demonstrate the potential to address unmet medical needs for the disease or condition. Fast Track designation applies to the combination of the product candidate and the specific indication for which it is being studied. The FDA may consider for review sections of the NDA or BLA for a Fast Track review designation on a rolling basis before the complete application is submitted, if the sponsor provides a schedule for the submission of the sections of the NDA or BLA, the FDA agrees to accept sections of the NDA or BLA and determines that the schedule is acceptable, and the sponsor pays any required user fees upon submission of the first section of the NDA or BLA.

A product candidate intended to treat a serious or life-threatening disease or condition may also be eligible for Breakthrough Therapy designation to expedite its development and review. A product candidate can receive Breakthrough Therapy designation if preliminary clinical evidence indicates that the product candidate, alone or in combination with one or more other drugs or biologics, may demonstrate substantial improvement over existing therapies on one or more clinically significant endpoints, such as substantial treatment effects observed early in clinical development. The designation includes all of the fast track program features, as well as more intensive FDA interaction and guidance beginning as early as Phase 1 and an organizational commitment to expedite the development and review of the product candidate, including involvement of senior managers.

Any product candidate submitted to the FDA for approval, including a product candidate with a Fast Track designation or Breakthrough Therapy designation, may also be eligible for other types of FDA programs intended to expedite development and review, such as priority review. A BLA or NDA is eligible for priority review if the product candidate is designed to treat a serious condition, and if approved, would provide a significant improvement in safety or effectiveness compared to marketed products. The FDA will attempt to direct additional resources to the evaluation of an application designated for priority review in an effort to facilitate the review. The FDA endeavors to review applications with priority review designations within six months of the filing date as compared to ten months for review of original BLAs and new molecular entity NDAs under its standard review goals.

In addition, depending on the designs of the applicable clinical trials, a product candidate may be eligible for accelerated approval. Drug and biologic product candidates intended to treat serious or life threatening diseases or conditions may be eligible for accelerated approval upon a determination that the product candidate has an effect on 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. As a condition of approval, the FDA may require that a sponsor of a drug or biologic receiving accelerated approval perform adequate and well controlled confirmatory clinical trials to verify and describe the anticipated clinical benefit, and may require that such confirmatory trials be underway prior to granting accelerated approval. A product receiving accelerated approval may be subjected to expedited withdrawal procedures if the sponsor fails to conduct any required confirmatory trials in a timely manner, or if such trials fail to verify the predicted clinical benefit. In addition, the FDA requires as a condition for accelerated approval pre approval of promotional materials, which could adversely impact the timing of the commercial launch of the product.

Fast Track designation, Breakthrough Therapy designation, priority review and accelerated approval do not change the standards for approval but may expedite the development or approval process.

***Post-approval requirements***

Once an approval is granted, the FDA may withdraw the approval if compliance with regulatory standards is not maintained or if problems occur after the product reaches the market. Later discovery of previously unknown

problems with a product may result in restrictions on the product or even complete withdrawal of the product from the market. After approval, some types of changes to the approved product, such as adding new indications, certain manufacturing changes and additional labeling claims, are subject to further FDA review and approval. Drug and biologics manufacturers and other entities involved in the manufacture and distribution of approved drugs and biologics are required to register their establishments with the FDA and certain state agencies, and are subject to periodic unannounced inspections by the FDA and certain state agencies for compliance with cGMP regulations and other laws and regulations.

Any drug products manufactured or distributed pursuant to FDA approvals will be subject to continuing regulation by the FDA, including, among other things, record-keeping requirements, reporting of adverse experiences with the drug, providing the FDA with updated safety and efficacy information, drug sampling and distribution requirements, complying with certain electronic records and signature requirements, and complying with FDA promotion and advertising requirements. The FDA strictly regulates labeling, advertising, promotion and other types of information on products that are placed on the market and imposes requirements and restrictions on drug and biologics manufacturers, such as those related to direct-to-consumer advertising, the prohibition on promoting products for uses or in patient populations that are not described in the product's approved labeling (known as "off-label use"), industry-sponsored scientific and educational activities, and promotional activities involving the internet. Discovery of previously unknown problems or the failure to comply with the applicable regulatory requirements may result in restrictions on the marketing of a product or withdrawal of the product from the market as well as possible civil or criminal sanctions. Failure to comply with the applicable U.S. requirements at any time during the product development process, approval process or after approval, may subject an applicant or manufacturer to administrative or judicial civil or criminal sanctions and adverse publicity. FDA sanctions could include refusal to approve pending applications, withdrawal of an approval, clinical hold, warning or untitled letters, product recalls, product seizures, total or partial suspension of production or distribution, injunctions, fines, refusals of government contracts, mandated corrective advertising or communications with doctors, debarment, restitution, disgorgement of profits, or civil or criminal penalties.

***Marketing Exclusivity***

Market exclusivity provisions under the FDCA can also delay the submission or the approval of certain marketing applications. The FDCA provides a five-year period of non-patent data exclusivity within the United States to the first applicant to obtain approval of an NDA for a new chemical entity. A drug is a new chemical entity if the FDA has not previously approved any other new drug containing the same active moiety, which is the molecule or ion responsible for the action of the drug substance. During the exclusivity period, the FDA may not approve or even accept for review an abbreviated new drug application ("ANDA") or a NDA submitted under Section 505(b)(2), or 505(b)(2) NDA, submitted by another company for another drug based on the same active moiety, regardless of whether the drug is intended for the same indication as the original innovative drug or for another indication, where the applicant does not own or have a legal right of reference to all the data required for approval. However, an application may be submitted after four years if it contains a certification of patent invalidity or non-infringement to one of the patents listed with the FDA by the innovator NDA holder. The FDCA alternatively provides three years of non-patent exclusivity for an NDA, or supplement to an existing NDA if new clinical investigations, other than bioavailability studies, that were conducted or sponsored by the applicant are deemed by the FDA to be essential to the approval of the application, for example new indications, dosages or strengths of an existing drug. This three-year exclusivity covers only the modification for which the drug received approval on the basis of the new clinical investigations and does not prohibit the FDA from approving ANDAs or 505(b)(2) NDAs for drugs containing the active agent for the original indication or condition of use. Five-year and three-year exclusivity will not delay the submission or approval of a full NDA. However, an applicant submitting a full NDA would be required to conduct or obtain a right of reference to all of the preclinical studies and adequate and well-controlled clinical trials necessary to demonstrate safety and effectiveness.

Pediatric exclusivity is a type of marketing exclusivity available in the United States for both drug and biological products. Pediatric exclusivity under the Best Pharmaceuticals for Children Act provides for an additional six months of exclusivity, appended to periods of existing regulatory exclusivities or patent terms, if a sponsor conducts clinical trials in children in response to a written request from the FDA. If such written request does not include clinical trials in neonates, the FDA is required to include its rationale for not requesting those clinical trials. The FDA may

request studies on approved or unapproved indications in separate written requests. The issuance of a written request does not require the sponsor to undertake the described clinical trials. In addition, orphan drug exclusivity, as described above, may offer a seven year period of marketing exclusivity, except in certain circumstances.

***Biosimilars and Exclusivity***

The Affordable Care Act includes a subtitle called the Biologics Price Competition and Innovation Act of 2009 ("BPCIA"), which created an abbreviated approval pathway for biological products that are biosimilar to or interchangeable with an FDA-licensed reference biological product.

Biosimilarity, which requires that there be no clinically meaningful differences between the biological product and the reference product in terms of safety, purity, and potency, can be shown through analytical studies, animal studies, and a clinical study or studies. Interchangeability requires that a product is biosimilar to the reference product and the product must demonstrate that it can be expected to produce the same clinical results as the reference product in any given patient and, for products that are administered multiple times to an individual, the biologic and the reference biologic may be alternated or switched after one has been previously administered without increasing safety risks or risks of diminished efficacy relative to exclusive use of the reference biologic.

Under the BPCIA, an application for a biosimilar product may not be submitted to the FDA until four years following the date that the reference product was first licensed by the FDA. In addition, the approval of a biosimilar product may not be made effective by the FDA until twelve years from the date on which the reference product was first licensed. During this twelve-year period of exclusivity, another company may still market a competing version of the reference product if the FDA approves 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 BPCIA also created certain exclusivity periods for biosimilars approved as interchangeable products.

***Government Regulation Outside of the United States***

In addition to regulations in the United States, we are subject to a variety of regulations in other jurisdictions governing, among other things, clinical trials, and any commercial sales and distribution of our product once approved.

Whether or not we obtain FDA approval for a product candidate, we must obtain the requisite approvals from regulatory authorities in foreign countries prior to the commencement of clinical trials or marketing of the product candidates in those countries. The requirements and process governing the conduct of clinical trials, product licensing, pricing and reimbursement vary from country to country. Failure to comply with applicable foreign regulatory requirements, may be subject to, among other things, fines, suspension or withdrawal of regulatory approvals, product recalls, seizure of products, operating restrictions and criminal prosecution.

*Non-Clinical Studies and Clinical Trials*

Similar to the U.S., the various phases of non-clinical and clinical research in the European Union ("EU") are subject to significant regulatory controls.

Non-clinical studies are performed to demonstrate the health or environmental safety of new chemical or biological substances. Non-clinical (pharmaco-toxicological) studies must be conducted in compliance with the principles of good laboratory practice ("GLP") as set forth in EU Directive 2004/10/EC (unless otherwise justified for certain particular medicinal products, e.g., radio-pharmaceutical precursors for radio-labelling purposes). In particular, non-clinical studies, both in vitro and in vivo, must be planned, performed, monitored, recorded, reported and archived in accordance with the GLP principles, which define a set of rules and criteria for a quality system for the organizational process and the conditions for non-clinical studies. These GLP standards reflect the Organization for Economic Co-operation and Development requirements.

Certain countries outside of the United States have a similar process that requires the submission of a clinical study application much like the IND prior to the commencement of human clinical studies.

Clinical studies of medicinal products in the EU must be conducted in accordance with EU and national regulations and the International Conference for Harmonization of Technical Requirements for Pharmaceuticals for Human Use ("ICH") guidelines on GCP as well as the applicable regulatory requirements and the ethical principles that have their origin in the Declaration of Helsinki. If the sponsor of the clinical trial is not established within the EU, it must appoint an EU entity to act as its legal representative. The sponsor must take out a clinical trial insurance policy, and in most EU member states, the sponsor is liable to provide 'no fault' compensation to any study subject injured in the clinical trial.

The regulatory landscape related to clinical trials in the EU has been subject to recent changes. The EU Clinical Trials Regulation ("CTR") which was adopted in April 2014 and repeals the EU Clinical Trials Directive, became applicable on January 31, 2022. Unlike directives, the CTR is directly applicable in all EU member states without the need for member states to further implement it into national law. The CTR notably harmonizes the assessment and supervision processes for clinical trials throughout the EU via a Clinical Trials Information System, which contains a centralized EU portal and database.

While the EU Clinical Trials Directive required a separate clinical trial application ("CTA") to be submitted in each member state in which the clinical trial takes place, to both the competent national health authority and an independent ethics committee, much like the FDA and IRB respectively, the CTR introduces a centralized process and only requires the submission of a single application for multi-center trials. The CTR allows sponsors to make a single submission to both the competent authority and an ethics committee in each member state, leading to a single decision per member state. The CTA must include, among other things, a copy of the trial protocol and an investigational medicinal product dossier containing information about the manufacture and quality of the medicinal product under investigation. The assessment procedure of the CTA has been harmonized as well, including a joint assessment by all member states concerned, and a separate assessment by each member state with respect to specific requirements related to its own territory, including ethics rules. Each member state's decision is communicated to the sponsor via the centralized EU portal. Once the CTA is approved, clinical study development may proceed.

The CTR foresees a three-year transition period. The extent to which ongoing and new clinical trials will be governed by the CTR varies. Clinical trials for which an application was submitted (i) prior to January 31, 2022 under the EU Clinical Trials Directive, or (ii) between January 31, 2022 and January 31, 2023 and for which the sponsor has opted for the application of the EU Clinical Trials Directive remain governed by said Directive until January 31, 2025. After this date, all clinical trials (including those which are ongoing) will become subject to the provisions of the CTR.

Medicines used in clinical trials must be manufactured in accordance with Good Manufacturing Practices ("GMP"). Other national and EU-wide regulatory requirements may also apply.

*Marketing Authorization*

In the EU, medicinal products can only be placed on the market after obtaining a marketing authorization ("MA"). To obtain regulatory approval of an investigational medicinal product under EU regulatory systems, we must submit a MA application ("MAA"). The process for doing this depends, among other things, on the nature of the medicinal product. There are two types of Mas:

"Centralized MAs" are issued by the European Commission through the centralized procedure, based on the opinion of the European Medicines Agency's ("EMA") Committee for Human Medicinal Products ("CHMP") and are valid across the entire territory of the EU. The centralized procedure is compulsory for certain types of medicines such as: (i) medicinal products derived from biotechnological processes, such as genetic engineering, (ii) medicinal products that contain a new active substance indicated for the treatment of certain diseases, such as HIV/AIDS, cancer, diabetes, neurodegenerative or autoimmune diseases and other immune dysfunctions and viral diseases, (iii) designated orphan medicines and (iv) advanced therapy medicinal products ("ATMPs"), such as gene therapy, somatic cell therapy or tissue-engineered medicines. The centralized procedure may at the request of the applicant also be used in certain other cases and in particular for any other products containing new active substances not authorized in the EU or for product candidates which constitute a significant therapeutic, scientific, or technical innovation or for which the granting of authorization would be in the interests of public health in the EU. It is likely that the centralized procedure would apply

to the product candidates we are developing.

Under the centralized procedure, the maximum timeframe for the evaluation of a MAA by the EMA is 210 days, excluding clock stops. In exceptional cases, the CHMP might perform an accelerated review of a MA in no more than 150 days (not including clock stops). Innovative products that target an unmet medical need and are expected to be of major public health interest may be eligible for a number of expedited development and review programs, such as the PRIority MEdicines ("PRIME") scheme, which provides incentives similar to the breakthrough therapy designation in the U.S. PRIME is a voluntary scheme aimed at enhancing the EMA's support for the development of medicines that target unmet medical needs. It is based on increased interaction and early dialogue with companies developing promising medicines, to optimize their product development plans and speed up their evaluation to help them reach patients earlier. Product developers that benefit from PRIME designation can expect to be eligible for accelerated assessment but this is not guaranteed. Many benefits accrue to sponsors of product candidates with PRIME designation, including but not limited to, early and proactive regulatory dialogue with the EMA, frequent discussions on clinical trial designs and other development program elements, and accelerated MAA assessment once a dossier has been submitted. Importantly, a dedicated contact and rapporteur from the CHMP is appointed early in the PRIME scheme facilitating increased understanding of the product at EMA's committee level. An initial meeting initiates these relationships and includes a team of multidisciplinary experts at the EMA to provide guidance on the overall development and regulatory strategies.

MAs have an initial duration of five years. After these five years, the authorization may be renewed for an unlimited period on the basis of a reevaluation of the risk-benefit balance.

*Data and Marketing Exclusivity*

The EU also provides opportunities for market exclusivity. Upon receiving MA, reference products generally receive eight years of data exclusivity and an additional two years of market exclusivity. If granted, data exclusivity prevents generic or biosimilar applicants from relying on the preclinical and clinical trial data contained in the dossier of the reference product when applying for a generic or biosimilar MA in the EU during a period of eight years from the date on which the reference product was first authorized in the EU. During the additional two year period of market exclusivity, a generic or biosimilar MAA can be submitted, and the innovator's data may be referenced, but no generic or biosimilar product can be marketed until 10 years have elapsed from the initial MA of the reference product in the EU. The overall ten-year market exclusivity period may be extended to a maximum of eleven years if, during the first eight years of those 10 years, the MA holder obtains an authorization for one or more new therapeutic indications, which, during the scientific evaluation prior to their authorization, are held to bring a with significant clinical benefit in comparison with existing therapies is approved. However, there is no guarantee that a product will be considered by the EU's regulatory authorities to be a new chemical or biological entity, and products may not qualify for data exclusivity.

There is a special regime for biosimilars, or biological medicinal products that are similar to a reference medicinal product but that do not meet the definition of a generic medicinal product, for example, because of differences in raw materials or manufacturing processes. For such products, the results of appropriate preclinical or clinical trials must be provided, and guidelines from the EMA detail the type of quantity of supplementary data to be provided for different types of biological product. There are no such guidelines for complex biological products, such as gene or cell therapy medicinal products, and so it is unlikely that biosimilars of those products will currently be approved in the EU. However, guidance from the EMA states that they will be considered in the future in light of the scientific knowledge and regulatory experience gained at the time.

*Orphan Medicinal Products*

The criteria for designating an "orphan medicinal product" in the EU are similar in principle to those in the United States. A medicinal product may be designated as orphan if its sponsor can establish that: (1) it is intended for the diagnosis, prevention or treatment of a life threatening or chronically debilitating condition; (2) either (a) such condition affects not more than five in 10,000 persons in the EU when the application is made, or (b) the product, without the benefits derived from the orphan status, would not generate sufficient return in the EU to justify the necessary investment; and (3) there exists no satisfactory method of diagnosis, prevention or treatment of such condition authorized for marketing in the EU, or if such a method exists, the product will be of significant benefit to those affected

by the condition.

The application for orphan designation must be submitted before the MAA. Orphan medicinal products are eligible for incentives such as reduction of fees or fee waivers, protocol assistance, and access to the centralized procedure and are, upon grant of a MA, entitled to ten years of market exclusivity for the approved therapeutic indication. During the ten-year market exclusivity period, the regulatory authorities cannot accept another MAA, or grant a MA, or accept an application to extend an existing MA for a period of ten years for the same indication, in respect of a similar medicinal product. An orphan product can also obtain an additional two years of market exclusivity in the EU for orphan medicinal products that have also complied with an agreed pediatric investigation plan ("PIP"). No extension to any supplementary protection certificate can be granted on the basis of pediatric studies for orphan indications. Orphan designation does not convey any advantage in, or shorten the duration of, the regulatory review and approval process.

The 10-year market exclusivity may be reduced to six years if, at the end of the fifth year, it is established that the product no longer meets the criteria for which it received orphan designation, including where it is shown that the product is sufficiently profitable not to justify maintenance of market exclusivity or where the prevalence of the condition has increased above the threshold. In addition, MA may be granted to a similar product for the same indication at any time if (1) the second applicant can establish that its product, although similar, is safer, more effective or otherwise clinically superior; (2) the applicant consents to a second orphan medicinal product application; or (3) the applicant cannot supply enough orphan medicinal product.

*Pediatric Development*

In the EU, MAAs for new medicinal products have to include the results of trials conducted in the pediatric population, in compliance with a PIP agreed with the EMA's Pediatric Committee ("PDCO"). The PIP sets out the timing and measures proposed to generate data to support a pediatric indication of the drug for which an MA is being sought. The PDCO can grant a deferral of the obligation to implement some or all of the measures of the PIP until there are sufficient data to demonstrate the efficacy and safety of the product in adults. Further, the obligation to provide pediatric clinical trial data can be waived by the PDCO when these data are not needed or appropriate because the product is likely to be ineffective or unsafe in children, the disease or condition for which the product is intended occurs only in adult populations, or when the product does not represent a significant therapeutic benefit over existing treatments for pediatric patients. Once the MA is obtained in all the EU member states and study results are included in the product information, even when negative, the product is eligible for a six-months supplementary protection certificate extension (if any is in effect at the time of approval) or, in the case of orphan pharmaceutical products, a two year extension of the orphan market exclusivity is granted.

*Post-Approval Requirements*

Similar to the United States, both MA holders and manufacturers of medicinal products are subject to comprehensive regulatory oversight by the EMA, the European Commission and/or the competent regulatory authorities of the member states. The holder of a MA must establish and maintain a pharmacovigilance system and appoint an individual qualified person for pharmacovigilance ("QPPV") who is responsible for the establishment and maintenance of that system, and oversees the safety profiles of medicinal products and any emerging safety concerns. Key obligations include expedited reporting of suspected serious adverse reactions and submission of periodic safety update reports ("PSURs").

All new MAAs must include a risk management plan ("RMP"), describing the risk management system that the company will put in place and documenting measures to prevent or minimize the risks associated with the product. The regulatory authorities may also impose specific obligations as a condition of the MA. Such risk-minimization measures or post-authorization obligations may include additional safety monitoring, more frequent submission of PSURs, or the conduct of additional clinical trials or post-authorization safety studies.

The advertising and promotion of medicinal products is also subject to laws concerning promotion of medicinal products, interactions with physicians, misleading and comparative advertising and unfair commercial practices. All

advertising and promotional activities for the product must be consistent with the approved summary of product characteristics, and therefore all off-label promotion is prohibited. Direct-to-consumer advertising of prescription medicines is also prohibited in the EU. Although general requirements for advertising and promotion of medicinal products are established under EU directives, the details are governed by regulations in each member state and can differ from one country to another.

Failure to comply with EU and member state laws that apply to the conduct of clinical trials, manufacturing approval, MA of medicinal products and marketing of such products, both before and after grant of the MA, manufacturing of pharmaceutical products, statutory health insurance, bribery and anti-corruption or with other applicable regulatory requirements may result in administrative, civil or criminal penalties. These penalties could include delays or refusal to authorize the conduct of clinical trials, or to grant MAs, product withdrawals and recalls, product seizures, suspension, withdrawal or variation of the MA, total or partial suspension of production, distribution, manufacturing or clinical trials, operating restrictions, injunctions, suspension of licenses, fines and criminal penalties.

The aforementioned EU rules are generally applicable in the European Economic Area ("EEA"), which consists of the 27 EU member states plus Norway, Liechtenstein and Iceland.

For other countries outside of the EU, such as countries in Eastern Europe, Latin America or Asia, the requirements governing the conduct of clinical trials, product licensing, pricing and reimbursement vary from country to country. In all cases, again, the clinical trials are conducted in accordance with GCP and the applicable regulatory requirements and the ethical principles that have their origin in the Declaration of Helsinki.

If we fail to comply with applicable foreign regulatory requirements, we may be subject to, among other things, fines, suspension or withdrawal of regulatory approvals, product recalls, seizure of products, operating restrictions and criminal prosecution.

***Other Healthcare Laws***

In addition to FDA restrictions on marketing of pharmaceutical and biological products, other U.S. federal and state and foreign healthcare regulatory laws restrict business practices in the pharmaceutical industry, which include, but are not limited to, state and federal anti-kickback, fraud & abuse, false claims, consumer fraud and transparency laws regarding drug pricing and payments or other transfers of value made to physicians and other licensed healthcare professionals. These laws may affect our sales, marketing and other promotional activities by limiting the kinds of financial arrangements we may have with physicians, customers and third party payors including discount practices, customer support, education and training programs, physician consulting and other service arrangements. In addition, manufacturers can be held liable under the False Claims Act even when they do not submit claims directly to government payors if they are deemed to "cause" the submission of false or fraudulent claims by, for example, providing inaccurate billing or coding information to customers or promoting a product off label. These laws are broadly written, and it is often difficult to determine precisely how these laws will be applied to specific circumstances. Such laws include:

- The federal Anti-Kickback Statute, which prohibits, among other things, any person or entity from knowingly and willfully offering, paying, soliciting, receiving or providing any remuneration, directly or indirectly, overtly or covertly, to induce or in return for purchasing, leasing, ordering or arranging for or recommending the purchase, lease or order of any item or service reimbursable, in whole or in part, under Medicare, Medicaid or other federal healthcare programs. A person or entity does not need to have actual knowledge of the federal Anti-Kickback Statute or specific intent to violate it to have committed a violation;

- The federal false claims laws, including the False Claims Act, which prohibit any person or entity from, among other things, knowingly presenting, or causing to be presented, a false, fictitious or fraudulent claim for payment to, or approval by, the federal government or knowingly making, using or causing to be made or used a false record or statement material to a false or fraudulent claim to the federal government. In addition, the government may assert that a claim including items or services resulting from a violation of

the federal Anti-Kickback Statute constitutes a false or fraudulent claim for purposes of the False Claims Act;

- The federal Health Insurance Portability and Accountability Act of 1996 ("HIPAA"), which prohibits, among other actions, knowingly and willfully executing, or attempting to execute, a scheme to defraud any healthcare benefit program, including private third-party payors, knowingly and willfully embezzling or stealing from a healthcare benefit program, willfully obstructing a criminal investigation of a healthcare offense, and knowingly and willfully falsifying, concealing or covering up a material fact or making any materially false, fictitious or fraudulent 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 to have committed a violation;

- The Physician Payments Sunshine Act, which imposed, among other things, new annual reporting requirements for covered manufacturers for certain payments and "transfers of value" provided to physicians (as defined by statute), certain non-physician practitioners including physician assistants and nurse practitioners, and teaching hospitals, as well as ownership and investment interests held by physicians and their immediate family members; and

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

To the extent that any of our product candidates, once approved, are sold in a foreign country, we may be subject to similar foreign laws and regulations, which may include, for instance, applicable post-marketing requirements, including safety surveillance, anti-fraud and abuse laws, and implementation of corporate compliance programs and reporting of payments or other transfers of value to healthcare professionals.

Violation of any of such laws or any other governmental regulations that may apply could result in significant penalties, including, without limitation, administrative, civil and criminal penalties, damages, fines, disgorgement, contractual damages, reputational harm, diminished profits and future earnings, the curtailment or restructuring of operations, exclusion from participation in federal and state healthcare programs and individual imprisonment.

***Coverage and Reimbursement***

Significant uncertainty exists as to the coverage and reimbursement status of any pharmaceutical or biological product for which we obtain regulatory approval. In the United States and markets in other countries, patients who are prescribed treatments for their conditions and providers performing the prescribed services generally rely on third-party payors to reimburse all or part of the associated healthcare costs. Patients are unlikely to use our products unless coverage is provided and reimbursement is adequate to cover a significant portion of the cost of our products. Sales of any product candidates for which we receive regulatory approval for commercial sale will therefore depend, in part, on the availability of coverage and adequate reimbursement from third-party payors. Third- party payors include government authorities, managed care plans, private health insurers and other organizations.

The process for determining whether a third-party payor will provide coverage for a pharmaceutical or biological product typically is separate from the process for setting the price of such product or for establishing the reimbursement rate that the payor will pay for the product once coverage is approved. Third-party payors may limit coverage to specific products on an approved list, also known as a formulary, which might not include all of the FDA-approved products for a particular indication. A decision by a third-party payor not to cover our product candidates could reduce physician utilization of our products once approved and have a material adverse effect on our sales, results of operations and financial condition. Moreover, a third-party payor's decision to provide coverage for a pharmaceutical or biological product does not imply that an adequate reimbursement rate will be approved. Adequate third-party reimbursement may not be available to enable us to maintain price levels sufficient to realize an appropriate return on our investment in product development. In addition, coverage and reimbursement for new products can differ

significantly from payor to payor. One third-party payor's decision to cover a particular medical product or service does not ensure that other payors will also provide coverage for the medical product or service, or will provide coverage at an adequate reimbursement rate. As a result, the coverage determination process will require us to provide scientific and clinical support for the use of our products to each payor separately and will be a time consuming process.

The containment of healthcare costs has become a priority of federal, state and foreign governments, and the prices of pharmaceutical or biological products have been a focus in this effort. Third-party payors are increasingly challenging the prices charged for medical products and services, examining the medical necessity and reviewing the cost-effectiveness of pharmaceutical products, biological products, medical devices and medical services, in addition to questioning safety and efficacy. If these third-party payors do not consider our product candidates to be cost-effective compared to other available therapies, they may not cover our products after FDA approval or, if they do, the level of payment may not be sufficient to allow us to sell our products at a profit.

***Healthcare Reform***

A primary trend in the U.S. healthcare industry and elsewhere is cost containment. Government authorities and other third-party payors have attempted to control costs by limiting coverage and the amount of reimbursement for particular medical products. For example, in March 2010, the Affordable Care Act, or ACA, was enacted, which, among other things, increased the minimum Medicaid rebates owed by most manufacturers under the Medicaid Drug Rebate Program; introduced a new methodology by which rebates owed by manufacturers under the Medicaid Drug Rebate Program are calculated for drugs that are inhaled, infused, instilled, implanted or injected; extended the Medicaid Drug Rebate Program to utilization of prescriptions of individuals enrolled in Medicaid managed care plans; subjected drug manufacturers to new annual fees based on pharmaceutical companies' share of sales to federal healthcare programs, and created a new Patient Centered Outcomes Research Institute to oversee, identify priorities in and conduct comparative clinical effectiveness research, along with funding for such research. Since its enactment, there have been judicial, executive and Congressional legislative challenges to certain aspects of the ACA. On June 17, 2021, the U.S. Supreme Court dismissed the most recent judicial challenge to the ACA brought by several states without specifically ruling on the constitutionality of the ACA.

In addition, the Budget Control Act of 2011 and due to subsequent legislative amendments included, among other things, aggregate reductions of Medicare payments to providers that will remain in effect through 2032, with the exception of a temporary suspension from May 1, 2020 through March 31, 2022, unless additional Congressional action is taken. On January 2, 2013, the American Taxpayer Relief Act 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 addition, in March 2021, the American Rescue Plan Act of 2021 was signed into law, which eliminated the statutory Medicaid drug rebate cap, beginning January 1, 2024. The rebate was previously capped at 100% of a drug's average manufacturer price.

Moreover, there has recently been heightened governmental scrutiny over the manner in which manufacturers set prices for their marketed products, which has resulted in several Congressional inquiries and proposed and enacted legislation designed, among other things, to bring more transparency to product pricing, review the relationship between pricing and manufacturer patient programs and reform government program reimbursement methodologies for pharmaceutical products. On August 16, 2022, the Inflation Reduction Act of 2022, or IRA, was signed into law. Among other things, the IRA requires manufacturers of certain drugs to engage in price negotiations with Medicare (beginning in 2026), imposes rebates under Medicare Part B and Medicare Part D to penalize price increases that outpace inflation (first due in 2023), and replaces the Part D coverage gap discount program with a new discounting program (which began in 2025). The IRA permits the Secretary of the Department of Health and Human Services (HHS) to implement many of these provisions through guidance, as opposed to regulation, for the initial years. HHS has issued and will continue to issue guidance implementing the IRA. On August 29, 2023, HHS announced the list of the first ten drugs that will be subject to price negotiations, although the Medicare drug price negotiation program is currently subject to legal challenges. For that and other reasons, it is currently unclear how the IRA will be effectuated. In addition, individual states in the United States have also become increasingly active in implementing regulations designed to control pharmaceutical product pricing, including price or patient reimbursement constraints, discounts, restrictions on

certain product access and marketing cost disclosure, drug price reporting and other transparency measures and, in some cases, mechanisms to encourage importation from other countries and bulk purchasing. Some states have enacted legislation creating so-called prescription drug affordability boards, which ultimately may attempt to impose price limits on certain drugs in these states. Furthermore, there has been increased interest by third party payors and governmental authorities in reference pricing systems and publication of discounts and list prices.

Similar political, economic and regulatory developments are occurring in the EU and may affect the ability of pharmaceutical companies to profitably commercialize their products. In addition to continuing pressure on prices and cost containment measures, legislative developments at the EU or member state level may result in significant additional requirements or obstacles. The delivery of healthcare in the EU, including the establishment and operation of health services and the pricing and reimbursement of medicines, is almost exclusively a matter for national, rather than EU, law and policy. National governments and health service providers have different priorities and approaches to the delivery of health care and the pricing and reimbursement of products in that context. In general, however, the healthcare budgetary constraints in most EU member states have resulted in restrictions on the pricing and reimbursement of medicines by relevant health service providers. Coupled with ever-increasing EU and national regulatory burdens on those wishing to develop and market products, this could restrict or regulate post-approval activities and affect the ability of pharmaceutical companies to commercialize their products. In international markets, reimbursement and healthcare payment systems vary significantly by country, and many countries have instituted price ceilings on specific products and therapies.

In the future, there may continue to be additional proposals relating to the reform of the U.S. healthcare system and international healthcare systems. We expect that additional state, federal and foreign healthcare reform measures will be adopted in the future, any of which could limit the amounts that federal, state and foreign governments will pay for healthcare products and services, which could result in limited coverage and reimbursement and reduced demand for our products, once approved, or additional pricing pressures. Any reduction in reimbursement from Medicare or other government funded programs may result in a similar reduction in payments from private payors. The implementation of cost containment measures or other healthcare reforms may prevent us from being able to generate revenue, attain profitability or commercialize our product candidates.

**Data Privacy and Security**

Numerous state, federal and foreign laws, including consumer protection laws and regulations, govern the collection, dissemination, use, access to, confidentiality and security of personal information, including health-related information. In the United States, numerous federal and state laws and regulations, including data breach notification laws, health information privacy and security laws, and federal and state consumer protection laws and regulations that govern the collection, use, disclosure, and protection of health-related and other personal information could apply to our operations or the operations of our partners. In addition, certain foreign laws govern the privacy and security of personal information, including health-related information in certain circumstances, many of which differ from each other in significant ways and may not have the same effect, thus complicating compliance efforts. Failure to comply with these laws, where applicable, can result in the imposition of significant civil and/or criminal penalties and private litigation. Privacy and security laws, regulations, and other obligations are constantly evolving, may conflict with each other to complicate compliance efforts, and can result in investigations, proceedings, or actions that lead to significant civil and/or criminal penalties and restrictions on data processing.

**Research and Development Expenses**

Our research and development expenses were $19.4 million, $16.5 million and $24.5 million for the years ended December 31, 2024, 2023, and 2022, respectively. Please see “Management’s Discussion and Analysis of Financial Condition and Results of Operations-Research and Development Expenses” for additional detail regarding our research and development activities.

**Environment**

Our third-party manufacturers are subject to inspections by the FDA for compliance with cGMP and other U.S. regulatory requirements, including U.S. federal, state and local regulations regarding environmental protection and

hazardous and controlled substance controls, among others. Environmental laws and regulations are complex, change frequently and have tended to become more stringent over time. We have incurred, and may continue to incur, significant expenditures to ensure we are in compliance with these laws and regulations. We would be subject to significant penalties for failure to comply with these laws and regulations.

**Human Capital Resources**

As of December 31, 2024, we had 31 total employees, all of whom were full-time and 23 of whom were primarily engaged in research and development activities.

Our human capital resources objectives include, as applicable, identifying, recruiting, retaining, incentivizing and integrating our existing and additional employees. We strive to attract and retain the most talented employees in the industry by offering competitive compensation and benefits that support their health, financial and emotional well-being. The principal purposes of our compensation plans are to attract, retain and motivate selected employees and directors. We use a combination of fixed and variable compensation including base salary, cash-based performance bonuses and stock-based compensation awards.

**Facilities**

We currently lease approximately 20,916 square feet of office and research and development facilities in South San Francisco, California. This facility lease will expire in February 2028.

We previously leased approximately 27,280 square feet of office and research and development facilities in Burlingame, California. Approximately 7,585 square feet was subleased to Angel Pharmaceuticals through January 2023. This facility lease expired in January 2025.

**Corporate Information**

We were incorporated in Delaware on January 27, 2014 and began operations in November 2014. Our principal executive offices are located at 901 Gateway Boulevard, South San Francisco, California 94080, and our telephone number is (650) 900 4520. Our website address is http://www.corvuspharma.com. The information on our website is not incorporated by reference in this Annual Report on Form 10-K or in any other filings we make with the SEC.

We are a “smaller reporting company” as defined in the Exchange Act. We take advantage of certain of the scaled disclosures available to smaller reporting companies and will be able to take advantage of these scaled disclosures for so long as the market value of our voting and non-voting common stock held by non-affiliates is less than $250 million measured on the last business day of our second fiscal quarter, or our annual revenue is less than $100 million during the most recently completed fiscal year and the market value of our voting and non-voting common stock held by non-affiliates is less than $700 million measured on the last business day of our second fiscal quarter.

**Available Information**

We file electronically with the SEC our annual reports on Form 10-K, quarterly reports on Form 10-Q and current reports on Form 8-K pursuant to Section 13(a) or 15(d) of the Securities Exchange Act of 1934, as amended. We make available on our website at http://www.corvuspharma.com, free of charge, copies of these reports, as soon as reasonably practicable after we electronically file such material with, or furnish it to, the SEC. The public may read or copy any materials we file with the SEC. The SEC maintains a website that contains reports, proxy and information statements, and other information regarding issuers that file electronically with the SEC. The address of that website is www.sec.gov. The information on or accessible through the SEC and our website is not incorporated into, and is not considered part of, this filing. Further, our references to the URLs for these websites are intended to be inactive textual references only.

**Item 1A.**

**Risk Factors**

*Our business involves significant risks, some of which are described below. You should consider carefully the risks and uncertainties described below, together with all of the other information in this Annual Report on Form 10-K, including our audited consolidated financial statements and related notes included elsewhere in this Annual Report on Form 10-K and "Management's Discussion and Analysis of Financial Condition and Results of Operations." If any of the following risks are realized, our business, financial condition, results of operations and prospects could be materially and adversely affected. Additional risks and uncertainties not presently known to us or that we currently deem immaterial may also impair our business operations.*

**Risks Related to Our Limited Operating History, Financial Condition and Need for Additional Capital**

***We have incurred significant operating losses since our inception and expect to incur significant losses for the foreseeable future. We may never generate any revenue or become profitable or, if we achieve profitability, we may not be able to sustain it.***

We are a clinical-stage biopharmaceutical company that has never generated revenue from the sale of our product candidates. Biopharmaceutical product development is a highly speculative undertaking and involves a substantial degree of risk. To date, we have focused primarily on developing our lead product candidates, soquelitinib, ciforadenant and mupadolimab, and researching additional product candidates. We have incurred significant operating losses since we were founded in January 2014 and have not yet generated any revenue from sales. If our product candidates are not approved, we may never generate any revenue. We incurred a net loss of $62.3 million, $27.0 million and $41.3 million for the years ended December 31, 2024, 2023 and 2022, respectively. We had an accumulated deficit of $397.0 million as of December 31, 2024. We expect to continue to incur losses for the foreseeable future, and we anticipate these losses will increase as we continue our development of, seek regulatory approval for and, if approved, begin to commercialize soquelitinib, ciforadenant and mupadolimab, and as we develop other product candidates. Even if we achieve profitability in the future, we may not be able to sustain it in subsequent periods. Our prior losses, combined with expected future losses, have had and will continue to have an adverse effect on our stockholders' equity and results of operations.

***The report of our independent registered public accounting firm included a "going concern" explanatory paragraph.***

We will require substantial funds to finance our research and development programs and support our operations. Our cash, cash equivalents and marketable securities were $52.0 million at December 31, 2024. Given our planned expenditures for the next year, we have concluded, and our independent registered public accounting firm has agreed with our conclusion that there is a substantial doubt regarding our ability to continue as a going concern for a period of at least 12 months beyond the filing of this Annual Report on Form 10-K. As a result, the report of our independent registered public accounting firm on our financial statements for the year ended December 31, 2024 includes an explanatory paragraph regarding the existence of substantial doubt about our ability to continue as a going concern. Any such inability to continue as a going concern may result in our stockholders losing their entire investment. There is no guarantee that we will become profitable or secure additional financing on acceptable terms. Further, the inclusion of disclosures expressing substantial doubt about our ability to continue as a going concern could materially adversely affect our stock price and our ability to raise new capital or enter into business development or collaboration agreements.

We have prepared our consolidated financial statements on a going concern basis, which contemplates the realization of assets and the satisfaction of liabilities and commitments in the normal course of business. Our audited consolidated financial statements included in this Annual Report on Form 10-K do not include any adjustments to reflect the possible inability to continue as a going concern within at least 12 months after the issuance of such financial statements.

***We will require substantial additional financing to achieve our goals, and a failure to obtain this necessary capital when needed on acceptable terms, or at all, could force us to delay, limit, reduce or terminate our product development, other operations or commercialization efforts.***

Since our inception, the majority of our efforts have been focused on the research and development of soquelitinib, ciforadenant and mupadolimab. We believe that we will continue to expend substantial resources for the foreseeable future as we continue clinical development of, seek regulatory approval for and, if approved, prepare for the commercialization of soquelitinib, ciforadenant, and mupadolimab, as well as product candidates under our other development programs. These expenditures will include costs associated with research and development, conducting preclinical studies and clinical trials, obtaining regulatory approvals, manufacturing and supply, sales and marketing and general operations. In addition, other unanticipated costs may arise. Because the outcome of any clinical trial and/or regulatory approval process is highly uncertain, we may not be able to accurately estimate the actual amounts necessary to successfully complete the development, regulatory approval process and commercialization of soquelitinib, ciforadenant and mupadolimab or any other product candidates.

As of December 31, 2024, we had capital resources consisting of cash, cash equivalents and marketable securities of $52.0 million. Given our planned expenditures for the next year, we do not expect our existing capital resources to be sufficient to fund our operations through a period of at least 12 months beyond the filing of this Annual Report on Form 10-K. As a result, unless we receive additional funds from an outside source, we anticipate not being able to fund the completion of our ongoing and planned clinical trials and remaining development of any of soquelitinib, including any potential registration trial for soquelitinib, ciforadenant or mupadolimab. In addition, while Angel Pharmaceuticals has received outside investment of approximately $41.0 million in connection with its formation and licensing of certain of our intellectual property, such cash is not available for our use. Our operating plan may change as a result of many factors, including those described below as well as others currently unknown to us, and we will need to seek additional funds, through public or private equity, and debt financings or other sources, such as strategic collaborations. Such financing would result in dilution to stockholders, imposition of debt covenants and repayment obligations or other restrictions that may affect our business. If we raise additional capital through strategic collaboration agreements, we may have to relinquish valuable rights to our product candidates, including possible future revenue streams. For example, in October 2020 we formed Angel Pharmaceuticals with a group of investors in China to create a new China-based biopharmaceutical company with a mission to bring innovative quality medicines to Chinese patients for treatment of serious diseases including cancer, autoimmune diseases and infectious diseases. We granted Angel Pharmaceuticals a license to rights to develop and commercialize our three clinical-stage candidates – soquelitinib, ciforadenant and mupadolimab – in greater China and Angel obtained global rights to our BTK inhibitor preclinical programs. In addition, additional funding may not be available to us on acceptable terms, or at all, and any additional fundraising efforts may divert our management from their day-to-day activities, which may adversely affect our ability to develop and commercialize our product candidates.

The amount and timing of any expenditures needed to implement our development and commercialization programs will depend on numerous factors, including, but not limited to:

- the type, number, scope, progress, expansions, results of and timing of our ongoing and planned clinical trials of soquelitinib (including the potential registration trial), ciforadenant and mupadolimab and any of our planned preclinical studies and clinical trials of other product candidates which we are pursuing or may choose to pursue in the future;

- the need for, and the progress, costs and results of, any additional clinical trials of soquelitinib, ciforadenant and mupadolimab or any of our other product candidates we may initiate based on the results of our planned clinical trials or discussions with the FDA or other regulatory agencies, including any additional trials the FDA or other regulatory agencies may require;

- the costs of obtaining, maintaining and enforcing our patents and other intellectual property rights;

- the costs and timing of obtaining or maintaining manufacturing for soquelitinib, ciforadenant and mupadolimab and our other product candidates, including commercial manufacturing if any product candidate is approved;
- the costs and timing of establishing sales and marketing capabilities;
- our ability to achieve sufficient market acceptance, coverage and reimbursement from third-party payors and adequate market share for our product candidates;
- the terms and timing of establishing collaborations, license agreements and other partnerships;
- whether the FDA or other regulatory agencies accepts data from any clinical trials of our product candidates conducted by Angel Pharmaceuticals in China;
- costs associated with any new product candidates that we may develop, in-license or acquire;
- Angel Pharmaceuticals' ability to develop and commercialize product candidates in China;
- general economic conditions, such as rising inflation;
- the effect of competing technological and market developments;
- our ability to attract, hire and retain qualified personnel;
- our ability to establish and maintain partnering arrangements for development; and
- the costs associated with being a public company.

Several of these factors are outside of our control and if we are unable to obtain funding on a timely basis, we will be unable to complete the clinical trials for soquelitinib, ciforadenant and mupadolimab and our other product candidates, and we may be required to significantly curtail some or all of our activities.

**Risks Related to the Discovery and Development of Our Product Candidates**

***Our product candidates are in various stages of development and may fail or suffer delays that materially and adversely affect their commercial viability. If we are unable to advance our product candidates through clinical development, obtain regulatory approval and ultimately commercialize such 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 most advanced product candidates, soquelitinib, ciforadenant and mupadolimab. We have no products on the market and 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. Before obtaining regulatory approval for the commercial distribution of our product candidates, we or our collaborator must conduct extensive preclinical tests and clinical trials to demonstrate sufficient safety and efficacy of our product candidates in patients.

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

- negative or inconclusive results from our clinical trials, the clinical trials of our collaborators, including Angel Pharmaceuticals, 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 participants in our clinical trials, the clinical trials of our collaborators or by individuals using drugs or therapeutic biologics similar to our product candidates;
- delays in submitting Investigational New Drug Applications ("INDs") or comparable foreign applications or delays or failure 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 research subjects in clinical trials;
- high drop-out rates of research subjects;
- inadequate supply or quality of product candidate components or materials or other supplies necessary for the conduct of our clinical trials or the clinical trials of our collaborators;
- greater than anticipated clinical trial costs;
- delay in the development, approval or certification of companion diagnostic tests for our product candidates;
- unfavorable FDA or other regulatory agency inspection and review of a clinical trial site;
- 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; or
- varying interpretations of data by the FDA and similar foreign regulatory agencies.

We could find that the product candidates we or our collaborators pursue are not safe or effective. Furthermore, if one or more of our product candidates generally prove to be ineffective, unsafe or commercially unviable, the development of our entire platform and pipeline could be delayed, potentially permanently. Any of these occurrences may materially and adversely affect our business, financial condition, results of operations and prospects.

Of the large number of drugs in development in the pharmaceutical industry, only a small percentage result in the submission of a New Drug Application ("NDA") or Biologics License Application ("BLA") to the FDA or comparable marketing applications to foreign regulatory authorities, and even fewer are approved for commercialization. Furthermore, even if we do receive regulatory approval to market soquelitinib, ciforadenant or mupadolimab, any such approval may be subject to limitations on the indicated uses for which we may market the product. Accordingly, even if we are able to obtain the requisite financing to continue to fund our development programs, we cannot assure our stockholders that soquelitinib, ciforadenant or mupadolimab will be successfully developed or commercialized. If we or any of our existing or potential future collaborators are unable to develop, or obtain regulatory approval for, or, if approved, successfully commercialize soquelitinib, ciforadenant or mupadolimab, we may not be able to generate sufficient revenue to continue our business.

***Clinical drug development involves a lengthy and expensive process with an uncertain outcome, and the results of preclinical studies and early clinical trials are not necessarily predictive of future results. Any product candidate we or any of our existing or potential future collaborators advance into clinical trials, including soquelitinib, ciforadenant and mupadolimab, may not have favorable results in later clinical trials, if any, or receive regulatory approval.***

Clinical testing is expensive and can take many years to complete, and its outcome is inherently uncertain. Failure can occur at any time during the clinical trial process. The results of preclinical studies and early clinical trials of our product candidates may not be predictive of the results of later-stage clinical trials. Product candidates in later stages of clinical trials may fail to show the desired safety and efficacy traits despite having progressed through preclinical studies and initial clinical trials. A number of companies in the biopharmaceutical industry have suffered significant setbacks in advanced clinical trials due to lack of efficacy or adverse safety profiles, notwithstanding promising results in earlier trials.

Under our collaboration with Angel Pharmaceuticals, Angel is responsible for the clinical development and commercialization, including all related expenses, of the licensed pipeline programs in greater China, and for the pre-clinical BTK program globally. Clinical trials conducted by Angel Pharmaceuticals will be subject to many of the same risks as our ongoing clinical programs.

We cannot be certain that our ongoing or planned clinical trials or any other future clinical trials will be successful. Any safety concerns observed in any one of our clinical trials in our targeted indications could limit the prospects for regulatory approval of our product candidates in those and other indications, which could have a material adverse effect on our business, financial condition and results of operations.

In addition, the FDA's and other regulatory authorities' policies with respect to clinical trials may change and additional government regulations may be enacted. For instance, the regulatory landscape related to clinical trials in the European Union ("EU") recently evolved. The EU Clinical Trials Regulation ("CTR") which was adopted in April 2014 and repeals the EU Clinical Trials Directive, became applicable on January 31, 2022. While the EU Clinical Trials Directive required a separate clinical trial application ("CTA") to be submitted in each member state in which the clinical trial takes place, to both the competent national health authority and an independent ethics committee, the CTR introduces a centralized process and only requires the submission of a single application for multi-center trials. The CTR allows sponsors to make a single submission to both the competent authority and an ethics committee in each member state, leading to a single decision per member state. The assessment procedure of the CTA has been harmonized as well, including a joint assessment by all member states concerned, and a separate assessment by each member state with respect to specific requirements related to its own territory, including ethics rules. Each member state's decision is communicated to the sponsor via the centralized EU portal. Once the CTA is approved, clinical study development may proceed. The CTR foresees a three-year transition period. The extent to which ongoing and new clinical trials will be governed by the CTR varies. Clinical trials for which an application was submitted (i) prior to January 31, 2022 under the EU Clinical Trials Directive, or (ii) between January 31, 2022 and January 31, 2023 and for which the sponsor has opted for the application of the EU Clinical Trials Directive remain governed by said Directive until January 31, 2025. After this date, all clinical trials (including those which are ongoing) will become subject to the provisions of the CTR. Compliance with the CTR requirements by us, our collaborators and third-party service providers, such as contract research organizations ("CROs"), may impact our developments plans.

If we are slow or unable to adapt to changes in existing requirements or the adoption of new requirements or policies governing clinical trials, our development plans may also be impacted.

***Any termination or suspension of, or delays in the commencement or completion of, our planned clinical trials could result in increased costs to us, delay or limit our ability to generate revenue and adversely affect our commercial prospects.***

Before we can initiate clinical trials in the United States or in foreign countries for any of our product and development candidates, we must submit the results of preclinical testing to the FDA or foreign regulatory authorities along with other information, including information about product candidate chemistry, manufacturing and controls and

our proposed clinical trial protocol, as part of an IND or similar application. In addition, we may rely in part on preclinical, clinical and quality data generated by CROs and other third parties for regulatory submissions for our product candidates. If these third parties do not make timely regulatory submissions for our product candidates, it will delay our plans for our clinical trials. If those third parties do not make this data available to us, we will likely have to develop all necessary preclinical and clinical data on our own, which will lead to significant delays and increase development costs of the product candidate. In addition, the FDA or foreign regulatory authorities may require us to conduct additional preclinical testing for any product candidate before it allows us to initiate clinical testing under any IND or similar, which may lead to additional delays and increase the costs of our preclinical development. Delays in the completion of our planned clinical trials for product candidates could significantly affect our product development costs.

While we initiated several clinical trials, we do not know whether any of our other planned trials, will begin on time in the future or whether any of our trials will be completed on schedule, if at all. The commencement and completion of clinical trials can be delayed for a number of reasons, including delays related to:

- the FDA or foreign regulatory authorities failing to grant permission to proceed or placing a clinical trial on hold;
- subjects failing to enroll or remain in our trial at the rate we expect;
- subjects choosing an alternative treatment for the indication for which we are developing soquelitinib, ciforadenant and mupadolimab or other product candidates, or participating in competing clinical trials;
- lack of adequate funding to continue the clinical trial;
- subjects experiencing severe or unexpected drug-related adverse effects;
- a facility manufacturing soquelitinib, ciforadenant or mupadolimab, any of our other product candidates or any of their components being ordered by the FDA or other regulatory authorities to temporarily or permanently shut down due to violations of good manufacturing practice ("cGMP") regulations or other applicable requirements, or infections or cross-contaminations of product candidates in the manufacturing process;
- any changes to our manufacturing process that may be necessary or desired;
- any failure or delay in reaching an agreement with CROs and clinical trial sites;
- third-party clinical investigators losing the licenses or permits necessary to perform our clinical trials, not performing our clinical trials on our anticipated schedule or consistent with the clinical trial protocol, good clinical practices ("GCP") or regulatory requirements or other third parties not performing data collection or analysis in a timely or accurate manner;
- third-party contractors becoming debarred or suspended or otherwise penalized by the FDA or other government or regulatory authorities for violations of regulatory requirements, in which case we may need to find a substitute contractor, and we may not be able to use some or all of the data produced by such contractors in support of our marketing applications;
- one or more Institutional Review Boards ("IRBs") or other reviewing bodies refusing to approve, suspending or terminating the trial at an investigational site, precluding enrollment of additional subjects, or withdrawing its approval of the trial; or
- patients failing to complete a trial or return for post-treatment follow-up.

In addition, we could also encounter delays if a clinical trial is suspended or terminated by us, by the IRBs of the institutions in which such trials are being conducted, by the Data Safety Monitoring Board for such trial or by the

FDA or other regulatory authorities. Such authorities may impose such a suspension or termination due to a number of factors, including failure to conduct the clinical trial in accordance with regulatory requirements or our clinical protocols, inspection of the clinical trial operations or trial site by the FDA or other regulatory authorities resulting in the imposition of a clinical hold, unforeseen safety issues or adverse side effects, failure to demonstrate a benefit from using a drug, changes in governmental regulations or administrative actions or lack of adequate funding to continue the clinical trial. In addition, changes in regulatory requirements and policies may occur, and we may need to amend clinical trial protocols to comply with these changes. Amendments may require us to resubmit our clinical trial protocols to IRBs or other reviewing bodies for reexamination, which may impact the costs, timing or successful completion of a clinical trial.

If we experience delays in the completion of, or termination of, any clinical trial of our product candidates, the commercial prospects of our product candidates will be harmed, and our ability to generate product revenues from any of these product candidates will be delayed. In addition, any delays in completing our clinical trials will increase our costs, slow down our product candidate development and approval process and jeopardize our ability to commence product sales and generate revenues. See also the risk factor below titled "*If we encounter difficulties enrolling subjects in our clinical trials, our clinical development activities could be delayed or otherwise adversely affected*."

In addition, many of the factors that cause, or lead to, termination or suspension of, or a delay in the commencement or completion of, clinical trials may also ultimately lead to the denial of regulatory approval of a product candidate. For example, if we make manufacturing or formulation changes to our product candidates, we may need to conduct additional studies to bridge our modified product candidates to earlier versions. Further, if one or more clinical trials are delayed, our competitors may be able to bring products to market before we do, and the commercial viability of soquelitinib, ciforadenant and mupadolimab or other product candidates could be significantly reduced. Any of these occurrences may harm our business, financial condition and prospects significantly.

***Interim "top-line" and preliminary data from our clinical trials that we announce or publish from time to time 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 may publicly disclose interim, top-line or preliminary data from our clinical trials, which is based on a preliminary analysis of then-available data, and the results and related findings and conclusions are subject to change following a more comprehensive review 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. As a result, the top-line or preliminary results that we report may differ from future results of the same studies, or different conclusions or considerations may qualify such results, once additional data have been received and fully evaluated. Top-line or preliminary data also remain subject to audit and verification procedures that may result in the final data being materially different from the top-line or preliminary data we previously published. As a result, top-line and preliminary data should be viewed with caution until the final data are available.

From time to time, we may also disclose interim data from our preclinical studies and clinical trials. Interim data from clinical trials that we may complete are subject to the risk that one or more of the clinical outcomes may materially change as patient enrollment continues and more patient data become available. Adverse differences between interim data and final data could significantly harm our business 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 impact the value of the particular program, the approvability or commercialization of the particular product candidate or product and our company in general. In addition, the information we choose to publicly disclose regarding a particular study or clinical trial is based on what is typically extensive information, and you or others may not agree with what we determine is material or otherwise appropriate information to include in our disclosure.

If the interim, top-line or preliminary data that we report differ from actual results, or if others, including regulatory authorities, disagree with the conclusions reached, our ability to obtain approval for, and commercialize, our product candidates may be harmed, which could harm our business, operating results, prospects or financial condition.

***Our product candidates are subject to extensive regulation, compliance with which is costly and time consuming, and such regulation may cause unanticipated delays or prevent the receipt of the required approvals to commercialize our product candidates.***

The clinical development, manufacturing, labeling, storage, record-keeping, advertising, promotion, import, export, marketing and distribution of our product candidates are subject to extensive regulation by the FDA in the United States and by comparable authorities in foreign markets. In the United States, we are not permitted to market our product candidates until we receive regulatory approval from the FDA. The process of obtaining regulatory approval is expensive, often takes many years and can vary substantially based upon the type, complexity and novelty of the product candidates involved, as well as the target indications and patient population. Approval policies or regulations may change, and the FDA and comparable authorities have substantial discretion in the drug approval process, including the ability to delay, limit or deny approval of a product candidate for many reasons. Despite the time and expense invested in clinical development of product candidates, regulatory approval is never guaranteed.

The FDA or comparable foreign regulatory authorities, including in China, can delay, limit or deny approval of a product candidate for many reasons, including:

- such authorities may disagree with the design or implementation of our or any of our existing or potential future collaborators' clinical trials;
- we or any of our existing or potential future collaborators may be unable to demonstrate to the satisfaction of the FDA or other regulatory authorities that a product candidate is safe, pure, potent or effective for any indication;
- such authorities may not accept clinical data from trials which are conducted at clinical facilities or in countries where the standard of care is potentially different from that of the United States;
- we or any of our existing or potential future collaborators may be unable to demonstrate that a product candidate's clinical and other benefits outweigh its safety risks;
- such authorities may disagree with our interpretation of data from preclinical studies or clinical trials;
- approval may be granted only for indications that are significantly more limited than what we apply for and/or with other significant restrictions on distribution and use;
- such authorities may find deficiencies in the manufacturing processes or facilities of third-party manufacturers with which we or any of our existing or potential future collaborators contract for clinical and commercial supplies; or
- the approval policies or regulations of such authorities may significantly change in a manner rendering our or any of our existing or potential future collaborators' clinical data insufficient for approval.

With respect to foreign markets, approval procedures vary among countries and, in addition to the foregoing risks, may involve additional product testing, administrative review periods and agreements with pricing authorities. In addition, events raising questions about the safety of certain marketed pharmaceuticals may result in increased cautiousness by the FDA and comparable foreign regulatory authorities, including in China, in reviewing new drugs based on safety, efficacy or other regulatory considerations and may result in significant delays in obtaining regulatory approvals. Any delay in obtaining, or inability to obtain, applicable regulatory approvals would prevent us or any of our existing or potential future collaborators from commercializing our product candidates.

***We are conducting and plan to conduct clinical trials for soquelitinib, ciforadenant and mupadolimab, and we and Angel Pharmaceuticals may in the future, conduct additional clinical trials of product candidates at sites outside the United States, and the FDA may not accept data from trials conducted in foreign locations.***

We are conducting oncology clinical trials with soquelitinib in North America, Australia and South Korea and with ciforadenant in North America in collaboration with the Kidney Cancer Research Consortium. In addition, Angel Pharmaceuticals has initiated clinical trials in China for soquelitinib, mupadolimab and plans to initiate a clinical trial for ciforadenant. The acceptance of study data from clinical trials conducted outside the U.S. or another jurisdiction by the FDA or comparable foreign regulatory authority may be subject to certain conditions or may not be accepted at all. In cases where data from foreign clinical trials are intended to serve as the sole basis for marketing approval in the U.S., the FDA will generally not approve the application on the basis of foreign data alone unless (i) the data are applicable to the U.S. population and U.S. medical practice; (ii) the trials were performed by clinical investigators of recognized competence and pursuant to GCP regulations; and (iii) the data may be considered valid without the need for an on-site inspection by the FDA, or if the FDA considers such inspection to be necessary, the FDA is able to validate the data through an on-site inspection or other appropriate means. In addition, even where the foreign study data are not intended to serve as the sole basis for approval, if the trials were not subject to an IND, the FDA will not accept the data as support for an application for marketing approval unless the study is well-designed and well-conducted in accordance with GCP requirements and the FDA is able to validate the data from the study through an onsite inspection if deemed necessary. Many foreign regulatory authorities have similar approval requirements. In addition, such foreign trials would be subject to the applicable local laws of the foreign jurisdictions where the trials are conducted. There can be no assurance that the FDA or any comparable foreign regulatory authority will accept data from trials conducted outside of the U.S. or the applicable jurisdiction. If the FDA or such foreign regulatory authority does not accept the data from our or Angel Pharmaceuticals' clinical trials for soquelitinib, ciforadenant or mupadolimab, or any other product candidates, it would likely result in the need for additional trials, which would be costly and time-consuming and delay or permanently halt our development of soquelitinib, ciforadenant or mupadolimab or any other product candidates.

***If we encounter difficulties enrolling subjects in our clinical trials, our clinical development activities could be delayed or otherwise adversely affected.***

Subject 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, the risk that enrolled patients will not complete a clinical trial, our ability to recruit clinical trial investigators with the appropriate competencies and experience, 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 that may be approved for the indications we are investigating. We will be required to identify and enroll a sufficient number of subjects for each of our clinical trials. Potential subjects for any planned clinical trials may not be adequately diagnosed or identified with the diseases which we are targeting or may not meet the entry criteria for our studies. We also may encounter difficulties in identifying and enrolling subjects with a stage of disease appropriate for our planned clinical trials. We may not be able to initiate or continue clinical trials if we are unable to locate a sufficient number of eligible subjects to participate in the clinical trials required by the FDA or other foreign regulatory agencies. In addition, the process of finding and diagnosing subjects may prove costly.

If patients are unwilling to participate in our studies for any reason, including the existence of competitive clinical trials for similar patient populations, the availability of approved therapies or negative perceptions of the safety or efficacy of our product candidates, the timeline for recruiting subjects, conducting studies and obtaining regulatory approval of our product candidates may be delayed. Our inability to enroll a sufficient number of subjects for any of our future clinical trials would result in significant delays or may require us to abandon one or more clinical trials altogether.

We believe we have appropriately considered the above factors in our trials when determining expected clinical trial timelines, but we cannot assure our stockholders that our assumptions are correct or that we will not experience delays in enrollment, which would result in the delay of completion of such trials beyond our expected timelines.

***The occurrence of serious complications or side effects in connection with use of our product candidates, either in clinical trials or post-approval, could lead to discontinuation of our clinical development programs, refusal of regulatory authorities to approve our product candidates or, post-approval, revocation of marketing authorizations or refusal to approve new indications, which could severely harm our business, prospects, operating results and financial condition.***

During the conduct of clinical trials, patients report changes in their health, including illnesses, injuries and discomforts, to their study doctor. Often, it is not possible to determine whether or not the product candidate being studied caused these conditions. It is possible that as we test our product candidates in larger, longer and more extensive clinical programs with different dosing regimens and in combination with other immunotherapies, or as use of these product candidates becomes more widespread if they receive 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 subjects.

Side effects are often only detectable after investigational products are tested in large-scale, Phase 3 clinical trials or, in some cases, after they are made available to patients on a commercial scale after approval. Results of our current clinical trials and any future clinical trials we undertake could reveal a high and unacceptable severity and prevalence of these or other side effects. In such an event, our 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. Drug-related side effects could affect patient recruitment or the ability of enrolled patients to complete the trial or result in potential product liability claims. Any of these occurrences may harm our business, financial condition and prospects significantly.

In addition, if one or more of our product candidates receives marketing approval, and we or others later identify undesirable side effects caused by such products, a number of potentially significant negative consequences could result, including:

- regulatory authorities may withdraw approvals of such product;
- regulatory authorities may require additional warnings on the label;
- 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; and
- our reputation may suffer.

Any of these events could prevent us from achieving or maintaining market acceptance of the particular product candidate, if approved, and could significantly harm our business, results of operations and prospects.

***A Fast Track Designation from the FDA, even if granted for any of our product candidates, 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 regulatory approval.***

On July 29, 2024, the FDA granted Fast Track designation for soquelitinib for the [treatment of adult patients with relapsed or refractory peripheral T-cell lymphoma after at least two lines of systemic therapy]. Depending on the data from our preclinical and clinical studies, we may decide to seek additional Fast Track designations for some or all of our other product candidates. The Fast Track program is intended to expedite or facilitate the process for reviewing product candidates that meet certain criteria. Specifically, drugs and biologics are eligible for Fast Track designation if they are intended, alone or in combination with one or more drugs or biologics, to treat a serious or life-threatening disease or condition and demonstrate the potential to address unmet medical needs for the disease or condition. Fast Track designation applies to the combination of the product candidate and the specific indication for which it is being studied. The sponsor of a Fast Track product candidate has opportunities for more frequent interactions with the applicable FDA review team during product development and, once a BLA or NDA is submitted, the application may be eligible for priority review. A NDA or BLA submitted for a Fast Track product candidate may also be eligible for rolling review, where the FDA may consider for review sections of the application on a rolling basis before the complete application is submitted, if the sponsor provides a schedule for the submission of the sections of the NDA or BLA, the FDA agrees to accept sections of the NDA or BLA and determines that the schedule is acceptable, and the sponsor pays any required user fees upon submission of the first section of the application.

The FDA has broad discretion whether or not to grant this designation. 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 for any of our product candidates, such product candidates may not experience a faster development process, review or approval compared to conventional FDA procedures. The FDA may also withdraw Fast Track Designation if it believes that the designation is no longer supported by data from our clinical development program. Furthermore, such a designation does not increase the likelihood that soquelitinib or any other product candidate that may be granted Fast Track designation will receive regulatory approval in the U.S. Many product candidates that have received Fast Track Designation have ultimately failed to obtain approval.

***We may not be successful in our efforts to identify or discover additional product candidates.***

The success of our business depends primarily upon our ability to develop and commercialize soquelitinib, ciforadenant and mupadolimab. Although soquelitinib, ciforadenant and mupadolimab are currently in clinical development, our research programs may fail to identify other potential product candidates, or advance them into and through clinical development for a number of reasons. Our research methodology may be unsuccessful in identifying other potential product candidates or our other 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. It may also take greater human and financial resources to identify additional therapeutic opportunities for our product candidates or to develop suitable potential product candidates through our research programs than we will possess, thereby limiting our ability to diversify and expand our product candidate portfolio.

**Risks Related to Our Reliance on Third Parties**

***We rely, and expect to continue to rely, on third parties to conduct our clinical trials. If these third parties do not meet our deadlines or otherwise conduct the trials as required, our clinical development programs could be delayed or unsuccessful and we may not be able to obtain regulatory approval for or commercialize our product candidates when expected, or at all.***

We do not have the ability to conduct all aspects of our preclinical testing or clinical trials ourselves. As a result, we are dependent on third parties to conduct our ongoing and planned clinical trials for soquelitinib, ciforadenant and mupadolimab and expect to continue to be dependent on third parties to conduct any additional future clinical trials of soquelitinib, ciforadenant and mupadolimab and preclinical and clinical trials for our other product candidates. The timing of the initiation and completion of these trials will therefore be controlled by such third parties and may occur at times substantially different from our estimates. Specifically, we use and rely on medical institutions, clinical

investigators, CROs and consultants to conduct our trials in accordance with our clinical protocols and regulatory requirements. Such CROs, investigators and other third parties play a significant role in the conduct of these trials and subsequent collection and analysis of data, and we will control only certain aspects of their activities. Nevertheless, we are responsible for ensuring that each of our studies is conducted in accordance with the applicable protocol and legal, regulatory and scientific standards, and our reliance on the CROs and other third parties does not relieve us of our regulatory responsibilities. We and our CROs are required to comply with GCP requirements, which are regulations and guidelines enforced by the FDA, the competent authorities of the EU member states and comparable foreign regulatory authorities for all of our product candidates in clinical development.

Regulatory authorities enforce these GCPs through periodic inspections of trial sponsors, principal investigators and trial sites. If we or any of our CROs or trial sites fail to comply with applicable GCPs, the clinical data generated in our clinical trials may be deemed unreliable, and the FDA or comparable foreign regulatory authorities may require us to perform additional clinical trials before approving our marketing applications. In addition, our clinical trials must be conducted with product produced under cGMP or similar regulations. Our failure to comply with these regulations may require us to repeat clinical trials, which would delay the regulatory approval process.

There is no guarantee that any such CROs, investigators or other third parties will devote adequate time and resources to such trials or perform as contractually required. If any of these third parties fail to meet expected deadlines, adhere to our clinical protocols or meet regulatory requirements, or otherwise performs in a substandard manner, our clinical trials may be extended, delayed or terminated.

In addition, principal investigators for our clinical trials may serve as scientific advisors or consultants to us from time to time and may receive cash or equity compensation in connection with such services. If these relationships and any related compensation result in perceived or actual conflicts of interest, or the FDA or foreign regulatory authorities conclude that the financial relationship may have affected the interpretation of the study, the integrity of the data generated at the applicable clinical trial site may be questioned and the utility of the clinical trial itself may be jeopardized, which could result in the delay or rejection of any NDA, BLA or other applications we submit by the FDA or foreign regulatory authorities. Any such delay or rejection could prevent us from commercializing soquelitinib, ciforadenant and mupadolimab or our other product candidates.

***We rely on third parties to conduct some or all aspects of our manufacturing, research and preclinical and clinical testing, and these third parties may not perform satisfactorily.***

We do not expect to independently conduct all aspects of our manufacturing, research and preclinical and clinical testing. We currently rely, and expect to continue to rely, on third parties with respect to these items. If these third parties do not successfully carry out their contractual duties, meet expected deadlines or conduct our studies in accordance with regulatory requirements or our stated study plans and protocols, we may not be able to complete, or may be delayed in completing, the preclinical and clinical studies required to support future IND or other submissions and approval of our product candidates. Furthermore, any of these third parties may terminate its engagement with us at any time. If we need to enter into alternative arrangements, it could delay our product development activities, and we may not be able to negotiate alternative arrangements on commercially reasonable terms, or at all.

***We and our contract manufacturers are subject to significant regulation with respect to manufacturing our products and the contract manufacturers on which we rely may not continue to meet regulatory requirements.***

We do not currently have nor do we plan to acquire the infrastructure or internal capability to manufacture our clinical drug supplies for use in the conduct of our trials, and we lack the resources and the capability to manufacture any of our product candidates on a clinical or commercial scale. We currently rely on several different manufacturers who supply different parts of the ciforadenant and soquelitinib molecules, on one manufacturer for mupadolimab drug substance and on other third-party manufacturers to produce our other product candidates.

All entities involved in the preparation of therapeutics for clinical studies or commercial sale, including our existing contract manufacturers for our product candidates, are subject to extensive regulation. Components of a finished therapeutic product approved for commercial sale or used in late-stage clinical studies must be manufactured in

accordance with cGMP requirements. These regulations govern manufacturing processes and procedures, including record keeping, and the implementation and operation of quality systems to control and assure the quality of investigational products and products approved for sale. Poor control of production processes can lead to the introduction of adventitious agents or other contaminants, or to inadvertent changes in the properties or stability of our product candidates that may not be detectable in final product testing. We or our contract manufacturers must supply all necessary documentation in support of an NDA or BLA on a timely basis and must adhere to the FDA's Good Laboratory Practice regulations and cGMP regulations enforced by the FDA through its facilities inspection program. Our facilities and quality systems and the facilities and quality systems of some or all of our third-party contractors must successfully complete a pre-approval inspection for compliance with the applicable regulations as a condition of regulatory approval of our product candidates or any of our other potential products. In addition, the regulatory authorities may, at any time, audit or inspect our manufacturing facilities or those of our third-party contractors involved with the preparation of our product candidates or the associated quality systems for compliance with the regulations applicable to the activities being conducted. We do not control the manufacturing process of, and are completely dependent on, our contract manufacturing partners for compliance with cGMPs. Similar requirements must be complied with in foreign jurisdictions.

The regulatory authorities also may, at any time following approval of a product for sale, audit the manufacturing facilities of our third-party contractors. If any such inspection or audit identifies a failure to comply with applicable regulations or if a violation of our product specifications or applicable regulations occurs independent of such an inspection or audit, we or the relevant regulatory authority may require remedial measures that may be costly and/or time-consuming for us or a third party to implement and that may include the temporary or permanent suspension of a clinical study or commercial sales or the temporary or permanent closure of a facility. Such violations could also result in civil and/or criminal penalties, and the FDA or foreign regulatory authorities may impose regulatory sanctions including, among other things, refusal to approve a pending application for a new drug product or biologic product, revocation of a pre-existing approval or closing one or more manufacturing facilities.

In addition, if supply from an approved manufacturer is interrupted, there could be a significant disruption in commercial supply. An alternative manufacturer would need to be qualified through an NDA or BLA supplement which could result in further delay. The regulatory agencies may also require additional studies if a new manufacturer is relied upon for commercial production. Changing manufacturers may involve substantial costs and is likely to result in a delay in our desired clinical and commercial timelines.

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

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

In addition, the supply chain for the manufacturing of our product candidates is complicated and can involve several parties. If we were to experience any supply chain issues, our product supply could be seriously disrupted. We expect that the logistical challenges associated with our supply chain will grow more complex as we expand enrollment in our clinical trials for soquelitinib, ciforadenant and mupadolimab and as we commence any clinical trials for additional product candidates.

***Our reliance on third parties requires us to share our trade secrets, which increases the possibility that a competitor will discover them or that our trade secrets will be misappropriated or disclosed.***

Because we rely on third parties to research and develop and to manufacture our product candidates, we must share trade secrets with them. We seek to protect our proprietary technology in part by entering into confidentiality agreements and, if applicable, material transfer agreements, consulting agreements or other similar agreements with our advisors, employees, third-party contractors and consultants prior to beginning research or disclosing proprietary information. These agreements typically limit the rights of the third parties to use or disclose our confidential information, including our trade secrets. Despite the contractual provisions employed when working with third parties, the need to share trade secrets and other confidential information increases the risk that such trade secrets become known by our competitors, are inadvertently incorporated into the technology of others, or are disclosed or used in violation of these agreements. Given that our proprietary position is based, in part, on our know-how and trade secrets, a competitor's independent discovery of our trade secrets or other unauthorized use or disclosure would impair our competitive position and may have a material adverse effect on our business.

In addition, these agreements typically restrict the ability of our advisors, employees, third-party contractors and consultants to publish data potentially relating to our trade secrets, although our agreements may contain certain limited publication rights. For example, any academic institution that we may collaborate with in the future will likely expect to be granted rights to publish data arising out of such collaboration. In the future we may also conduct joint research and development programs that may require us to share trade secrets under the terms of our research and development or similar agreements. Despite our efforts to protect our trade secrets, our competitors may discover our trade secrets, either through breach of our agreements with third parties, independent development or publication of information by any of our third-party collaborators. A competitor's discovery of our trade secrets would impair our competitive position and have an adverse impact on our business.

**Risks Related to Commercialization of Our Product Candidates**

***If we are unable to commercialize our product candidates or if we experience significant delays in obtaining regulatory approval for, or commercializing, any or all of our product candidates, our business will be materially and adversely affected.***

Our ability to generate product revenue will depend heavily on our ability to successfully develop and commercialize our product candidates. We do not expect that such commercialization of any of our product candidates will occur for at least the next several years, if ever. Our ability to commercialize our product candidates effectively will depend on several factors, including the following:

- successful completion of preclinical studies and clinical trials, including the ability to demonstrate safety and efficacy of our product candidates;
- managing the complexity of our clinical trial designs;
- receipt of marketing approvals from the FDA and similar foreign regulatory authorities;
- establishing commercial manufacturing capabilities by making arrangements with third-party manufacturers;
- successfully launching commercial sales of any approved products, whether alone or in collaboration with others;
- acceptance of any approved products by patients, the medical community and third-party payors;
- establishing market share while competing with other therapies;

- a continued acceptable safety profile of any approved products;
- maintaining compliance with post-approval regulation and other requirements; and
- qualifying for, identifying, registering, maintaining, enforcing and defending intellectual property rights and claims covering our product candidates.

If we experience significant delays or an inability to commercialize our product candidates, our business, financial condition and results of operations will be materially adversely affected.

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

We estimate the timing of the accomplishment of various scientific, clinical, regulatory 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 will be based on a variety of assumptions, and the actual timing of these milestones can vary dramatically compared to our estimates, in some cases for reasons beyond our control. If we do not meet these milestones as publicly announced, the commercialization of our products may be delayed and, as a result, our stock price may decline.

***Any approved products could be subject to restrictions or withdrawal from the market, and we may be subject to penalties if we fail to comply with regulatory requirements or if we experience unanticipated problems with our product candidates, when and if any of them are approved.***

Following potential approval of any of our product candidates, the FDA or foreign regulatory authorities may impose significant restrictions on a product's indicated uses or marketing or impose ongoing requirements for potentially costly and time consuming post-approval studies, post-market surveillance or clinical trials. Following approval, if any, of soquelitinib, ciforadenant and mupadolimab or any other product candidate, such candidate will also be subject to ongoing FDA or foreign regulatory authorities' requirements governing the labeling, packaging, storage, distribution, safety surveillance, advertising, promotion, recordkeeping and reporting of safety and other post-market information. If we or a regulatory agency discovers previously unknown problems with a product, such as adverse events of unanticipated severity or frequency, or problems with the facility where the product is manufactured, a regulatory agency may impose restrictions on that product, the manufacturing facility or us, including requesting recall or withdrawal of the product from the market or suspension of manufacturing.

If we or the manufacturing facilities for soquelitinib, ciforadenant and mupadolimab or any other product candidate that may receive regulatory approval, if any, fail to comply with applicable regulatory requirements, a regulatory agency may:

- issue warning letters or untitled letters;
- seek an injunction or impose civil or criminal penalties or monetary fines;
- suspend or withdraw regulatory approval;
- suspend any ongoing clinical trials;
- refuse to approve pending applications or supplements or applications filed by us;
- suspend or impose restrictions on operations, including costly new manufacturing requirements; or

- seize or detain products, refuse to permit the import or export of product or request that we initiate a product recall.

The occurrence of any event or penalty described above may inhibit our ability to commercialize our product candidates and generate revenue.

The FDA has the authority to require a risk evaluation and mitigation strategy ("REMS") as part of an NDA or BLA or after approval, which may impose further requirements or restrictions on the distribution or use of an approved drug, 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. Similar risk exist in foreign jurisdictions.

In addition, if soquelitinib, ciforadenant and mupadolimab or any of our other product candidates is approved, our product labeling, advertising and promotion will be subject to regulatory requirements and continuing regulatory review. The FDA and foreign regulatory authorities strictly regulate the promotional claims that may be made about prescription products. In particular, a product may not be promoted for uses that are not approved by the FDA or foreign regulatory authorities as reflected in the product's approved labeling. If we receive marketing approval for a product candidate, physicians may nevertheless prescribe it to their patients in a manner that is inconsistent with the approved label. If we are found to have promoted such off-label uses, we may become subject to significant liability. The FDA and other agencies actively enforce the laws and regulations prohibiting the promotion of off-label uses, and a company that is found to have improperly promoted off-label uses may be subject to significant sanctions. The federal government has levied large civil and criminal fines against companies for alleged improper promotion and has enjoined several companies from engaging in off-label promotion. The FDA has also requested that companies enter into consent decrees or permanent injunctions under which specified promotional conduct is changed or curtailed.

Any government investigation of alleged violations of law could require us to expend significant time and resources in response, and could generate negative publicity. Any failure to comply with ongoing regulatory requirements may significantly and adversely affect our ability to commercialize our product candidates.

Further, the FDA's and other regulatory authorities' policies may change and additional government regulations may be enacted that could prevent, limit or delay regulatory approval of our product candidates.

We also 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 be subject to enforcement action and we may not achieve or sustain profitability.

***Disruptions at the FDA and other government agencies caused by funding shortages, staff reductions or global health concerns could hinder their ability to hire, retain or deploy key leadership and other personnel, or otherwise prevent new or modified products from being developed, approved or commercialized in a timely manner or at all, which could negatively impact our business.***

The ability of the FDA and foreign regulatory authorities to review and/or approve new products can be affected by a variety of factors, including government budget and funding levels, staff reductions, statutory, regulatory, and policy changes, the FDA's or foreign regulatory authorities' ability to hire and retain key personnel and accept the payment of user fees, and other events that may otherwise affect the FDA's or foreign regulatory authorities' ability to perform routine functions. Average review times at the FDA and foreign regulatory authorities have fluctuated in recent years as a result. 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 such as the EMA, following its relocation to Amsterdam and resulting staff changes, may also slow the time necessary for new drugs and biologics or modifications to approved drugs or biologics to be reviewed and/or approved by necessary government agencies, which would adversely affect our

business. For example, in recent years, the U.S. government has shut down several times and certain regulatory agencies, such as the FDA, have had to furlough critical FDA employees and stop critical activities.

In addition, during the COVID-19 pandemic, the FDA experienced administrative delays and postponed most inspections of domestic and foreign manufacturing facilities at various points. If a prolonged government shutdown occurs, or if funding shortages, staffing reductions or renewed 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.

***Even if we receive regulatory approval we still may not be able to successfully commercialize soquelitinib, ciforadenant and mupadolimab or any other product candidate, and the revenue that we generate from sales, if any, could be limited.***

Even if soquelitinib, ciforadenant and mupadolimab or any of our other product candidates receive regulatory approval, they may not gain market acceptance among physicians, patients, healthcare payors or the medical community. The degree of market acceptance of our product candidates will depend on a number of factors, including:

- demonstration of clinical efficacy and safety compared to other more-established products;
- the indications for which our product candidates are approved;
- the limitation of our targeted patient population and other limitations or warnings contained in any FDA-approved labeling;
- acceptance of a new formulation by healthcare providers and their patients;
- our ability to obtain and maintain sufficient third-party coverage and reimbursement from government healthcare programs, including Medicare and Medicaid, private health insurers and other third-party payors;
- the willingness of patients to pay out-of-pocket in the absence of third-party coverage and reimbursement;
- the prevalence and severity of any adverse effects;
- pricing and cost-effectiveness;
- the timing of market introduction of our product candidates as well as competitive drugs;
- the effectiveness of our or any of our existing or potential future collaborators' sales and marketing strategies; and
- unfavorable publicity relating to the product candidate.

If any product candidate is approved but does not achieve an adequate level of acceptance by physicians, hospitals, healthcare payors or patients, we may not generate sufficient revenue from that product candidate and may not become or remain profitable. Our efforts to educate the medical community and third-party payors regarding the benefits of soquelitinib, ciforadenant and mupadolimab or any of our other product candidates may require significant resources and may never be successful.

***Failure to obtain or maintain adequate coverage and reimbursement for our product candidates, if approved, could limit our ability to market those products and decrease our ability to generate revenue.***

Successful commercial sales of any approved products will depend on the availability of adequate coverage and reimbursement from government health administration authorities, private health insurers and other third-party payors. Each third-party payor separately decides which products it will cover and establishes the reimbursement level, and there is no guarantee that any of our product candidates that may be approved for marketing by regulatory authorities will receive adequate coverage or reimbursement levels. Obtaining and maintaining coverage approval for a product candidate is time-consuming, costly and may be difficult. We may be required to conduct expensive pharmacoeconomic studies to justify coverage and reimbursement or the level of coverage and reimbursement relative to other therapies. If coverage and adequate reimbursement are not available or limited, we may not be able to successfully commercialize any product candidate for which we obtain marketing approval. Government authorities and third-party payors have attempted to control costs by limiting coverage and the amount of reimbursement for particular medications. Increasingly, third-party payors are requiring that drug companies provide them with predetermined discounts from list prices and are challenging the prices charged for drugs and biologics. Even if we obtain coverage for a given product, the resulting reimbursement rates may be inadequate and may affect the demand for, or the price of, any product candidate for which we obtain marketing approval.

***Recently enacted legislation, future legislation and healthcare reform measures may increase the difficulty and cost for us to obtain marketing approval for and commercialize our product candidates and affect the prices we may obtain.***

In the United States and some foreign jurisdictions, there have been, and we expect there will continue to be, a number of legislative and regulatory changes to the healthcare system, including cost-containment measures that may reduce or limit coverage and reimbursement for newly approved drugs and biologics and affect our ability to profitably sell any product candidates for which we obtain marketing approval.

For example, in March 2010, the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act, collectively referred to as the ACA, was enacted with a goal of reducing the cost of healthcare and substantially changing the way healthcare is financed by both governmental and private insurers. The ACA, among other things, subjected biological products to potential competition by lower-cost biosimilars; addressed a new methodology by which rebates owed by manufacturers under the Medicaid Drug Rebate Program are calculated for drugs that are inhaled, infused, instilled, implanted or injected; increased the minimum Medicaid rebates owed by manufacturers under the Medicaid Drug Rebate Program; extended the rebate program to individuals enrolled in Medicaid managed care organizations; established annual fees and taxes on manufacturers of certain prescription drugs; and established a new Patient-Centered Outcomes Research Institute to oversee, identify priorities and conduct comparative clinical effectiveness research, along with funding for such research.

Since its enactment, there have been judicial, executive and Congressional challenges to certain aspects of the ACA. On June 17, 2021, the U.S. Supreme Court dismissed the most recent judicial challenge to the ACA brought by several states without specifically ruling on the constitutionality of the ACA.

Other legislative changes have been proposed and adopted in the U.S. since the ACA was enacted. On March 11, 2021, the American Rescue Plan Act of 2021 was signed into law, which eliminated the statutory Medicaid drug rebate cap, beginning January 1, 2024. The rebate was previously capped at 100% of a drug's average manufacturer price, or AMP. More recently, on August 16, 2022, the Inflation Reduction Act of 2022, or IRA, was signed into law. Among other things, the IRA requires manufacturers of certain drugs to engage in price negotiations with Medicare (beginning in 2026), with prices that can be negotiated subject to a cap; imposes rebates under Medicare Part B and Medicare Part D to penalize price increases that outpace inflation (first due in 2023); and replaces the Part D coverage gap discount program with a new discounting program (which began in 2025). The IRA permits the Secretary of the Department of Health and Human Services (HHS) to implement many of these provisions through guidance, as opposed to regulation, for the initial years. HHS has issued and will continue to issue guidance implementing the IRA. CMS has published the negotiated prices for the initial ten drugs, which will first be effective in 2026, and the list of the subsequent 15 drugs that will be subject to negotiation, although the Medicare drug price negotiation program is

currently subject to legal challenges. While the impact of the IRA on the pharmaceutical industry cannot yet be fully determined, it is likely to be significant.

Additionally, individual states in the United States have also become increasingly active in passing legislation and implementing regulations designed to control pharmaceutical product pricing, including price or patient reimbursement constraints, discounts, restrictions on certain product access and marketing cost disclosure, drug price reporting and other transparency measures, and, in some cases, designed to encourage importation from other countries and bulk purchasing. Some states have enacted legislation creating so-called prescription drug affordability boards, which ultimately may attempt to impose price limits on certain drugs in these states.

We expect that the ACA, these new laws and other healthcare reform measures that may be adopted in the future may result in additional reductions in Medicare and other healthcare funding, more rigorous coverage criteria, new payment methodologies and additional downward pressure on the price that we receive for any approved product. Any reduction in reimbursement from Medicare or other government programs may result in a similar reduction in payments from private payors. The implementation of cost containment measures or other healthcare reforms may prevent us from being able to generate revenue, attain profitability or commercialize our product candidates, if approved.

In the EU, similar political, economic and regulatory developments may affect our ability to profitably commercialize our product candidates, if approved. In addition to continuing pressure on prices and cost containment measures, legislative developments at the EU or member state level may result in significant additional requirements or obstacles that may increase our operating costs. The delivery of healthcare in the EU, including the establishment and operation of health services and the pricing and reimbursement of medicines, is almost exclusively a matter for national, rather than EU, law and policy. National governments and health service providers have different priorities and approaches to the delivery of health care and the pricing and reimbursement of products in that context. In general, however, the healthcare budgetary constraints in most EU member states have resulted in restrictions on the pricing and reimbursement of medicines by relevant health service providers. Coupled with ever-increasing EU and national regulatory burdens on those wishing to develop and market products, this could prevent or delay marketing approval of our product candidates, restrict or regulate post-approval activities and affect our ability to commercialize our product candidates, if approved. In markets outside of the United States and EU, reimbursement and healthcare payment systems vary significantly by country, and many countries have instituted price ceilings on specific products and therapies.

We cannot predict the likelihood, nature or extent of government regulation that may arise from future legislation or administrative action in the United States, the EU or any other jurisdiction. If we or any third parties we may engage are slow or unable to adapt to changes in existing requirements or the adoption of new requirements or policies, or if we or such third parties are not able to maintain regulatory compliance, our product candidates may lose any regulatory approval that may have been obtained and we may not achieve or sustain profitability.

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

The ACA includes a subtitle called the Biologics Price Competition and Innovation Act of 2009 ("BPCIA"), which created an abbreviated approval pathway for biological products that are biosimilar to or interchangeable with an FDA-licensed reference biological product. Under the BPCIA, an application for a biosimilar product may not be submitted to the FDA until four years following the date that the reference product was first licensed by the FDA. In addition, the approval of a biosimilar product may not be made effective by the FDA until twelve years from the date on which the reference product was first licensed. During this twelve-year period of exclusivity, another company may still market a competing version of the reference product if the FDA approves 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 its product.

Mupadolimab, which we evaluated in a Phase 1/1b oncology clinical trial is regulated by the FDA as a biological product. We believe that mupadolimab and any of our future product candidates, if approved as a biological product under a BLA, should qualify for the twelve-year period of exclusivity. However, there is a risk that this exclusivity could be shortened due to Congressional action or otherwise, or that the FDA will not consider our product

candidates to be reference products for competing products, potentially creating the opportunity for generic competition sooner than anticipated. Other aspects of the BPCIA, some of which may impact the BPCIA exclusivity provisions, have also been the subject of recent litigation. Jurisdictions in addition to the United States have established abbreviated pathways for regulatory approval of biological products that are biosimilar to earlier approved reference products. For example, the EU has had an established regulatory pathway for biosimilars since 2006. Moreover, the extent to which a biosimilar, once approved, could be substituted for any one of our reference products in a way that is similar to traditional generic substitution for non-biological products will depend on a number of marketplace factors.

***We may fail to obtain orphan drug designations from the FDA for our product candidates, and even if we obtain such designations, we may be unable to maintain the benefits associated with orphan drug designation, including the potential for market exclusivity.***

Under the Orphan Drug Act, the FDA may grant orphan drug designation to a drug or biologic intended to treat a rare disease or condition, which is defined as one occurring in a patient population of fewer than 200,000 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 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 opportunities for grant funding towards clinical trial costs, tax advantages and user-fee waivers. In addition, if a product that has orphan drug designation subsequently receives the first FDA approval for the disease or condition 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 NDA or BLA, to market the same drug or biologic for the same disease or 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.

On February 8, 2024, we announced that the FDA granted Orphan Drug Designation for soquelitinib for the treatment of T cell lymphoma. We also believe many of the targeted indications of our other product candidates, could qualify for orphan drug designation. As a result, we may seek to obtain additional orphan drug designations in the future. Even if we obtain such designations, we may not be the first to obtain marketing approval of our product candidate for the orphan-designated disease or condition due to the uncertainties associated with developing pharmaceutical products. In addition, exclusive marketing rights in the United States may be limited if we seek approval for a disease or condition broader than the orphan-designated disease or 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 can be approved for the same disease or condition. Even after an orphan product is approved, the FDA can subsequently approve the same drug for the same disease or condition if the FDA concludes that the later drug 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, nor gives the drug any advantage in the regulatory review or approval process. In addition, while we may seek orphan drug designation for our other product candidates, we may never receive such designations.

***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 are currently focusing on soquelitinib and ciforadenant. 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.

***We may form additional strategic alliances and collaborative partnerships in the future, and we may not realize the benefits of such alliances.***

We may form strategic alliances, create joint ventures or collaborations or enter into licensing arrangements with third parties that we believe will complement or augment our existing business, including for the continued development or commercialization of our product candidates. These relationships may result in or include non-recurring and other charges, increased near- and long-term expenditures, the issuance of securities that dilute our existing stockholders or disruptions to our management and business. In addition, we face significant competition in seeking appropriate strategic partners, and the negotiation process is time-consuming and complex. Moreover, we may not be successful in our efforts to establish a strategic partnership or other alternative arrangements for our product candidates because third parties may view the risk of failure in future clinical trials as too significant or the commercial opportunity for our product candidates as too limited. We cannot be certain that, following a strategic transaction or license, we will achieve the revenue or specific net income that justifies such transaction.

Even if we are successful in our efforts to establish strategic alliances or collaborative partnerships, the terms that we agree upon may not be favorable to us, and we may not be able to maintain such strategic alliances or collaborative partnerships if, for example, development or approval of a product candidate is delayed, the safety of a product candidate is questioned or sales of an approved product candidate are unsatisfactory. In addition, any existing or potential future strategic alliances or collaborative partnerships may be terminable by our strategic partners, and we may not be able to adequately protect our rights under these agreements. Furthermore, strategic partners may negotiate for certain rights to control decisions regarding the development and commercialization of our product candidates, if approved, and may not conduct those activities in the same manner as we do. Any termination of strategic alliances or collaborative partnerships we enter into in the future, or any delay in entering into collaborative partnership agreements related to our product candidates, could delay the development and commercialization of our product candidates and reduce their competitiveness if they reach the market, which could have a material adverse effect on our business, financial condition and results of operations.

In October 2020, we formed Angel Pharmaceuticals with a group of investors in China to create a new China-based biopharmaceutical company with a mission to bring innovative quality medicines to Chinese patients for treatment of serious diseases including cancer, autoimmune diseases and infectious diseases. We granted Angel Pharmaceuticals a license to rights to develop and commercialize our three clinical-stage candidates – soquelitinib, ciforadenant and mupadolimab – in greater China and obtained global rights to our BTK inhibitor preclinical programs. While certain of our executive officers and directors will initially be on the board of directors of Angel Pharmaceuticals, we have limited control over it and so we will be subject to many of the same risks set forth above with respect to all collaborations. Additionally, any actions taken by the Chinese government to implement trade policy changes, financial restrictions, or increased regulatory scrutiny on U.S. companies could negatively impact Angel Pharmaceuticals. For instance, China has previously taken or threatened to take trade and other actions in retaliation against U.S. policies, and is likely to continue to do so. Past or future developments in this regard may have a material adverse effect on the economies, financial markets, and currency exchange rates in China and the United States. Tensions between the United States and China have increased over the past few years as a result of disputes in areas including trade policy, intellectual property, cybersecurity and data privacy, as well as due to geopolitical conflicts such as the war between Ukraine and Russia. Our interests in Angel Pharmaceuticals could be harmed if relations between the United States and China worsen or if either government imposes additional policies, tariffs or sanctions and our business could encounter increased regulatory scrutiny in China, as well as adverse media or public attention in China, as a result of the deteriorating bilateral relationship

Angel Pharmaceuticals will also be subject to many of the same risks that are set forth in this “Risk Factors” section pertaining to operations, government regulation, and intellectual property, which may adversely affect Angel Pharmaceuticals’ ability to develop and commercialize products.

***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.***

Our competitors have developed, are developing or will develop product candidates and processes competitive with our product candidates. Competitive therapeutic treatments include those that have already been approved and accepted by the medical community and any new treatments 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 may attempt to develop product candidates. In particular, there is intense and rapidly evolving competition in the immunoregulatory therapeutics field. Our competitors include larger and better funded pharmaceutical, biopharmaceutical, biotechnological and therapeutics companies. Moreover, we also compete with universities and other research institutions that may be active in oncology research and could be in direct competition with us. We also compete with these organizations to recruit management, scientists and clinical development personnel, which could negatively affect our level of expertise and our ability to execute our business plan. We will also face competition in establishing clinical trial sites, registering subjects for clinical trials and in identifying and in-licensing new product candidates. Smaller or early-stage companies may also prove to be significant competitors, particularly through collaborative arrangements with large and established companies.

Kyowa Hakko Kirin has approval in Japan and the US for istradefylline, an A2A antagonist, in Parkinson's disease. Within oncology, Novartis has announced an exclusive licensing agreement with Palobiofarma SL and is conducting a Phase 1 trial with an A2A antagonist. AstraZeneca plc is conducting clinical trials with an A2A antagonist for use in cancer therapy. Merck KgaA has entered into a pre-clinical collaboration with Domain Therapeutics Inc. to develop programs targeting the adenosine pathway. In addition, Redoxtherapies, Inc., which was acquired by Juno Therapeutics and subsequently by Celgene, and Arcus Biosciences, Inc. are developing A2A receptor antagonists for cancer. Astra Zeneca, Bristol-Myers Squib, and Novartis in partnership with Surface Oncology, Inc. have initiated clinical trials with anti-CD73 antibodies in cancer patients. Recently, Astra Zeneca reported positive results in a Phase 2 clinical trial in Stage 3 NSCLC with the combination of durvalumab and their anti CD73 antibody, oleclumab. More generally, in the field of immuno-oncology, there are large pharmaceutical companies with approved products or products in late-stage development that target other immune checkpoints, including PD-1, PD-L1 or CTLA-4. These companies include Bristol-Myers Squibb (nivolumab, ipilimumab), Merck (pembrolizumab), Genentech (atezolizumab) and AstraZeneca (durvalumab, tremelimumab).

Many of our competitors have significantly greater financial, technical, manufacturing, marketing, sales and supply resources or experience than we do. 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.

***The market opportunities for our product candidates may be limited to those patients who are ineligible for or have failed prior treatments and may be small.***

Cancer therapies are sometimes characterized as first-line, second-line or third-line, which refers to the number of prior therapies required to be used prior to administration of the relevant therapy, and the FDA commonly approves new therapies initially s for later-line uses. When cancer is detected early enough, first line therapy is sometimes adequate to cure the cancer or prolong life without a cure. Whenever first-line therapy, usually chemotherapy, hormone therapy, surgery or a combination of these, proves unsuccessful, second-line therapy may be administered. Second-line therapies often consist of more chemotherapy, radiation, antibody drugs, tumor targeted small molecules or a combination of these. Third-line therapies can include bone marrow transplantation, antibody and small molecule targeted therapies, more invasive forms of surgery and new technologies. In markets with approved therapies, we expect

to initially seek approval of our product candidates as a later stage therapy for patients who have failed other approved treatments. Subsequently, for those drugs that prove to be sufficiently beneficial, if any, we would expect to seek approval as a second-line therapy and potentially as a first-line therapy, but there is no guarantee that our product candidates, even if approved, would be approved for second-line or first-line therapy. In addition, we may have to conduct additional clinical trials prior to gaining approval for second-line or first-line therapy.

Our projections of both the number of people who have the cancers we are targeting, as well as the subset of people with these cancers in a position to receive later stage therapy and who have the potential to benefit from treatment with our product candidates, are based on our beliefs and estimates. These estimates have been derived from a variety of sources, including scientific literature, surveys of clinics, patient foundations or market research and may prove to be incorrect. Further, new studies may change the estimated incidence or prevalence of these cancers. The number of patients may turn out to be lower than expected. In addition, the potentially addressable patient population for our product candidates may be limited or may not be amenable to treatment with our product candidates. Even if we obtain significant market share for our product candidates, we may never achieve profitability without obtaining regulatory approval for additional indications, including use as a first or second-line therapy.

***We have no sales, marketing or distribution capabilities, and we may have to invest significant resources to develop these capabilities.***

We have no internal sales, marketing or distribution capabilities. If soquelitinib, ciforadenant and mupadolimab or any of our other product candidates ultimately receives regulatory approval, we may not be able to effectively market and distribute the product candidate. We may have to seek collaborators or invest significant amounts of financial and management resources to develop internal sales, distribution and marketing capabilities, some of which will be committed prior to any confirmation that soquelitinib, ciforadenant and mupadolimab or any of our other product candidates will be approved, if at all. We may not be able to enter into collaborations or hire consultants or external service providers to assist us in sales, marketing and distribution functions on acceptable financial terms or at all. Even if we determine to perform sales, marketing and distribution functions ourselves, we could face a number of additional related risks, including:

- we may not be able to attract and build an effective marketing department or sales force;
- the cost of establishing a marketing department or sales force may exceed our available financial resources and the revenue generated by soquelitinib, ciforadenant and mupadolimab or any other product candidates that we may develop, in-license or acquire; and
- our direct sales and marketing efforts may not be successful.

***Governments may impose price controls, which may adversely affect our future profitability.***

We intend to seek approval to market our product candidates in both the United States and in foreign jurisdictions. In some foreign countries, particularly in the EU, the pricing of prescription pharmaceuticals is subject to governmental control. In these countries, pricing negotiations with governmental authorities can take considerable time after the receipt of marketing approval for a product candidate. To obtain reimbursement or pricing approval in some countries, we may be required to conduct clinical trials to compare the cost-effectiveness of our product candidates to other available therapies, which is time-consuming and costly. If reimbursement of our future products is unavailable or limited in scope or amount, or if pricing is set at unsatisfactory levels, we may be unable to achieve or sustain profitability.

**Risks Related to Our Business Operations**

***Our operating results may fluctuate significantly, which makes our future operating results difficult to predict and could cause our operating results to fall below expectations or any guidance we may provide.***

Our quarterly and annual operating results may fluctuate significantly, which makes it difficult for us to predict our future operating results. These fluctuations may occur due to a variety of factors, many of which are outside of our control, including, but not limited to:

- the timing and cost of, and level of investment in, research, development and commercialization activities relating to our product candidates, which may change from time to time;
- coverage and reimbursement policies with respect to our product candidates, if approved, and potential future drugs that compete with our product candidates;
- the cost of manufacturing our product candidates, which may vary depending on the quantity of production and the terms of our agreements with manufacturers;
- expenditures that we may incur to acquire, develop or commercialize additional product candidates and technologies;
- the level of demand for any approved products (if any), which may vary significantly;
- macroeconomic conditions such as increased interest and inflationary pressures;
- future accounting pronouncements or changes in our accounting policies; and
- the timing and success or failure of clinical trials for our product candidates or competing product candidates, or any other change in the competitive landscape of our industry, including consolidation among our competitors or partners.

The cumulative effects of these factors could result in large fluctuations and unpredictability in our quarterly and annual operating results. As a result, comparing our operating results on a period-to-period basis may not be meaningful. Investors should not rely on our past results as an indication of our future performance.

This variability and unpredictability could also result in our failing to meet the expectations of industry or financial analysts or investors for any period. If our revenue or operating results fall below the expectations of analysts or investors or below any forecasts we may provide to the market, or if the forecasts we provide to the market are below the expectations of analysts or investors, the price of our common stock could decline substantially. Such a stock price decline could occur even when we have met any previously publicly stated revenue or earnings guidance we may provide.

***We are dependent on the services of our President and Chief Executive Officer, Richard A. Miller, M.D., and other key executives, and if we are not able to retain these members of our management or recruit additional management, clinical and scientific personnel, our business will suffer.***

We are dependent on the principal members of our management and scientific staff. The loss of service of any of our management could harm our business. In addition, we are dependent on our continued ability to attract, retain and motivate highly qualified management, clinical and scientific personnel. If we are not able to retain our management, particularly our President and Chief Executive Officer, Dr. Miller, and to attract, on acceptable terms, additional qualified personnel necessary for the continued development of our business, we may not be able to sustain our operations or grow. Although we have executed employment agreements with each member of our current executive

management team, including Dr. Miller, these agreements are terminable at will with or without notice and, therefore, we may not be able to retain their services as expected.

We will need to expand and effectively manage our managerial, operational, financial and other resources in order to successfully pursue our clinical development and commercialization efforts. We may not be able to attract or retain qualified management and scientific and clinical personnel in the future due to the intense competition for qualified personnel among pharmaceutical, biotechnology and other businesses, particularly in the San Francisco Bay Area. Our industry has experienced a high rate of turnover of management personnel in recent years. If we are not able to attract, integrate, retain and motivate necessary personnel to accomplish our business objectives, we may experience constraints that will significantly impede the achievement of our development objectives, our ability to raise additional capital and our ability to implement our business strategy.

In addition, we do not currently maintain "key person" life insurance on the lives of our executives or any of our employees. This lack of insurance means that we may not have adequate compensation for the loss of the services of these individuals.

***We may encounter difficulties in managing our growth and expanding our operations successfully.***

We will need to grow our organization substantially to continue development and pursue the potential commercialization of soquelitinib, ciforadenant and mupadolimab and our other product candidates. As we seek to advance soquelitinib, ciforadenant and mupadolimab and other product candidates, we will need to expand our financial, development, regulatory, manufacturing, marketing and sales capabilities or contract with third parties to provide these capabilities for us. As our operations expand, we expect that we will need to manage additional relationships with various strategic partners, suppliers and other third parties. Our future financial performance and our ability to commercialize our product candidates and to compete effectively will depend, in part, on our ability to manage any future growth effectively.

***We are subject to various federal and state healthcare laws and regulations, and our failure to comply with these laws and regulations could harm our results of operations and financial condition.***

Although we do not currently have any products on the market, if we obtain FDA or foreign approval for any of our product candidates and begin commercializing those products in the United States or abroad, our operations may be directly, or indirectly through our customers and third-party payors, subject to various U.S. federal, state and foreign healthcare laws and regulations. These laws will affect our operations, sales and marketing practices, and our relationships with physicians and other customers and third-party payors. Such laws include:

- the federal Anti-Kickback Statute, which prohibits, among other things, persons or 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 healthcare program such as Medicare and Medicaid. A person or entity does not need to have actual knowledge of the federal Anti-Kickback Statute or specific intent to violate it to have committed a violation;

- the federal False Claims Act, which imposes criminal and civil penalties, including through civil whistleblower or qui tam actions, against individuals or entities for knowingly presenting, or causing to be presented, to the federal government, claims for payment that are false or fraudulent or making a false statement to avoid, decrease or conceal an obligation to pay money to the federal government; in addition, the government may assert that a claim including items or 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 federal Health Insurance Portability and Accountability Act of 1996 ("HIPAA"), which imposes criminal and civil liability for executing a scheme to defraud any healthcare benefit program or making false statements relating to healthcare matters. 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 to have committed a violation;

- the federal Physician Payment Sunshine Act, which requires manufacturers of drugs, devices, biologics and medical supplies for which payment is available under Medicare, Medicaid or the Children's Health Insurance Program (with certain exceptions) to report annually to the government information related to payments or other "transfers of value" made to physicians (defined to include doctors, dentists, optometrists, podiatrists and chiropractors), certain non-physician practitioners (physician assistants, nurse practitioners, clinical nurse specialists, certified registered nurse anesthetists, anesthesiology assistants and certified nurse midwives) and teaching hospitals, and requires applicable manufacturers and group purchasing organizations to report annually to the government ownership and investment interests held by the physicians described above and their immediate family members. Manufacturers are required to submit reports to the government by the 90th day of each calendar year; and

- analogous state and foreign laws and regulations, such as state anti-kickback and false claims laws, which may apply to sales or marketing arrangements and claims involving healthcare items or services reimbursed by non-governmental third-party payors, including private insurers; 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; and state laws that require drug manufacturers to report information related to payments and other transfers of value to physicians and other healthcare providers or marketing expenditures and pricing information.

Ensuring that our internal operations and business arrangements with third-parties comply with applicable healthcare laws and regulations could involve substantial costs. If our operations are found to be in violation of such laws or any other governmental laws and regulations that may apply to us, we may be subject to significant penalties, including civil, criminal and administrative penalties, damages, fines, exclusion from U.S. government funded healthcare programs, such as Medicare and Medicaid, disgorgement, individual imprisonment, contractual damages, reputational harm, diminished profits and the curtailment or restructuring of our operations.

***We and our current and any existing or future collaborators, third-party manufacturers and suppliers will or may use biological materials and may use hazardous materials, and any claims relating to improper handling, storage or disposal of these materials could be time consuming or costly.***

We and our current and any existing or future collaborators, third-party manufacturers or suppliers will or may use biological materials and may use hazardous materials, including chemicals and biological agents and compounds that could be dangerous to human health and safety of the environment. Our operations and the operations of our third-party manufacturers and suppliers also produce hazardous waste products. Federal, state and local laws and regulations govern the use, generation, manufacture, storage, handling and disposal of these materials and wastes. Compliance with applicable environmental laws and regulations may be expensive, and current or future environmental laws and regulations may impair our product development efforts. In addition, we cannot eliminate the risk of accidental injury or contamination from these materials or wastes. We do not carry specific biological or hazardous waste insurance coverage, and our property, casualty and general liability insurance policies specifically exclude coverage for damages and fines arising from biological or hazardous waste exposure or contamination. In the event of contamination or injury, we could be held liable for damages or be penalized with fines in an amount exceeding our resources, and our clinical trials or regulatory approvals could be suspended.

***If product liability lawsuits are brought against us, we may incur substantial liabilities and may be required to limit commercialization of soquelitinib, ciforadenant and mupadolimab or our other product candidates.***

We face an inherent risk of product liability as a result of the clinical testing of soquelitinib, ciforadenant and mupadolimab, and the planned clinical testing of our other product candidates and will face an even greater risk if we commercialize our product candidates. For example, we may be sued if soquelitinib, ciforadenant and mupadolimab or our other product candidates allegedly cause injury or are found to be otherwise unsuitable during product testing, manufacturing, marketing or sale. Any such product liability claims may include allegations of defects in manufacturing,

defects in design, a failure to warn of dangers inherent in the product candidate, negligence, strict liability and a breach of warranties. Claims could also be asserted under state consumer protection acts.

If we cannot successfully defend ourselves against product liability claims, we may incur substantial liabilities or be required to limit or cease the commercialization of our product candidates. Even a successful defense would require significant financial and management resources. Regardless of the merits or eventual outcome, liability claims may result in:

- decreased demand for soquelitinib, ciforadenant and mupadolimab or our other product candidates;
- injury to our reputation;
- withdrawal of clinical trial participants;
- costs to defend the related litigation;
- a diversion of management's time and our resources;
- substantial monetary awards to trial participants or patients;
- product recalls, withdrawals or labeling, marketing or promotional restrictions;
- loss of revenue;
- the inability to commercialize soquelitinib, ciforadenant and mupadolimab or our other product candidates; and
- a decline in our stock price.

We have product liability insurance coverage in an amount and on terms and conditions that are customary for similarly situated companies and that are satisfactory to our Board of Directors. Our inability to retain sufficient product liability insurance at an acceptable cost to protect against potential product liability claims could prevent or inhibit the commercialization of soquelitinib, ciforadenant and mupadolimab or our other product candidates. Although we plan to maintain such insurance, any claim that may be brought against us could result in a court judgment or settlement in an amount that is not covered, in whole or in part, by our insurance or that is in excess of the limits of our insurance coverage. Our insurance policies will also have various exclusions, and we may be subject to a product liability claim for which we have no coverage. We may have to pay any amounts awarded by a court or negotiated in a settlement that exceed our coverage limitations or that are not covered by our insurance, and we may not have, or be able to obtain, sufficient capital to pay such amounts.

***We and any of our existing or potential future collaborators will be required to report to regulatory authorities if any products that may be approved in the future cause or contribute to adverse medical events, and any failure to do so would result in sanctions that would materially harm our business.***

If we and any of our existing or potential future collaborators are successful in commercializing our products, the FDA and foreign regulatory authorities would require that we and any of our existing or potential future collaborators report certain information about adverse medical events if those products may have caused or contributed to those adverse events. The timing of our obligation to report would be triggered by the date we become aware of the adverse event as well as the nature of the event. We and any of our existing or potential future collaborators or CROs may fail to report adverse events within the prescribed timeframe. If we or any of our existing or potential future collaborators or CROs fail to comply with such reporting obligations, the FDA or a foreign regulatory authority could take action, including criminal prosecution, the imposition of civil monetary penalties, seizure of our products or delay in approval or clearance of future products.

***Our employees, independent contractors, principal investigators, CROs, consultants and vendors may engage in misconduct or other improper activities, including noncompliance with regulatory standards and requirements.***

We are exposed to the risk that our employees, independent contractors, principal investigators, CROs, consultants and vendors may engage in misconduct or other illegal activity. Misconduct by these parties could include intentional, reckless and/or negligent conduct involving the improper use or misrepresentation of information obtained in the course of clinical trials, the creation of fraudulent data in our preclinical studies or clinical trials or illegal misappropriation of drug product, which could result in regulatory sanctions and cause serious harm to our reputation. It is not always possible to identify and deter misconduct by employees and other third parties, 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. In addition, we are subject to the risk that a person or government could allege such fraud or other misconduct, even if none occurred. 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 significant impact on our business, including the imposition of fines and other sanctions.

**Risks Related to Our Intellectual Property**

***Our rights to develop and commercialize our product candidates are subject in part to the terms and conditions of licenses granted to us by other companies. The patent protection, prosecution and enforcement for some of our product candidates may be dependent on third parties.***

We currently are heavily reliant upon licenses of certain patent rights and proprietary technology from third parties that is important or necessary to the development of our technology and products, including technology related to our product candidates. For example, we rely on our license agreement with Vernalis for rights with respect to the intellectual property covering ciforadenant and certain development candidates under our A2B receptor antagonist program. Further, we rely on our license agreement with The Scripps Research Institute for rights related to our lead development candidate for our anti-CD73 program, mupadolimab. These and other licenses we may enter into in the future may not provide adequate rights to use such intellectual property and technology in all relevant fields of use or in all territories in which we may wish to develop or commercialize our technology and products in the future. As a result, we may not be able to develop and commercialize our technology and products in fields of use and territories for which we are not granted rights pursuant to such licenses.

Licenses to additional third-party technology that may be required for our development programs may not be available in the future or may not be available on commercially reasonable terms, which could have a material adverse effect on our business and financial condition.

In some circumstances, we may not have the right to control the preparation, filing, prosecution and enforcement of patent applications, or to maintain the patents, covering technology that we license from third parties. In addition, some of our agreements with our licensors require us to obtain consent from the licensor before we can enforce patent rights, and our licensor may withhold such consent or may not provide it on a timely basis. Therefore, we cannot be certain that our licensors or collaborators will prosecute, maintain, enforce and defend such intellectual property rights in a manner consistent with the best interests of our business, including by taking reasonable measures to protect the confidentiality of know-how and trade secrets, or by paying all applicable prosecution and maintenance fees related to intellectual property registrations for any of our product candidates. We also cannot be certain that our licensors have drafted or prosecuted the patents and patent applications licensed to us in compliance with applicable laws and regulations, which may affect the validity and enforceability of such patents or any patents that may issue from such applications. If they fail to do so, this could cause us to lose rights in any applicable intellectual property that we in-license, and as a result our ability to develop and commercialize products or product candidates may be adversely affected and we may be unable to prevent competitors from making, using and selling competing products.

***Our success depends on our ability to protect our intellectual property and our proprietary technologies.***

Our commercial success depends in part on our ability to obtain and maintain patent protection and trade secret protection for our product candidates, proprietary technologies and their uses as well as our ability to operate without infringing upon the proprietary rights of others. We generally seek to protect our proprietary position by filing patent applications in the United States and abroad related to our product candidates, proprietary technologies and their uses that are important to our business. There can be no assurance that our patent applications or those of our licensors will result in additional patents being issued or that issued patents will afford sufficient protection against competitors with similar technology, nor can there be any assurance that the patents issued will not be infringed, designed around or invalidated by third parties. Even issued patents may later be found invalid or unenforceable or may be modified or revoked in proceedings instituted by third parties before various patent offices or in courts. The degree of future protection for our proprietary rights is uncertain. Only limited protection may be available and may not adequately protect our rights or permit us to gain or keep any competitive advantage. This failure to properly protect the intellectual property rights relating to our product candidates could have a material adverse effect on our financial condition and results of operations.

While we have rights to issued composition-of-matter patents in the United States and corresponding issued patents in certain foreign territories covering soquelitinib, mupadolimab and ciforadenant, we cannot be certain that the claims in any of our patent applications covering composition-of-matter of our other product candidates will be considered patentable by the United States Patent and Trademark Office ("USPTO"), courts in the United States or by the patent offices and courts in foreign countries, nor can we be certain that the claims in our issued composition-of-matter patents will not be found invalid or unenforceable if challenged.

The patent application process is subject to numerous risks and uncertainties, and there can be no assurance that we or any of our existing or potential future collaborators will be successful in protecting our product candidates by obtaining and defending patents. These risks and uncertainties include the following:

- 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, the noncompliance with which can result in abandonment or lapse of a patent or patent application, and partial or complete loss of patent rights in the relevant jurisdiction;

- patent applications may not result in any patents being issued;

- patents that may be issued or in-licensed may be challenged, invalidated, modified, revoked, circumvented, found to be unenforceable or otherwise may not provide any competitive advantage;

- our competitors, many of whom have substantially greater resources than we do and many of whom have made significant investments in competing technologies, may seek or may have already obtained patents that will limit, interfere with or eliminate our ability to make, use and sell our potential product candidates;

- there may be significant pressure on the U.S. government and international governmental bodies to limit the scope of patent protection both inside and outside the United States for disease treatments that prove successful, as a matter of public policy regarding worldwide health concerns; and

- countries other than the United States may have patent laws less favorable to patentees than those upheld by U.S. courts, allowing foreign competitors a better opportunity to create, develop and market competing product candidates.

The patent prosecution process is also expensive and time-consuming, and we may not be able to file and prosecute all necessary or desirable patent applications at a reasonable cost or in a timely manner. It is also possible that we will fail to identify patentable aspects of our research and development output before it is too late to obtain patent protection. Although we enter into non-disclosure and confidentiality agreements with parties who have access to

patentable aspects of our research and development output, such as our employees, corporate collaborators, outside scientific collaborators, CROs, contract manufacturers, consultants, advisors and other third parties, any of these parties may breach such agreements and disclose such output before a patent application is filed, thereby jeopardizing our ability to seek patent protection.

The issuance of a patent is not conclusive as to its inventorship, scope, validity or enforceability, and our patents, if issued, or the patent rights that we license from others, may be challenged in the courts or patent offices in the United States and abroad. Such challenges may result in loss of exclusivity or in patent claims being narrowed, invalidated or held unenforceable, which could limit our ability to stop others from using or commercializing similar or identical products, or limit the duration of the patent protection of our products and product candidates. 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 intellectual property may not provide us with sufficient rights to exclude others from commercializing products similar or identical to ours.

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

In addition, we rely on the protection of our trade secrets, including unpatented know-how, technology and other proprietary information to maintain our competitive position. Although we have taken steps to protect our trade secrets and unpatented know-how, including entering into confidentiality agreements with third parties, and confidential information and inventions agreements with employees, consultants and advisors. Despite these efforts, we cannot provide any assurances that all such agreements have been duly executed, and 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 inside and outside the United States are less willing or unwilling to protect trade secrets. Moreover, third parties may still obtain this information or may come upon this or similar information independently, and we would have no right to prevent them from using that technology or information to compete with us. If any of these events occurs or if we otherwise lose protection for our trade secrets, the value of this information may be greatly reduced and our competitive position would be harmed. If we do not apply for patent protection prior to such publication or if we cannot otherwise maintain the confidentiality of our proprietary technology and other confidential information, then our ability to obtain patent protection or to protect our trade secret information may be jeopardized.

***Our commercial success depends significantly on our ability to operate without infringing the patents and other proprietary rights of third parties. Claims by third parties that we infringe their proprietary rights may result in liability for damages or prevent or delay our developmental and commercialization efforts.***

Our commercial success depends in part on our avoiding infringement of the patents and proprietary rights of third parties. Other entities may have or obtain patents or proprietary rights that could limit our ability to make, use, sell, offer for sale or import our product candidates and future approved products or impair our competitive position. 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, reexaminations, inter partes review ("IPR") proceedings and post-grant review ("PGR") proceedings before the USPTO and/or corresponding foreign patent offices. Numerous third-party U.S. and foreign issued patents and pending patent applications exist in the fields in which we are developing product candidates. There may be third-party patents or patent applications with claims to materials, formulations, methods of manufacture or methods for treatment related to the use or manufacture of our product candidates. As the biotechnology 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. Because patent applications are maintained as confidential for a certain period of time, until the relevant application is published we may be unaware of third-party patent applications that, if issued as patents, may be infringed by commercialization of soquelitinib, ciforadenant and mupadolimab or our other product candidates, and cannot be certain that we were the first to file a patent application related to a product candidate or technology. Moreover, because patent applications can take many years to issue, there may be currently-pending patent applications that may later result

in issued patents that our product candidates may infringe. In addition, identification of third-party patent rights that may be relevant to our technology 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. Any claims of patent infringement asserted by third parties would be time consuming and could:

- result in costly litigation;
- divert the time and attention of our technical personnel and management;
- cause development delays;
- prevent us from commercializing soquelitinib, ciforadenant and mupadolimab or our other product candidates until the asserted patent expires or is held finally invalid or not infringed in a court of law;
- require us to develop non-infringing technology, which may not be possible on a cost-effective basis; or
- require us to enter into royalty or licensing agreements, which may not be available on commercially reasonable terms, or at all.

Although no third party has asserted a claim of patent infringement against us as of the date of this report, others may hold proprietary rights that could prevent soquelitinib, ciforadenant and mupadolimab or our other product candidates from being marketed. Any patent-related legal action against us claiming damages and seeking to enjoin commercial activities relating to our product candidates or processes could subject us to potential liability for damages, including treble damages if we were determined to willfully infringe, and require us to obtain a license to manufacture or market soquelitinib, ciforadenant and mupadolimab or our other product candidates.

Defense of these claims, regardless of their merit, would involve substantial litigation expense and would be a substantial diversion of employee resources from our business. We cannot predict whether we would prevail in any such actions or that any license required under any of these patents would be made available on commercially acceptable terms, if at all. Moreover, even if we or our future strategic partners were able to obtain a license, the rights may be nonexclusive, which could result in our competitors gaining access to the same intellectual property. In addition, we cannot be certain that we could redesign our product candidates or processes to avoid infringement, if necessary. Accordingly, an adverse determination in a judicial or administrative proceeding, or the failure to obtain necessary licenses, could prevent us from developing and commercializing soquelitinib, ciforadenant and mupadolimab or our other product candidates, which could harm our business, financial condition and operating results. In addition, intellectual property litigation, regardless of its outcome, may cause negative publicity and could prohibit us from marketing or otherwise commercializing our product candidates and technology.

***We may be involved in lawsuits to protect or enforce our patents or the patents of our licensors, which could be expensive, time consuming, and unsuccessful. Further, our issued patents could be found invalid or unenforceable if challenged in court.***

Competitors may infringe our intellectual property rights or those of our licensors. To prevent infringement or unauthorized use, we may be required to file infringement claims, which can be expensive and time-consuming. In addition, in a patent infringement proceeding, a court may decide that a patent we own or in-license is not valid, is unenforceable and/or is not infringed. If we or any of our existing or potential future collaborators were to initiate legal proceedings against a third party to enforce a patent directed at one of our product candidates, the defendant could counterclaim that our patent is invalid and/or unenforceable in whole or in part. In patent litigation in the United States, defendant counterclaims alleging invalidity and/or unenforceability are commonplace. Grounds for a validity challenge include an alleged failure to meet any of several statutory requirements, including lack of novelty, obviousness or non-enablement. Grounds for an unenforceability assertion could include an allegation that someone connected with prosecution of the patent withheld relevant information from the USPTO or made a misleading statement during prosecution. Third parties may also raise similar claims before the USPTO, even outside the context of litigation. The

outcome following legal assertions of invalidity and unenforceability is unpredictable, and prior art could render our patents or those of our licensors invalid. If a defendant were to prevail on a legal assertion of invalidity and/or unenforceability, we would lose at least part, and perhaps all, of the patent protection on such product candidate. Such a loss of patent protection would have a material adverse impact on our business.

Interference 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 or those of our licensors. 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. Our defense of litigation or interference proceedings may fail and, even if successful, may result in substantial costs and distract our management and other employees. In addition, the uncertainties associated with litigation could have a material adverse effect on our ability to raise the funds necessary to continue our clinical trials, continue our research programs, license necessary technology from third parties or enter into development or manufacturing partnerships that would help us bring our product candidates to market.

Even if resolved in our favor, litigation or other legal proceedings relating to our intellectual property rights may cause us to incur significant expenses, and could distract our technical and management personnel from their normal responsibilities. 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. 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 conduct such litigation or proceedings adequately. 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. Uncertainties resulting from the initiation and continuation of patent litigation or other proceedings could compromise our ability to compete in the marketplace.

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.

***Recent patent reform legislation could increase the uncertainties and costs surrounding the prosecution of our patent applications and the enforcement or defense of our issued patents.***

On September 16, 2011, the Leahy-Smith America Invents Act ("Leahy-Smith Act") was signed into law. The Leahy-Smith Act includes a number of significant changes to U.S. patent law. These include provisions that affect the way patent applications will be prosecuted and may also affect patent litigation. In particular, under the Leahy-Smith Act, the United States transitioned in March 2013 to a "first to file" system in which the first inventor to file a patent application will be entitled to the patent. Third parties are allowed to submit prior art before the issuance of a patent by the USPTO, and may become involved in post-grant proceedings including opposition, derivation, reexamination, inter-partes review or interference proceedings challenging our patent rights or the patent rights of others. An adverse determination in any such submission, proceeding or litigation could reduce the scope or enforceability of, or invalidate, our patent rights, which could adversely affect our competitive position.

***We may not be successful in obtaining or maintaining necessary rights to our product candidates through acquisitions and in-licenses.***

We currently have rights to the intellectual property, through licenses from third parties and under patents that we own, to develop our product candidates. Because our programs may require the use of proprietary rights held by third parties, the growth of our business will depend in part on our ability to acquire, in-license or use these proprietary rights. For example, our product candidates may require specific formulations to work effectively and efficiently and the rights to these formulations may be held by others. We may be unable to acquire or in-license any compositions, methods of use, processes or other third-party intellectual property rights from third parties that we identify as necessary for our

product candidates. The licensing and acquisition of third-party intellectual property rights is a competitive area, and a number of more established companies are also pursuing strategies to license or acquire third-party intellectual property rights that we may consider attractive. These established companies may have a competitive advantage over us due to their size, cash resources and greater clinical development and commercialization capabilities. In addition, companies that perceive us to be a competitor may be unwilling to assign or license rights to us. We also may be unable to license or acquire third-party intellectual property rights on terms that would allow us to make an appropriate return on our investment.

We have collaborated with U.S. academic institutions and may in the future collaborate with U.S. and foreign academic institutions to accelerate our preclinical research or development under written agreements with these institutions. These institutions may provide us with an option to negotiate a license to any of the institution's rights in technology resulting from the collaboration. Regardless of such option, we may be unable to negotiate a license within the specified timeframe or under terms that are acceptable to us. If we are unable to do so, the institution may offer the intellectual property rights to other parties, potentially blocking our ability to pursue our program.

If we are unable to successfully obtain rights to required third-party intellectual property rights or maintain the existing intellectual property rights we have, we may have to abandon development of that program and our business and financial condition could suffer.

***We may fail to comply with any of our obligations under existing agreements pursuant to which we license or have otherwise acquired intellectual property rights or technology, which could result in the loss of rights or technology that are material to our business.***

Licensing of intellectual property is of critical importance to our business and involves complex legal, business and scientific issues. We are party to various agreements that we depend on for rights to use various technologies that are material to our business, including intellectual property rights covering ciforadenant and methods relating to its use and manufacture. In each of these cases, our rights to use the licensed intellectual property are subject to the continuation of and our compliance with the terms of these agreements. Disputes may arise regarding our rights to intellectual property licensed to us from a third party, including but not limited to:

- the scope of rights granted under the license agreement and other interpretation-related issues;
- the extent to which our technology and processes infringe on intellectual property of the licensor that is not subject to the licensing agreement;
- the sublicensing of patent and other rights;
- our diligence obligations under the license agreement and what activities satisfy those diligence obligations;
- the ownership of inventions and know-how resulting from the creation or use of intellectual property by us, alone or with our licensors and collaborators;
- the scope and duration of our payment obligations;
- our rights upon termination of such agreement; and
- the scope and duration of exclusivity obligations of each party to the agreement.

If disputes over intellectual property and other rights that we have licensed or acquired from third parties prevent or impair our ability to maintain our current licensing arrangements on acceptable terms, we may be unable to successfully develop and commercialize the affected product candidates. If we fail to comply with our obligations under

current or future licensing agreements, these agreements may be terminated or the scope of our rights under them may be reduced and we might be unable to develop, manufacture or market any product that is licensed under these agreements.

***We may be subject to claims that we have wrongfully hired an employee from a competitor or that we or our employees have wrongfully used or disclosed alleged confidential information or trade secrets of their former employers.***

As is common in the pharmaceutical industry, in addition to our employees, we engage the services of consultants to assist us in the development of our product candidates. Many of these consultants, and many of our employees, were previously employed at, or may have previously provided or may be currently providing consulting services to, other pharmaceutical companies including our competitors or potential competitors. We may become subject to claims that we, our employees or a consultant inadvertently or otherwise used or disclosed trade secrets or other information proprietary to their former employers or their former or current clients. Litigation may be necessary to defend against these claims. If we fail in defending any such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights, which could adversely affect our business. Even if we are successful in defending against these claims, litigation could result in substantial costs and be a distraction to our management team.

***We may be subject to claims challenging the inventorship or ownership of our patents and other intellectual property.***

We may also be subject to claims that former employees, collaborators or other third parties have an ownership interest in our patents or other intellectual property. Litigation may be necessary to defend against these and other claims challenging inventorship or ownership. If we fail in defending any such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights. 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 distraction to management and other employees.

***If we do not obtain patent term extension for our product candidates, our business may be materially harmed.***

Depending upon the timing, duration and specifics of potential FDA marketing approval of soquelitinib, ciforadenant, mupadolimab, or other product candidates, one or more of our U.S. patents may be eligible for limited patent term restoration under the Drug Price Competition and Patent Term Restoration Act of 1984 ("Hatch-Waxman Amendments"). The Hatch-Waxman Amendments permit a patent restoration term of up to five years as compensation for patent term lost during product development and the FDA regulatory review process. However, we may not be granted an extension because of, for example, failing to apply within applicable deadlines, failing to apply prior to expiration of relevant patents or otherwise failing to satisfy applicable requirements. Moreover, the applicable time period or the scope of patent protection afforded could be less than we request. If we are unable to obtain patent term extension or restoration or the term of any such extension is less than we request, our competitors may obtain approval of competing products following our patent expiration, and our revenue could be reduced, possibly materially.

***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 registered or unregistered 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, which we need to build name recognition among potential partners or customers in our markets of interest. At times, competitors may adopt trade names or trademarks similar to ours, thereby impeding our ability to build brand identity and possibly leading to market confusion. In addition, there could be potential trade name or trademark infringement claims brought by owners of other registered trademarks or trademarks that incorporate variations of our registered or unregistered trademarks or trade names. Over the long term, if we are unable to establish name recognition based on our trademarks and trade names, then we may not be able to compete effectively and our business may be adversely affected. Our efforts to enforce or protect our proprietary rights related to trademarks, trade secrets, domain names, copyrights or other intellectual property may be ineffective and could result in substantial costs and diversion of resources and could adversely affect our financial condition or results of operations.

***Changes in U.S. patent law could diminish the value of patents in general, thereby impairing our ability to protect our product candidates.***

As is the case with other biopharmaceutical companies, our success is heavily dependent on intellectual property, particularly patents. Obtaining and enforcing patents in the biopharmaceutical industry involve a high degree of technological and legal complexity. Therefore, obtaining and enforcing biopharmaceutical patents is costly, time consuming and inherently uncertain. In addition, Congress may pass patent reform legislation that is unfavorable to us. The Supreme Court has ruled on several patent cases in recent years, either narrowing the scope of patent protection available in certain circumstances or weakening the rights of patent owners in certain situations. 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 Congress, the federal courts and the USPTO, 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 we might obtain in the future.

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

While we have issued patents directed at soquelitinib, mupadolimab and ciforadenant in the United States and certain foreign territories, and pending patent applications directed at soquelitinib, ciforadenant, mupadolimab and other product candidates in other foreign countries, filing, prosecuting and defending patents on soquelitinib, ciforadenant, mupadolimab and our other product candidates in all countries throughout the world would be prohibitively expensive, and our intellectual property rights in some countries outside the United States can be less extensive than those in the United States. In addition, the laws of some foreign countries do not protect intellectual property rights to the same extent as federal and state laws in the United States. Consequently, we may not be able to prevent third parties from practicing our inventions in all countries outside the United States, or from selling or importing products made using our inventions in and into the United States or other jurisdictions. Competitors may use our technologies in jurisdictions where we have not obtained patent protection to develop their own products and, further, may export otherwise infringing products to territories where we have patent protection but enforcement is not as strong as that in the United States. These products may compete with our product candidates, and our patents or other intellectual property rights may not be effective or sufficient to prevent them from competing.

The legal systems of many foreign countries do not favor the enforcement of patents and other intellectual property protection, which could make it difficult for us to stop the infringement of our patents or marketing of competing products in violation of our proprietary rights. Proceedings to enforce our patent rights in foreign jurisdictions could result in substantial costs and divert our efforts and attention from other aspects of our business, could put our patents at risk of being invalidated or interpreted narrowly and our patent applications at risk of not issuing and could provoke third parties to assert claims against us. We may not prevail in any lawsuits that we initiate, and the damages or other remedies awarded, if any, may not be commercially meaningful. Accordingly, our efforts to enforce our intellectual property rights around the world may be inadequate to obtain a significant commercial advantage from the intellectual property that we develop or license.

***Intellectual property rights do not necessarily address all potential threats to our competitive advantage.***

The degree of future protection afforded by our intellectual property rights is uncertain because intellectual property rights have limitations, and may not adequately protect our business or permit us to maintain our competitive advantage. For example:

- others may be able to make adenosine antagonists that are similar to our product candidates but that are not covered by the claims of the patents that we own or have exclusively licensed;
- we or our licensors or future collaborators might not have been the first to make the inventions covered by the issued patent or pending patent application that we own or have exclusively licensed;
- we or our licensors or future collaborators might not have been the first to file patent applications covering certain of our inventions;

- others may independently develop similar or alternative technologies or duplicate any of our technologies without infringing our intellectual property rights;
- it is possible that our pending patent applications will not lead to issued patents;
- issued patents that we own or have exclusively licensed may be held invalid or unenforceable, as a result of legal challenges by our competitors;
- our competitors might conduct research and development activities in countries where we do not have patent rights and then use the information learned from such activities to develop competitive products for sale in our major commercial markets;
- we may not develop additional proprietary technologies that are patentable; and
- the patents of others may have an adverse effect on our business.

Should any of these events occur, they could significantly harm our business, results of operations and prospects.

**Risks Related to Our Common Stock**

***An active, liquid and orderly market for our common stock may not be sustained.***

Although our common stock is listed on The Nasdaq Global Market ("Nasdaq"), an active trading market for our common stock may not be sustained on Nasdaq or any other exchange in the future. The lack of an active market may impair our stockholders' ability to sell their shares at the time they wish to sell them or at a price that they consider reasonable. If an active market for our common stock is not sustained, it may also be difficult for our stockholders to sell shares without depressing the market price for the shares or at all. An inactive market may also impair our ability to raise capital by selling shares and may impair our ability to acquire other businesses, applications or technologies using our shares as consideration, which, in turn, could materially adversely affect our business. In any event, we have a limited public float and, as a result, our common stock has been and will likely continue to be less liquid than many other listed companies and trading may be adversely affected.

***The trading price of the shares of our common stock could be highly volatile, and investors in our common stock could incur substantial losses.***

Our stock price has been volatile. The stock market in general and the market for stock of pharmaceutical companies in particular have experienced extreme volatility that has often been unrelated to the operating performance of particular companies. The market price for our common stock may be influenced by those factors discussed in this "Risk Factors" section and many others, including:

- our ability to enroll subjects in our planned clinical trials;
- results of the clinical trials, and the results of trials of our competitors or those of other companies in our market sector;
- regulatory approval of soquelitinib, ciforadenant, mupadolimab and our other product candidates, or limitations to specific label indications or patient populations for its use, or changes or delays in the regulatory review process;
- Angel Pharmaceuticals' ability to develop and commercialize product candidates in China;

- regulatory developments in the United States and foreign countries; including changes in the policies of the U.S. or Chinese governments resulting in sanctions instituted by either government;
- changes in the structure of healthcare payment systems, especially in light of current reforms to the U.S. healthcare system;
- the success or failure of our efforts to acquire, license or develop additional product candidates;
- innovations or new products developed by us or our competitors;
- announcements by us or our competitors of significant acquisitions, strategic partnerships, joint ventures or capital commitments;
- manufacturing, supply or distribution delays or shortages;
- any changes to our relationship with any manufacturers, suppliers, collaborators or other strategic partners;
- achievement of product sales and profitability;
- variations in our financial results or those of companies that are perceived to be similar to us;
- market conditions in the pharmaceutical sector and issuance of securities analysts' reports or recommendations;
- the impact of political instability, natural disasters, war and/or events of terrorism, such as the military conflict between Ukraine and Russia, and the corresponding tensions created from such conflict between Russia, the United States and countries in Europe as well as other countries such as China;
- trading volume of our common stock;
- an inability to obtain additional funding on favorable terms, or at all;
- sales of our stock by insiders and stockholders;
- general economic, industry and market conditions, other events or factors such as increased interest rates, inflationary pressures and the occurrence of a recession or even depression, many of which are beyond our control;
- additions or departures of key personnel; and
- intellectual property, product liability or other litigation against us.

As a result of this volatility, investors may experience losses on their investment in our common stock.

In addition, in the past, stockholders have initiated class action lawsuits against pharmaceutical companies following periods of volatility in the market prices of these companies' stock. Such litigation, if instituted against us, could cause us to incur substantial costs and divert management's attention and resources, which could have a material adverse effect on our business, financial condition and results of operations.

***If we fail to adhere to the listing requirements of the Nasdaq Global Market our common stock could be delisted.***

If we are unable to comply with the listing requirements of the Nasdaq Global Market, our stock could be delisted for such failure. If our common stock is delisted from Nasdaq, we could be required to list on the over-the-counter, or OTC, market, which may adversely affect the price and trading liquidity of our common stock. Delisting from the Nasdaq may have other negative results, including the potential loss of confidence in us by employees and partners, the loss of institutional investor interest, fewer business development opportunities and greater difficulty in obtaining financing on favorable terms or at all.

***Our principal stockholders and management own a significant percentage of our stock and will be able to exert significant control over matters subject to stockholder approval.***

As of December 31, 2024, our executive officers, directors, holders of 5% or more of our capital stock based on publicly available filings made with the SEC and their respective affiliates beneficially owned approximately 39% of our outstanding common stock. Therefore, these stockholders have the ability to influence us through this ownership position. These stockholders may be able to determine all matters requiring stockholder approval. For example, these stockholders may be able to control elections of directors, amendments of our organizational documents, or approval of any merger, sale of assets, or other major corporate transaction. This may prevent or discourage unsolicited acquisition proposals or offers for our common stock that our stockholders may feel are in their best interest.

***We do not currently intend to pay dividends on our common stock, and, consequently, our stockholders' ability to achieve a return on their investment will depend on appreciation, if any, in the price of our common stock.***

We have never declared or paid any cash dividend on our common stock. We currently anticipate that we will retain future earnings for the development, operation and expansion of our business and do not anticipate declaring or paying any cash dividends for the foreseeable future. Any return to stockholders will therefore be limited to the appreciation of their stock. There is no guarantee that shares of our common stock will appreciate in value or even maintain the price at which stockholders have purchased their shares.

To the extent that we raise additional capital by issuing equity securities, the share ownership of existing stockholders will be diluted. For example, on August 6, 2024, we entered into the 2024 Sales Agreement with Jefferies to sell shares of our common stock, from time-to-time, with aggregate gross sales proceeds of up to $100,000,000 through an at-the-market equity offering program under which Jefferies will act as our sales agent. As of December 31, 2024, no shares of common stock had been sold under the 2024 Sales Agreement and $100.0 million remained available for sale under the 2024 Sales Agreement.

***Sales of a substantial number of shares of our common stock by our existing stockholders in the public market could cause our stock price to fall.***

Sales of a substantial number of shares of our common stock in the public market could occur at any 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. Moreover, certain holders of shares of our common stock have rights, subject to certain conditions, to require us to file registration statements covering their shares or to include their shares in registration statements that we may file for ourselves or other stockholders. We have registered and intend to continue to register all shares of common stock that we may issue under our equity compensation plans. Once we register these shares, they can be freely sold in the public market upon issuance, subject to volume limitations applicable to affiliates.

***We are a smaller reporting company and the reduced reporting requirements applicable to smaller reporting companies may make our common stock less attractive to investors.***

We are a smaller reporting company, which allows us to take advantage of exemptions from various reporting requirements that are applicable to other public companies that are not smaller reporting companies, including not being required to comply with the auditor attestation requirements of Section 404 of the Sarbanes-Oxley Act of 2002, as

amended, reduced disclosure obligations regarding executive compensation in our Annual Report and our periodic reports and proxy statements and providing only two years of audited financial statements in our Annual Report and our periodic reports. We will remain a smaller reporting company until (a) the aggregate market value of our outstanding common stock held by non-affiliates as of the last business day our most recently completed second fiscal quarter exceeds $250 million or (b) (1) we have over $100 million in annual revenues and (2) the aggregate market value of our outstanding common stock held by non-affiliates as of the last business day our most recently completed second fiscal quarter exceeds $700 million. We cannot predict whether investors will find our common stock less attractive if we rely on certain or all of these exemptions. If some investors find our common stock less attractive as a result, there may be a less active trading market for our common stock and our stock price may be more volatile and may decline.

***If we fail to maintain proper and effective internal control over financial reporting, our ability to produce accurate and timely consolidated financial statements could be impaired, investors may lose confidence in our financial reporting and the trading price of our common stock may decline.***

Pursuant to Section 404 of Sarbanes-Oxley, if and when we no longer qualify as a smaller reporting company, our independent registered public accounting firm will be required to attest to the effectiveness of our internal control over financial reporting. The rules governing the standards that must be met for management to assess our internal control over financial reporting are complex and require significant documentation, testing and possible remediation. To continue to comply with the requirements of being a reporting company under the Exchange Act, as we continue to grow, we will need to upgrade our systems including information technology; implement additional financial and management controls, reporting systems and procedures; and hire additional accounting and finance staff. If we or, if required, our auditors are unable to conclude that our internal control over financial reporting is effective, investors may lose confidence in our financial reporting and the trading price of our common stock may decline.

We cannot assure our stockholders that there will not be material weaknesses or significant deficiencies in our internal control over financial reporting in the future. Any failure to maintain internal control over financial reporting could severely inhibit our ability to accurately report our financial condition, results of operations or cash flows. If we are unable to conclude that our internal control over financial reporting is effective, or if our independent registered public accounting firm determines we have a material weakness or significant deficiency in our internal control over financial reporting once that firm begin its Section 404 reviews, investors may lose confidence in the accuracy and completeness of our financial reports, the market price of our common stock could decline, and we could be subject to sanctions or investigations by Nasdaq, the SEC or other regulatory authorities. Failure to remedy any material weakness in our internal control over financial reporting, or to implement or maintain other effective control systems required of public companies, could also restrict our future access to the capital markets.

***Provisions in our charter documents and under Delaware law could discourage a takeover that stockholders may consider favorable and may lead to entrenchment of management.***

Our amended and restated certificate of incorporation and amended and restated bylaws contain provisions that could significantly reduce the value of our shares to a potential acquiror or delay or prevent changes in control or changes in our management without the consent of our board of directors. The provisions in our charter documents include the following:

- a classified board of directors with three-year staggered terms, which may delay the ability of stockholders to change the membership of a majority of our board of directors;
- no cumulative voting in the election of directors, which limits the ability of minority stockholders to elect director candidates;
- the exclusive right of our Board of Directors, unless the Board of Directors grants such right to the stockholders, to elect a director to fill a vacancy created by the expansion of the board of directors or the resignation, death or removal of a director, which prevents stockholders from being able to fill vacancies on our board of directors;

- the required approval of at least 66 2/3% of the shares entitled to vote to remove a director for cause, and the prohibition on removal of directors without cause;

- the ability of our Board of Directors to authorize the issuance of shares of preferred stock and to determine the price and other terms of those shares, including preferences and voting rights, without stockholder approval, which could be used to significantly dilute the ownership of a hostile acquiror;

- the ability of our board of directors to alter our amended and restated bylaws without obtaining stockholder approval;

- the required approval of at least 66 2/3% of the shares entitled to vote to adopt, amend or repeal our amended and restated bylaws or repeal the provisions of our amended and restated certificate of incorporation regarding the election and removal of directors;

- a prohibition on stockholder action by written consent, which forces stockholder action to be taken at an annual or special meeting of our stockholders;

- an exclusive forum provision providing that the Court of Chancery of the State of Delaware will be the exclusive forum for certain actions and proceedings;

- the requirement that a special meeting of stockholders may be called only by the board of directors, which may delay the ability of our stockholders to force consideration of a proposal or to take action, including the removal of directors; and

- advance notice procedures that stockholders must comply with in order to nominate candidates to our board of directors or to propose matters to be acted upon at a stockholders' meeting, which may discourage or deter a potential acquiror from conducting a solicitation of proxies to elect the acquiror's own slate of directors or otherwise attempting to obtain control of us.

We are also subject to the anti-takeover provisions contained in Section 203 of the Delaware General Corporation Law. Under Section 203, a corporation may not, in general, engage in a business combination with any holder of 15% or more of its capital stock unless the holder has held the stock for three years or, among other exceptions, the board of directors has approved the transaction.

***Our amended and restated certificate of incorporation and amended and restated bylaws provide that the Court of Chancery of the State of Delaware is the exclusive forum for substantially all disputes between us and our stockholders, which could limit our stockholders' ability to obtain a favorable judicial forum for disputes with us or our directors, officers or employees.***

Our amended and restated certificate of incorporation and amended and restated bylaws provide 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, 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 provision may limit a stockholder's ability to bring a claim in a judicial forum that it finds favorable for disputes with us or our directors, officers or other employees, which may discourage such lawsuits against us and our directors, officers and other employees. Alternatively, if a court were to find this provision in our amended and restated certificate of incorporation and amended and restated bylaws to be inapplicable or unenforceable in an action, we may incur additional costs associated with resolving such action in other jurisdictions, which could adversely affect our business and financial condition. This provision would not apply to suits brought to enforce a duty or liability created by the Exchange Act or any other claim for which the U.S. federal courts have exclusive jurisdiction.

**General Risks**

***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. We are not permitted to market or promote any of our product candidates before we receive regulatory approval from applicable regulatory authorities in foreign markets, and we may never receive such regulatory approvals for any of our product candidates. To obtain separate regulatory approval in many other countries we must comply with numerous and varying regulatory requirements regarding safety and efficacy and governing, among other things, clinical trials, commercial sales, pricing and distribution of our product candidates. If we obtain regulatory approval of our product candidates and ultimately commercialize our product candidates in foreign markets, we would be subject to additional risks and uncertainties, including the burden of complying with complex and changing foreign regulatory, tax, accounting and legal requirements and the reduced protection of intellectual property rights in some foreign countries.

***Recent U.S. tax legislation and future changes to applicable U.S. or foreign tax laws and regulations may have a material adverse effect on our business, financial condition and results of operations.***

We are subject to income and other taxes in the U.S. and foreign jurisdictions. Changes in laws and policy relating to taxes or trade may have an adverse effect on our business, financial condition and results of operations. For example, the U.S. government recently enacted significant tax reform, and certain provisions of the new law may adversely affect us. Changes include, but are not limited to, a federal corporate tax rate decrease from 35% to 21% for tax years beginning after December 31, 2017, the transition of U.S. international taxation from a worldwide tax system to a more generally territorial system, and a one-time transition tax on the mandatory deemed repatriation of foreign earnings. The legislation is unclear in many respects and could be subject to potential amendments and technical corrections, and will be subject to interpretations and implementing regulations by the Treasury and Internal Revenue Service, any of which could mitigate or increase certain adverse effects of the legislation. In addition, it is unclear how these U.S. federal income tax changes will affect state and local taxation. Generally, future changes in applicable U.S. or foreign tax laws and regulations, or their interpretation and application could have an adverse effect on our business, financial conditions and results of operations.

***Our information technology systems, or those of any of our existing or potential future collaborators, CROs or other contractors or consultants, may fail or suffer security breaches, which could result in a material disruption of our product development programs.***

We maintain sensitive company data on our information technology systems, including our intellectual property, proprietary business information, clinical trial data, and personal information (collectively, "Confidential Information") of customers and our employees and contractors. We face a number of threats to our networks from unauthorized access, security breaches and other system disruptions. Despite the implementation of security measures, our information technology and other internal computer systems and those of our current and any future CROs and other contractors, consultants and collaborators are vulnerable to damage from cyberattacks, "phishing" attacks, computer viruses and malware (e.g., ransomware), malicious code, misconfigurations, "bugs" or other vulnerabilities, unauthorized access, natural disasters, terrorism, war and telecommunication and electrical failures.

Attacks upon information technology systems are increasing in their frequency, levels of persistence, sophistication and intensity, and are being conducted by sophisticated and organized groups and individuals with a wide range of motives and expertise. Furthermore, because the techniques used to obtain unauthorized access to, or to sabotage or disrupt, systems change frequently and often are not recognized until launched against a target, we may be unable to anticipate these techniques or implement adequate preventative measures. We may also experience security breaches that may remain undetected for an extended period. Even if identified, we may be unable to adequately investigate or remediate incidents or breaches due to attackers increasingly using tools and techniques that are designed to circumvent controls, to avoid detection, and to remove or obfuscate forensic evidence. As a result of the continued hybrid working environment, we may also face increased cybersecurity risks due to our reliance on internet technology and the number of our and our service providers' employees who are working remotely, which may create additional

opportunities for cybercriminals to exploit vulnerabilities. There can also be no assurance that our and our current and future CROs' and other contractors', consultants' and collaborators' cybersecurity risk management program and processes, including policies, controls or procedures, will be fully implemented, complied with or effective in protecting our systems, networks and Confidential Information.

We and certain of our service providers are from time to time, subject to cyberattacks and security incidents. While we do not believe that we have experienced any significant system failure, accident or security breach to date, any such security breach may compromise Confidential Information stored on our networks, or those of our vendors, and may result in significant data losses or theft of our Confidential Information. Further, if such an event were to occur and cause interruptions in our operations, it could result in a material disruption of our development programs and our business operations, whether due to a loss of our trade secrets or other similar disruptions. For example, the loss of clinical trial data from completed or future clinical trials could result in delays in our regulatory approval efforts and significantly increase our costs to recover or reproduce the data. In addition, such a breach may require notification to governmental agencies, or affected individuals pursuant to applicable data privacy and security laws. We would also be exposed to a risk of loss, including financial assets or litigation and potential liability, which could materially adversely affect our business, reputation, financial condition, results of operations and prospects. We also rely on third parties to manufacture our product candidates, and similar events relating to their computer systems could also have a material adverse effect on our business. To the extent that any disruption or security breach were to result in a loss of, or damage to, our data or applications, or inappropriate disclosure of Confidential Information, we could incur liability and the further development and commercialization of our product candidates could be delayed. Any adverse impact to the availability, integrity or confidentiality of our or third-party systems or Confidential Information can result in legal claims or proceedings (such as class actions), regulatory investigations and enforcement actions, fines and penalties, negative reputational impacts that cause us to lose existing or future customers, and/or significant incident response, system restoration or remediation and future compliance costs. Our existing general liability and cyber liability insurance policies may not cover, or may cover only a portion of, any potential claims related to security breaches to which we are exposed, or may not be adequate to indemnify us for all or any portion of liabilities that may be imposed.

***Changes in and failures to comply with U.S. and foreign privacy and data protection laws, regulations and standards may adversely affect our business, operations and financial performance.***

We are subject to or affected by numerous federal, state and foreign laws and regulations, as well as regulatory guidance, governing the collection, use, disclosure, retention, and security of personal data, such as information that we collect about patients and healthcare providers in connection with clinical trials in the United States and abroad. The global data protection landscape is rapidly evolving, and implementation standards and enforcement practices are likely to remain uncertain for the foreseeable future. This evolution may create uncertainty in our business, affect our or our collaborators', service providers' and contractors' ability to operate in certain jurisdictions or to collect, store, transfer use and share personal information, necessitate the acceptance of more onerous obligations in our contracts, result in liability or impose additional costs on us.

In the U.S., HIPAA imposes, among other things, certain standards relating to the privacy, security, transmission and breach reporting of individually identifiable health information. Certain states have also adopted comparable privacy and security laws and regulations, which govern the privacy, processing and protection of health-related and other personal information. Depending on the facts and circumstances, we could be subject to criminal penalties if we knowingly obtain, use, or disclose individually identifiable health information that was provided to us by a HIPAA-covered entity in a manner that is not authorized or permitted by HIPAA.

Further, the California Consumer Privacy Act, as amended by the California Privacy Rights Act (collectively, the "CCPA") requires covered businesses that process the personal information of California residents to, among other things: provide certain disclosures to California residents regarding the business's collection, use, and disclosure of their personal information; receive and respond to requests from California residents to access, delete, and correct their personal information, or to opt out of certain disclosures of their personal information, and enter into specific contractual provisions with service providers that process California resident personal information on the business's behalf. Similar laws have been proposed in other states and are continuing to be proposed at the state and federal level, and if passed, such laws may have potentially conflicting requirements that would make compliance challenging.

Our operations abroad may also be subject to increased scrutiny or attention from data protection authorities. Many countries in these regions have established or are in the process of establishing privacy and data security legal frameworks with which we, our collaborators, service providers, including our CRO, and contractors must comply. For example, the General Data Protection Regulation (the "GDPR"), which went into effect in May 2018, imposes strict requirements for processing the personal data of individuals within the EEA, including clinical trial data. The GDPR has and will continue to increase compliance burdens on us, including by mandating potentially burdensome documentation requirements and granting certain rights to individuals to control how we collect, use, disclose, retain and process information about them. The processing of sensitive personal data, such as physical health condition, may impose heightened compliance burdens under the GDPR and is a topic of active interest among foreign regulators. The GDPR provides for robust regulatory enforcement and fines of up to €20 million or 4% of the annual global revenue of the noncompliant company, whichever is greater. Among other requirements, the GDPR regulates transfers of personal data subject to the GDPR to third countries that have not been found to provide adequate protection to such personal data, including the United States, and the efficacy and longevity of current transfer mechanisms between the EEA, and the United States remains uncertain. Case law from the Court of Justice of the European Union ("CJEU") states that reliance on the standard contractual clauses - a standard form of contract approved by the European Commission as an adequate personal data transfer mechanism - alone may not necessarily be sufficient in all circumstances and that transfers must be assessed on a case-by-case basis. On July 10, 2023, the European Commission adopted its Adequacy Decision in relation to the new EU-US Data Privacy Framework ("DPF"), rendering the DPF effective as a GDPR transfer mechanism to U.S. entities self-certified under the DPF. As supervisory authorities issue further guidance on personal data export mechanisms, including circumstances where the standard contractual clauses cannot be used, and/or start taking enforcement action, we could suffer additional costs, complaints and/or regulatory investigations or fines, and/or if we are otherwise unable to transfer personal data between and among countries and regions in which we operate, it could affect the manner in which we provide our services, the geographical location or segregation of our relevant systems and operations, and could adversely affect our financial results.

Further, from January 1, 2021, we had to comply with the GDPR and the United Kingdom ("UK") GDPR, which, together with the amended UK Data Protection Act 2018, retains the GDPR in UK national law, the latter regime having the ability to separately fine up to the greater of £17.5 million or 4% of global turnover. On October 12, 2023, the UK Extension to the DPF came into effect (as approved by the UK Government), as a data transfer mechanism from the UK to U.S. entities self-certified under the DPF.

As we expand into other foreign countries and jurisdictions, we may be subject to additional laws and regulations that may affect how we conduct business. The cost of compliance with these laws, regulations and standards is high and is likely to increase in the future. Any failure or perceived failure by us or our collaborators, service providers and contractors to comply with federal, state or foreign laws or regulation, our internal policies and procedures or our contracts governing processing of personal information could result in negative publicity, diversion of management time and effort and proceedings against us by governmental entities or others. In many jurisdictions, enforcement actions and consequences for noncompliance are rising.

***Our operations could be subject to earthquakes, power shortages, telecommunications failures, water shortages, floods, hurricanes, typhoons, fires, extreme weather conditions, medical epidemics and pandemics, such as the COVID-19 pandemic, and other natural or manmade disasters or business interruptions, for which we are predominantly self-insured.***

Our corporate headquarters and laboratory are located in the San Francisco Bay Area. This location has in the past experienced severe earthquakes and other natural disasters. Earthquakes, extreme weather conditions, or other natural disasters, power-shortages, telecommunications failures, fires, medical epidemics and pandemics, such as the COVID-19 pandemic, and other natural or manmade disasters could severely disrupt our operations or those of our collaboration partners and have a material adverse effect on our business, results of operations, financial condition and prospects. If a natural disaster, power outage or other event occurred that prevented us from using all or a significant portion of our headquarters, that damaged critical infrastructure (such as 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 currently are limited and are unlikely to prove adequate 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.

***If any of our suppliers of the drug substance we use for the development of our product candidates are unable to provide such drug substance, our business could be disrupted and seriously harmed.***

We currently rely on several different manufacturers who supply different parts of the ciforadenant molecule and soquelitinib molecule, on one manufacturer for mupadolimab drug substance and on other third-party manufacturers to produce our other product candidates. Our ability to obtain clinical supplies of soquelitinib, ciforadenant and mupadolimab or our other product candidates could be disrupted if the operations of these suppliers were affected by a man-made or natural disaster or other business interruption. The occurrence of any of these business disruptions could seriously harm our operations and financial condition and increase our costs and expenses.

***Our ability to use net operating loss carryforwards and other tax attributes may be limited.***

We have incurred substantial losses during our history and do not expect to become profitable in the near future, and we may never achieve profitability. To the extent that we continue to generate taxable losses, unused losses will carry forward to offset future taxable income, if any, until such unused losses expire. As of December 31, 2024, we had federal net operating loss ("NOL") carryforwards of approximately $243.8 million and state NOL carryforwards of approximately $317.8 million available to offset future taxable income. If not utilized, the federal and state NOL carryforwards will begin to expire in various years beginning in 2034. As of December 31, 2024, we also had $10.2 million of federal research and development tax credit, $0.5 million of federal orphan drug credit, and $5.4 million of state research and development tax credit carryforwards available to reduce future income taxes. The federal research and development tax credits will begin to expire in 2036, if not utilized. The state research and development tax credits have no expiration date. Utilization of NOL carryforwards and credits may be subject to an annual limitation due to the "ownership change" provisions under Sections 382 and 383 of the Internal Revenue Code of 1986, as amended. An "ownership change" is generally defined as a cumulative change in the ownership interest of significant stockholders over a rolling three-year period in excess of 50 percentage points. Similar provisions under state tax law may also apply. If finalized, Treasury Regulations currently proposed under Section 382 of the Code may further limit our ability to utilize our pre-change NOLs or credits if we undergo a future ownership change. We may experience an ownership change in the future as a result of subsequent shifts in our stock ownership, some of which changes are outside our control. Such ownership changes could result in the expiration of our NOL carryforwards and other tax attributes before they can be utilized and, if we are profitable, our future cash flows could be adversely affected due to our increased tax liability.

Additionally, under the Tax Cut and Jobs Act (the "Tax Act"), as modified by the Coronavirus Aid, Relief, and Economic Security Act (the "CARES Act"), NOL carryforwards arising in tax years beginning after December 31, 2020 are limited to 80% of taxable income. Under the Tax Act, federal NOL carryforwards arising in tax years beginning after December 31, 2017 may be carried forward indefinitely. Under the CARES Act, federal NOL carryforwards arising in tax years beginning after December 31, 2017 and before January 1, 2021 may be carried back to each of the five tax years preceding the tax year of such loss. The changes in the carryforward and carryback periods as well as the limitation on use of NOL carryforwards may significantly impact our ability to use NOL carryforwards, particularly for tax years beginning after December 31, 2020, as well as the timing of any such use, and could adversely affect our results of operations.

***If securities or industry analysts do not publish research or reports or publish unfavorable research or reports about our business, our stock price and trading volume could decline.***

The trading market for our common stock is influenced by the research and reports that industry or securities analysts publish about us or our business. If any of the analysts who cover us issue an adverse or misleading opinion regarding us, our business model, our intellectual property or our stock performance, or if our target studies and operating results fail to meet the expectations of analysts, our stock price would likely decline. If one or more of these 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 our stock price or trading volume to decline.

**Item 1B. Unresolved Staff Comments**

None

**Item 1C. Cybersecurity**

***Cybersecurity Risk Management and Strategy***

We have developed and implemented a cybersecurity risk management program intended to protect the confidentiality, integrity, and availability of our critical systems and information. Our cybersecurity risk management program includes a cybersecurity incident response plan.

Our cybersecurity risk management program includes:

- risk assessments designed to help identify material cybersecurity risks to our critical systems, information, products, services, and our broader enterprise information technology environment;
- a security team principally responsible for managing (1) our cybersecurity risk assessment processes, (2) our security controls, and (3) our response to cybersecurity incidents;
- the use of external service providers, where appropriate, to assess, test or otherwise assist with aspects of our security controls;
- cybersecurity awareness training of our employees, incident response personnel, and senior management; and
- a cybersecurity incident response plan that includes procedures for responding to cybersecurity incidents.

We have not identified risks from known cybersecurity threats, including as a result of any prior cybersecurity incidents, that have materially affected or are reasonably likely to materially affect us, including our operations, business strategy, results of operations, or financial condition.

***Cybersecurity Governance***

Our Board considers cybersecurity risk as part of its risk oversight function and has delegated to the Audit Committee ("Committee") oversight of cybersecurity and other information technology risks. The Committee oversees management's implementation of our cybersecurity risk management program.

The Committee has received reports from management on our cybersecurity risks and will receive such reports on a periodic basis going forward. In addition, management updates the Committee, as necessary, regarding any material cybersecurity incidents, as well as any incidents with lesser impact potential.

The Committee reports to the full Board regarding its activities which include those related to cybersecurity.

As part of our management team, Leiv Lea, our Chief Financial Officer, who has over fifteen years of experience overseeing information technology systems for public companies, is responsible for assessing and managing our material risks from cybersecurity threats. Mr. Lea has primary responsibility for our overall cybersecurity risk management program and supervises our retained external information technology and cybersecurity consultants. Mr. Lea supervises efforts to prevent, detect, mitigate, and remediate cybersecurity risks and incidents through various means, which may include briefings from security personnel and alerts and reports produced by security tools deployed in the Company's information technology environment.

**Item 2. Properties**

We currently lease approximately 20,916 square feet of office and research and development facilities in South San Francisco, California. This facility lease will expire in January 2028.

We previously leased approximately 27,280 square feet of office and research and development facilities in Burlingame, California. Approximately 7,585 square feet was subleased to Angel Pharmaceuticals through January 2023. This facility lease expired in January 2025.

**Item 3. Legal Proceedings**

We are not currently a party to any material litigation or legal proceedings; however, we may from time to time be involved in various legal proceedings incident to the ordinary course of our business.

**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 has been listed on The Nasdaq Global Market under the symbol "CRVS" since March 23, 2016. Prior to that there was no public trading market for our common stock. The following table sets forth for the indicated periods the high and low sales prices per share for our common stock on the Nasdaq stock market.

| | Price Range | |
|---|---|---|
| | High | Low |
| **2024** | | |
| First Quarter | $ 2.58 | $ 1.65 |
| Second Quarter | $ 2.35 | $ 1.30 |
| Third Quarter | $ 6.15 | $ 1.75 |
| Fourth Quarter | $ 10.00 | $ 3.77 |
| **2023** | | |
| First Quarter | $ 0.94 | $ 0.61 |
| Second Quarter | $ 4.19 | $ 0.72 |
| Third Quarter | $ 3.16 | $ 1.37 |
| Fourth Quarter | $ 1.92 | $ 1.05 |

**Holders of Record**

As of March 25, 2025, there were approximately 16 stockholders of record of our common stock. The actual number of stockholders is greater than this number of record holders, and includes stockholders who are beneficial owners, but whose shares are held in street name by brokers and other nominees. This number of holders of record also does not include stockholders whose shares may be held in trust by other entities.

**Dividend Policy**

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

**Securities Authorized for Issuance Under Equity Compensation Plans**

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

**Use of Proceeds from Registered Securities**

None.

**Recent Sales of Unregistered Equity Securities**

None.

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

**Overview**

We are a clinical stage biopharmaceutical company developing product candidates that precisely target proteins that are critical to immune cell maturation and function. We believe our proprietary product candidates have broad potential to address cancers, immune mediated diseases and inflammatory diseases. Our lead product candidate, soquelitinib (formerly CPI-818), is designed to bind specifically to a protein, interleukin 2 inducible T cell kinase (ITK), involved in T cell activation, T cell receptor signaling and T cell differentiation and function. Based on the proposed mechanism of action, we believe soquelitinib has the potential to be utilized to inhibit the production of a number of inflammatory cytokines involved in diseases such as atopic dermatitis, asthma, psoriasis and fibrotic diseases. In preclinical studies, Soquelitinib has affected T cell differentiation leading to enhanced function of T cells involved in tumor cell killing.

Since the immune cells targeted by our product candidates play a role in many diseases, our strategy is to leverage our research and development capabilities by evaluating our product candidates in clinical trials where there is an understanding of the role of specific T cells in the target indication and where we believe such product candidates have the broadest potential. We believe this strategy has enabled us to move rapidly from preclinical to clinical trials in diverse disease areas, each with large unmet needs. Soquelitinib entered a registrational, Phase 3 clinical trial for relapsed T cell lymphomas and is also being evaluated in a randomized, placebo controlled Phase 1 trial in patients with atopic dermatitis. We have two additional product candidates which are in clinical development for the treatment of various solid tumors, also based on modulation of immune function.

To date, the majority of our efforts have been focused on the research, development and advancement of soquelitinib, ciforadenant, and mupadolimab, and we have not generated any revenue from product sales and, as a result, we have incurred significant losses. We expect to continue to incur significant research and development and general and administrative expenses related to our operations. Our net loss for the years ended December 31, 2024 and 2023 was $62.3 million and $27.0 million, respectively. As of December 31, 2024, we had an accumulated deficit of $397.0 million. We expect our losses will increase as we continue our development of, seek regulatory approval for and begin to commercialize soquelitinib, ciforadenant and mupadolimab, and as we develop other product candidates. Even if we achieve profitability in the future, we may not be able to sustain profitability in subsequent periods.

Since our inception and through December 31, 2024, we have funded our operations primarily through the sale and issuance of stock, including through our initial public offering ("IPO") in March 2016, in which we raised net proceeds of $70.6 million, a follow-on offering of our common stock in March 2018, in which we raised net proceeds of $64.9 million, a follow on offering of our common stock in February 2021, in which we raised net proceeds of $32.0 million and a registered direct offering in May 2024, in which we sold shares of our common stock, pre-funded warrants and common warrants for net proceeds of $30.3 million. Immediately prior to the consummation of the IPO, all of our outstanding shares of redeemable convertible preferred stock were converted into 14.3 million shares of our common stock.

On August 6, 2024, we entered into an open market sale agreement (the "2024 Sales Agreement") with Jefferies LLC ("Jefferies") to sell shares of our common stock, from time-to-time, with aggregate gross sales proceeds of up to $100.0 million, through an at-the-market equity offering program under which Jefferies will act as our sales agent. The

issuance and sale of shares of common stock pursuant to the 2024 Sales Agreement are deemed an "at-the-market" offering under the Securities Act of 1933, as amended. Jefferies is entitled to compensation for its services of up to 3.0% of the gross proceeds of any shares of common stock sold through Jefferies under the 2024 Sales Agreement.

During the year ended December 31, 2024, we did not sell any shares of common stock under our at-the-market offering program and $100.0 million remained available for sale under the 2024 Sales Agreement.

Our three product candidates, soquelitinib, ciforadenant and mupadolimab, are in clinical development by us and / or our partner, Angel Pharmaceuticals. Except for Greater China, we own the world-wide rights to these product candidates.

As a result of our ongoing development efforts, we anticipate needing to spend substantial resources for the foreseeable future. Consequently, we will need additional financing to support our continuing operations. Until such time as we can generate significant revenue from product sales, if ever, we expect to finance our operations through a combination of public or private equity or debt financings or other sources, which may include collaborations with third parties. Such financing could result in dilution to stockholders and may include the imposition of debt covenants and repayment obligations or other restrictions that may affect our business. If we raise additional capital through strategic collaboration agreements, we may have to relinquish valuable rights to our product candidates, including potential future revenue streams. Adequate additional financing may not be available to us on acceptable terms, or at all. For example, the trading prices for our and other biopharmaceutical companies' stock have been highly volatile as a result of factors such as the impacts of pandemics and increases in inflation rates or interest rates. As a result, we may face difficulties raising capital through sales of our common stock and any such sales may be on unfavorable terms. Our inability to raise capital as and when needed would have a negative impact on our financial condition and our ability to pursue our business strategy. We will need to generate significant revenue to achieve profitability, and we may never do so.

As of December 31, 2024, we had capital resources consisting of cash, cash equivalents and marketable securities of approximately $52.0 million. Based on our currently available cash resources and our currently planned level of operations and cash flows for at least the 12 month period subsequent to the date of issuance of the consolidated financial statements included elsewhere in this Annual Report on Form 10-K, we will require additional funding by the first quarter of 2026. In accordance with applicable accounting standards, we evaluated whether there are conditions and events, considered in the aggregate, that raise substantial doubt about our ability to continue as a going concern for at least 12 months beyond the date of issuance of the consolidated financial statements included elsewhere in this Annual Report on Form 10-K. Under the applicable accounting standards, the receipt of potential funding from future equity issuances cannot be considered probable, as these events are outside our control. Accordingly, management has concluded that substantial doubt exists about our ability to continue as a going concern for at least 12 months from the date the consolidated financial statements included elsewhere in this Annual Report on Form 10-K are issued. See "Risk Factors—Risks Related to Our Limited Operating History, Financial Condition and Need for Additional Capital."

We currently have no manufacturing capabilities and do not intend to establish any such capabilities. We have no commercial manufacturing facilities for our product candidates. As such, we are dependent on third parties to supply our product candidates according to our specifications, in sufficient quantities, on time, in compliance with appropriate regulatory standards and at competitive prices.

**Components of Results of Operations**

***Revenue***

To date, we have not generated any revenues. We do not expect to receive any revenues from any product candidates that we develop unless and until we obtain regulatory approval and commercialize our products or enter into revenue-generating collaboration agreements with third parties.

**Research and Development Expenses**

Our research and development expenses consist primarily of costs incurred to conduct research and development of our product candidates. We record research and development expenses as incurred. Research and development expenses include:

- employee-related expenses, including salaries, benefits, travel and non-cash stock-based compensation expense;
- external research and development expenses incurred under arrangements with third parties, such as contract research organizations, preclinical testing organizations, contract manufacturing organizations, academic and non-profit institutions and consultants;
- costs to acquire technologies to be used in research and development that have not reached technological feasibility and have no alternative future use;
- license fees; and
- other expenses, which include direct and allocated expenses for laboratory, facilities and other costs.

We plan to increase our research and development expenses substantially as we continue the development and potential commercialization of our product candidates. Our current planned research and development activities include the following:

- completion of our ongoing Phase 1/1b clinical trial for soquelitinib in relapsed T cell lymphomas;
- enrollment and completion of our ongoing Phase 3 registrational clinical trial for soquelitinib in PTCL;
- enrollment and completion of our ongoing Phase 1 clinical trial for soquelitinib in atopic dermatitis;
- completion of our Phase 1b/2 clinical trial with ciforadenant in collaboration with the Kidney Cancer Research Consortium;
- a potential Phase 2 clinical trial for soquelitinib in atopic dermatitis;
- a potential clinical trial for soquelitinib in solid tumors
- a potential clinical trial for soquelitinib in asthma;
- process development and manufacturing of drug supply of soquelitinib and ciforadenant; and
- preclinical studies under our other programs in order to select development product candidates.

In addition to our product candidates that are in clinical development, we believe it is important to continue substantial investment in potential new product candidates to build the value of our product candidate pipeline and our business.

Our expenditures on current and future preclinical and clinical development programs are subject to numerous uncertainties related to timing and cost to completion. The duration, costs and timing of clinical trials and development of product candidates will depend on a variety of factors, including many of which are beyond our control. The process of conducting the necessary clinical research to obtain regulatory approval is costly and time consuming, and the successful development of our product candidates is uncertain. The risks and uncertainties associated with our research and development projects are discussed more fully in “Part II, Item 1A—Risk Factors.” As a result of these risks and

uncertainties, we are unable to determine with any degree of certainty the duration and completion costs of our research and development projects or if, when or to what extent we will generate revenues from the commercialization and sale of any of our product candidates that obtain regulatory approval. We may never succeed in achieving regulatory approval for any of our product candidates.

**General and Administrative Expenses**

General and administrative expenses include personnel costs, expenses for outside professional services and allocated expenses. Personnel costs consist of salaries, benefits and stock-based compensation. Outside professional services consist of legal, accounting and audit services and other consulting fees. Allocated expenses consist of rent expense related to our office and research and development facility.

We expect that our general and administrative expenses will increase in the future as we increase our headcount to support our continued research and development and potential commercialization of one or more of our product candidates.

**Results of Operations**

*Comparison of the periods below as indicated (in thousands):*

| | Year ended December 31, | | | Change | Change |
|---|---|---|---|---|---|
| | 2024 | 2023 | 2022 | 2023 to 2024 | 2022 to 2023 |
| Operating expenses: | | | | | |
| Research and development | $ 19,385 | $ 16,526 | $ 24,468 | $ 2,859 | $ (7,942) |
| General and administrative | 8,163 | 6,881 | 8,097 | 1,282 | (1,216) |
| Total operating expenses | 27,548 | 23,407 | 32,565 | 4,141 | (9,158) |
| Loss from operations | (27,548) | (23,407) | (32,565) | (4,141) | 9,158 |
| Interest income and other expense, net | 1,824 | 1,584 | 654 | 240 | 930 |
| Gain from sale of property and equipment | 5 | — | 22 | 5 | (22) |
| Change in fair value of warrant liability | (33,377) | — | — | (33,377) | — |
| Sublease income - related party | — | 78 | 587 | (78) | (509) |
| Loss before equity method investment | (59,096) | (21,745) | (31,302) | (37,351) | 9,557 |
| Loss from equity method investment | (3,197) | (5,284) | (10,005) | 2,087 | 4,721 |
| Net loss | $ (62,293) | $ (27,029) | $ (41,307) | $ (35,264) | $ 14,278 |

*Research and Development Expenses*

Research and development expenses for the years ended December 31, 2024, 2023 and 2022, consisted of the following costs by program (specific program costs consist solely of external costs):

| | Year ended December 31, | | | Change | Change |
|---|---|---|---|---|---|
| | 2024 | 2023 | 2022 | 2023 to 2024 | 2022 to 2023 |
| Soquelitinib | $ 8,813 | $ 5,335 | $ 3,861 | $ 3,478 | $ 1,474 |
| Ciforadenant | 33 | 963 | 1,327 | (930) | (364) |
| Mupadolimab | 82 | 772 | 9,789 | (690) | (9,017) |
| Unallocated employee and overhead costs | 10,457 | 9,456 | 9,491 | 1,001 | (35) |
| | $ 19,385 | $ 16,526 | $ 24,468 | $ 2,859 | $ (7,942) |

For the year ended December 31, 2024, the increase in soquelitinib costs of $3.5 million as compared to the year ended December 31, 2023, primarily consisted of an increase of $2.3 million in clinical trial expenses, an increase of $0.8 million in drug manufacturing costs and an increase of $0.4 million in other outside services.

For the year ended December 31, 2024, the decrease in ciforadenant costs of $0.9 million as compared to the year ended December 31, 2023, primarily consisted of a release of a $0.7 million legacy clinical trial accrual and a decrease of $0.2 million in other outside services.

For the year ended December 31, 2024, the decrease in mupadolimab costs of $0.7 million as compared to the year ended December 31, 2023, primarily consisted of a decrease of $0.4 million in clinical trial expenses and a decrease of $0.3 million in drug manufacturing costs.

For the year ended December 31, 2024, the increase in unallocated costs of $1.0 million as compared to the year ended December 31, 2023, primarily consisted of an increase of $0.9 million in personnel related costs and an increase of $0.1 million in other outside services.

For the year ended December 31, 2023, the increase in soquelitinib costs of $1.5 million as compared to the year ended December 31, 2022, primarily consisted of an increase of $1.3 million in outside services and an increase of $0.6 million in clinical trial expenses, which was partially offset by a decrease of $0.4 million in drug manufacturing costs.

For the year ended December 31, 2023, the decrease in ciforadenant costs of $0.4 million as compared to the year ended December 31, 2022, primarily consisted of a decrease of $0.3 million in drug manufacturing costs and a decrease of $0.4 million in other outside services, which was partially offset by an increase of $0.3 million in clinical trial expenses.

For the year ended December 31, 2023, the decrease in mupadolimab costs of $9.0 million as compared to the year ended December 31, 2022, primarily consisted of a decrease of $7.3 million in drug manufacturing costs, a decrease of $1.4 million in clinical trial expenses and a decrease of $0.3 million in other outside services.

For the year ended December 31, 2023, the decrease in unallocated costs compared to the year ended December 31, 2022, was negligible.

*General and Administrative Expenses*

For the year ended December 31, 2024, the increase in general and administrative expenses of $1.3 million as compared to the year ended December 31, 2023, primarily consisted of an increase of $0.9 million in personnel and related costs and an increase of $0.4 million in other outside costs.

For the year ended December 31, 2023, the decrease in general and administrative expenses of $1.2 million as compared to the year ended December 31, 2022, primarily consisted of a decrease of $0.6 million in personnel and related costs and a decrease of $0.6 million in other outside costs.

*Interest Income and Other Expense, net*

For the year ended December 31, 2024, the increase in interest income and other expense, net of $0.2 million as compared to the year ended December 31, 2023, primarily consisted of an increase in interest income earned due to an increase in cash equivalents and marketable securities.

For the year ended December 31, 2023, the increase in interest income and other expense, net of $0.9 million as compared to the year ended December 31, 2022, primarily consisted of an increase in interest income earned due to an increase in interest rates.

*Gain from sale of property and equipment*

For the year ended December 31, 2024 and 2023, the gain from sale of property and equipment consisted of proceeds from the sale of laboratory equipment.

*Sublease income – related party*

For the year ended December 31, 2024, the decrease in sublease income – related party of $0.1 million as compared to the year ended December 31, 2023, was due to the expiration of the building sublease agreement with Angel Pharmaceuticals' in January 2023.

For the year ended December 31, 2023, the decrease in sublease income – related party of $0.5 million as compared to the year ended December 31, 2022, was due to the expiration of the building sublease agreement with Angel Pharmaceuticals' in January 2023.

*Loss from equity method investment*

For the year ended December 31, 2024, the decrease in loss from equity method investment of $2.1 million as compared to the year ended December 31, 2023, primarily consisted of a decrease in our share of Angel Pharmaceutical's loss for the year ended December 31, 2024.

For the year ended December 31, 2023, the decrease in loss from equity method investment of $4.7 million as compared to the year ended December 31, 2022, primarily consisted of a decrease in our share of Angel Pharmaceutical's loss for the year ended December 31, 2023.

**Liquidity and Capital Resources**

***Sources of Liquidity***

As of December 31, 2024, we had cash, cash equivalents and marketable securities of $52.0 million and an accumulated deficit of $397.0 million.

Since our inception and through December 31, 2024, we have funded our operations primarily through the sale and issuance of preferred and common stock, including through our IPO in March 2016, in which we raised net proceeds of approximately $70.6 million, a follow-on offering of our common stock in March 2018, in which we raised net proceeds of approximately $64.9 million, a follow on offering of our common stock in February 2021, in which we raised net proceeds of approximately $32.0 million and a registered direct offering in May 2024, in which we sold shares of our common stock, pre-funded warrants and common warrants for net proceeds of approximately $30.3 million. During the year ended December 31, 2024, we raised net proceeds of $18.6 million from the exercise of common warrants.

During the year ended December 31, 2024, we did not sell any shares of common stock under our at-the-market offering program. As of December 31, 2024, $100.0 million remained available for sale under the 2024 Sales Agreement.

***Funding Requirements***

Since our inception, we have incurred significant losses and negative cash flows from operations. We have an accumulated deficit of $397.0 million through December 31, 2024. We do not expect positive cash flows from operations in the foreseeable future, if ever. Historically, we have incurred operating losses as a result of ongoing efforts to develop our product candidates, including conducting ongoing research and development, clinical and preclinical studies and providing general and administrative support for these operations. We do not have any products approved for sale, and we do not expect to generate any meaningful revenue unless and until we obtain regulatory approval of and commercialize any of our current and future product candidates and/or enter into additional significant collaboration agreements with third parties, and we do not know when, or if, either will occur. We expect to continue to incur net operating losses for at least the next several years and we expect the losses to increase as we advance our soquelitinib, ciforadenant and mupadolimab product candidates, as well as any future product candidates, through clinical development, seek regulatory approval, prepare for and, if approved, proceed to commercialization and continue our research and development efforts. We are subject to all the risks typically related to the development of new product

candidates, and we may encounter unforeseen expenses, difficulties, complications, delays and other unknown factors that may adversely affect our business. We do not yet have a sales organization or commercial infrastructure and, accordingly, we will need to incur significant expenses to develop a sales organization and commercial infrastructure in advance of generating any commercial product sales. Moreover, we incur substantial costs associated with operating as a public company. We anticipate that we will need substantial additional funding in connection with our continuing operations.

Until we can generate a sufficient amount of revenue from the commercialization of our product candidates or from additional significant collaboration or license agreements with third parties, if ever, we expect to finance our future cash needs through private and public equity offerings, including our "at-the-market" offering program, debt financings, the potential exercise of outstanding common warrants with an exercise price of $3.50 per share and potential future collaboration, license and development agreements. Adequate funding may not be available to us on acceptable terms, or at all. If we are unable to raise additional capital in sufficient amounts or on terms acceptable to us, we will be required to significantly reduce our operating expenses and may have to significantly delay, scale back or discontinue the development of one or more of our current or future product candidates. If we raise additional funds by issuing equity or convertible debt securities, it could result in dilution to our existing stockholders and increased fixed payment obligations. 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. If we incur indebtedness, we could become subject to covenants that would restrict our operations and potentially impair our competitiveness, such as limitations on our ability to incur additional debt, limitations on our ability to acquire, sell or license intellectual property rights and other operating restrictions that could adversely impact our ability to conduct our business. Additionally, any future collaborations we enter into with third parties may provide capital in the near term, but we may have to relinquish valuable rights to our product candidates or grant licenses on terms that are not favorable to us. Any of the foregoing could significantly harm our business, financial condition and prospects.

We expect to incur substantial additional losses in the future as we conduct our planned research and development activities. We believe that our existing cash, cash equivalents and marketable securities will only be sufficient to fund our planned operating and capital needs into the first quarter of 2026 and will not be sufficient to enable us to fund our projected operations through at least the next 12 months from the date of this Annual Report on Form 10-K. These conditions raise substantial doubt about our ability to continue as a going concern for a period of at least 12 months from the date of the issuance of the consolidated financial statements included elsewhere in this Annual Report on Form 10-K. Our forecast of the period of time through which our financial resources will be adequate to support our operations is a forward-looking statement that involves risks and uncertainties, and actual results could vary materially based on a number of factors.

We have based our projections of operating capital requirements on assumptions that may prove to be incorrect and we may use all our available capital resources sooner than we expect. Because of the numerous risks and uncertainties associated with research, development and commercialization of product candidates, we are unable to estimate the exact amount of our operating capital requirements. Our future capital requirements depend on many factors, including:

- the progress, timing, costs and results of clinical trials for soquelitinib, including the potential registrational clinical trial for soquelitinib, and to a lesser extent, the timing, costs and results of the clinical trials for ciforadenant and mupadolimab;
- the timing, progress, costs and results of preclinical and clinical development activities for our other product candidates;
- the number and scope of preclinical and clinical programs we decide to pursue;
- the costs involved in prosecuting, maintaining and enforcing patent and other intellectual property rights;
- the cost and timing of regulatory approvals;

- our efforts to enhance operational systems and hire additional personnel, including personnel to support development of our product candidates and satisfy our obligations as a public company; and
- other factors described in the section of this Annual Report on Form 10-K entitled "Risk Factors."

**Summary of Statement of Cash Flows**

The following table summarizes our cash flows for the periods indicated (in thousands):

| | Year ended December 31, | | | Change | Change |
|---|---|---|---|---|---|
| | 2024 | 2023 | 2022 | 2023 to 2024 | 2022 to 2023 |
| Net cash provided by (used in): | | | | | |
| Operating activities | $ (25,424) | $ (23,935) | $ (27,023) | $ (1,489) | $ 3,088 |
| Investing activities | (27,484) | 15,541 | (23,276) | (43,025) | 38,817 |
| Financing activities | 49,028 | 7,855 | — | 41,173 | 7,855 |
| Net increase in cash and cash equivalents | $ (3,880) | $ (539) | $ (50,299) | $ (3,341) | $ 49,760 |

*Cash Flows from Operating Activities*

Cash used in operating activities during the year ended December 31, 2024 was $25.4 million, which primarily consisted of a net loss of $62.3 million, adjusted by net non-cash transactions of $38.5 million, that primarily consisted of $3.0 million of stock compensation expense, $3.2 million of loss from equity method investment and an increase of $33.4 million in the fair value of warrant liability, an increase of $1.6 million in prepaid and other current assets, an increase of $1.1 million in accounts payable, a decrease of $0.3 million in accrued and other current liabilities and a decrease of $0.3 million in operating lease liability net of operating lease right-of-use assets amortization.

Cash used in operating activities during the year ended December 31, 2023 was $23.9 million, which primarily consisted of a net loss of $27.0 million, adjusted by non-cash charges of $6.7 million, primarily consisting of $2.1 million of stock compensation expense and $5.3 million in loss from equity method investment, a decrease of $0.5 million in accounts payable, a decrease of $3.6 million in accrued and other liabilities and a decrease of $0.6 million in accounts receivable – related party.

Cash used in operating activities during the year ended December 31, 2022 was $27.0 million, which primarily consisted of a net loss of $41.3 million, adjusted by non-cash charges of $12.9 million, primarily consisting of $2.7 million of stock compensation expense and $10.0 million in loss from equity method investment, a decrease of $0.6 million in prepaid and other current assets, an increase of $0.4 million in accounts payable, an increase of $0.5 million in accrued and other liabilities and an increase of $0.1 million in accounts receivable – related party.

*Cash Flows from Investing Activities*

Cash used in investing activities during the year ended December 31, 2024 was $27.5 million, which consisted of purchases of marketable securities of $70.1 million, which were partially offset by maturities of marketable securities of $42.6 million.

Cash provided by investing activities during the year ended December 31, 2023 was $15.5 million, which consisted of proceeds from maturities of marketable securities of $62.6 million, which were partially offset by purchases of marketable securities of $47.0 million.

Cash used in investing activities during the year ended December 31, 2022 was $23.3 million, which consisted of purchases of marketable securities of $66.2 million and purchases of property and equipment of $0.3 million, which were partially offset by proceeds from maturities of marketable securities of $43.2 million.

*Cash Flows from Financing Activities*

Cash provided by financing activities during the year ended December 31, 2024 was $49.0 million, which primarily consisted of net proceeds of $16.4 million from the issuance of common stock, net proceeds of $5.0 million from the issuance of pre-funded warrants, proceeds of $8.9 million from the issuance of common warrants, proceeds of $18.6 million from the exercise of common warrants and proceeds of $0.1 million from the exercise of common stock options.

Cash provided by financing activities during the year ended December 31, 2023 was $7.9 million, which primarily consisted of $7.8 million in net proceeds from the issuance of common stock through our at-the-market offering program.

During the year ended December 31, 2022, there was no cash provided by or used in financing activities.

**Off-Balance Sheet Arrangements**

We have not entered into any off-balance sheet arrangements and do not have any holdings in variable interest entities.

**Contractual Obligations**

Our principal commitment consists of obligations under our non-cancelable operating lease for our facilities in South San Francisco, CA that expires in 2028.

**Critical Accounting Estimates**

Our management's discussion and analysis of our financial condition and results of operations is based on our consolidated financial statements, which have been prepared in accordance with United States generally accepted accounting principles ("U.S. GAAP"). The preparation of these consolidated financial statements requires our management to make judgments and estimates that affect the reported amounts of assets and liabilities and the disclosure of contingent assets and liabilities at the date of the consolidated financial statements, as well as the reported revenue generated and expenses incurred during the reporting periods. On an ongoing basis, our management evaluates its estimates including, but not limited to: those related to the accrual for certain liabilities, including accrued clinical trial liabilities; long-lived assets; going concern assessment; and the amounts of deferred tax assets and liabilities, including the related allowance. We base our estimates 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 judgments and estimates under different assumptions or conditions and any such differences may be material. We believe our critical accounting policy relating to clinical trial accruals reflects the more significant estimates and assumptions used in the preparation of our consolidated financial statements. Our significant accounting policies are more fully described in Note 2 of Notes to Consolidated Financial Statements in Part II, Item 8 of this Annual Report on Form 10-K.

***Clinical Trial Accruals***

Costs for preclinical studies and clinical trial activities are recognized based on an evaluation of the vendors' progress towards completion of specific tasks. We apply significant judgment in developing estimates for clinical trial accruals based on assumptions related to vendors' progress towards completion. In developing these estimates, we estimate vendors' progress towards completion using data such as clinical site activations, patient enrollment or information provided to us by our vendors regarding their actual costs incurred. Payments for these activities are based on the terms of individual contracts and payment timing may differ significantly from the period in which the services are performed. We determine accrual estimates through reports from and discussions with applicable personnel and outside service providers as to the progress or state of completion, or the services completed. Our estimates of accrued expenses as of each balance sheet date are based on the facts and circumstances known at the time.

***Recent Accounting Pronouncements***

See Note 2 in Item 8 "Financial Statements and Supplementary Data."

**Segment Information**

We have one primary business activity and operate as one reportable segment. See Note 4 in Item 8 "Financial Statements and Supplementary Data."

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

We are exposed to market risk related to changes in interest rates. We had cash, cash equivalents and marketable securities of $52.0 million as of December 31, 2024, which consisted of cash, U.S. Treasury securities and U.S. government agency securities. The interest-earning instruments carry a degree of interest rate risk; however, historical fluctuations of interest income have not been significant. Due to the short-term duration of our investment portfolio and the low risk profile of our investments, an immediate 10% increase in interest rates would not have a material effect on the fair market value of our portfolio.

We do not have any foreign currency or other derivative financial instruments.

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

**CORVUS PHARMACEUTICALS, INC.**

**ANNUAL REPORT ON FORM 10-K**

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## Report of Independent Registered Public Accounting Firm

To the Board of Directors and Stockholders of Corvus Pharmaceuticals, Inc.

### *Opinion on the Financial Statements*

We have audited the accompanying consolidated balance sheets of Corvus Pharmaceuticals, Inc. and its subsidiaries (the "Company") as of December 31, 2024 and 2023, and the related consolidated statements of operations and comprehensive loss, of changes in stockholders' equity and of cash flows for each of the three years in the period ended December 31, 2024, including the related notes (collectively referred to as the "consolidated financial statements"). In our opinion, the consolidated financial statements present fairly, in all material respects, the financial position of the Company as of 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 accounting principles generally accepted in the United States of America.

*Substantial Doubt About the Company's Ability to Continue as a Going Concern*

The accompanying consolidated financial statements have been prepared assuming that the Company will continue as a going concern. As discussed in Note 1 to the consolidated financial statements, the Company has incurred significant net operating losses and negative cash flows from operations since inception that raise substantial doubt about its ability to continue as a going concern. Management's plans in regard to these matters are also described in Note 1. The consolidated financial statements do not include any adjustments that might result from the outcome of this uncertainty.

### *Basis for Opinion*

These consolidated financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on the Company's consolidated financial statements based on our audits. We are a public accounting firm registered with the Public Company Accounting Oversight Board (United States) (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 of these consolidated financial statements in accordance with the standards of the PCAOB. Those standards require that we plan and perform the audits to obtain reasonable assurance about whether the consolidated financial statements are free of material misstatement, whether due to error or fraud. The Company is not required to have, nor were we engaged to perform, an audit of its internal control over financial reporting. As part of our audits we are required to obtain an understanding of internal control over financial reporting but not for the purpose of expressing an opinion on the effectiveness of the Company's internal control over financial reporting. Accordingly, we express no such opinion.

Our audits included performing procedures to assess the risks of material misstatement of the consolidated 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 consolidated 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 consolidated financial statements. We believe that our audits provide a reasonable basis for our opinion.

### *Critical Audit Matters*

The critical audit matter communicated below is a matter arising from the current period audit of the consolidated financial statements that was communicated or required to be communicated to the audit committee and that (i) relates to accounts or disclosures that are material to the consolidated financial statements and (ii) involved our especially challenging, subjective, or complex judgments. The communication of critical audit matters does not alter in any way our opinion on the consolidated 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.

*Clinical Trial Accruals*

As described in Notes 2 and 8 to the consolidated financial statements, the Company recorded $1.67 million in clinical trial accruals as of December 31, 2024. Management applies significant judgment in developing estimates for clinical trial accruals based on assumptions related to the vendors' progress towards completion. Management estimates the vendors' progress towards completion using data such as clinical site activations, patient enrollment or information provided to the Company by its vendors regarding actual costs incurred. Management determines accrual estimates through reports from and discussions with applicable personnel and outside service providers as to the progress or stage of completion, or the services completed.

The principal considerations for our determination that performing procedures relating to clinical trial accruals is a critical audit matter are (i) the significant judgment by management in estimating the clinical trial accruals and (ii) a high degree of auditor judgment, subjectivity, and effort in performing procedures and evaluating management's significant assumption related to the vendors' progress towards completion of clinical trials.

Addressing the matter involved performing procedures and evaluating audit evidence in connection with forming our overall opinion on the consolidated financial statements. These procedures included, among others (i) testing management's process for estimating the clinical trial accruals; (ii) evaluating the appropriateness of the method used by management to develop the estimate; (iii) testing the completeness and accuracy of data used to develop the estimate; and (iv) evaluating the reasonableness of the significant assumption related to the vendors' progress towards completion of clinical trials. Evaluating management's assumption related to the vendors' progress towards completion of clinical trials involved (i) obtaining and examining contract terms on a test basis to evaluate the completeness and consistency of the costs in the contract with the costs used in developing the estimate; (ii) verifying patient visits on a test basis; and (iii) considering whether this assumption was consistent with evidence obtained in other areas of the audit.

/s/ PricewaterhouseCoopers LLP

San Jose, California
March 25, 2025

We have served as the Company's auditor since 2015

**CORVUS PHARMACEUTICALS, INC.**

**CONSOLIDATED BALANCE SHEETS**

**(in thousands, except share data)**

| | December 31, 2024 | December 31, 2023 |
|---|---|---|
| **Assets** | | |
| Current assets: | | |
| Cash and cash equivalents | $ 8,740 | $ 12,620 |
| Marketable securities | 43,224 | 14,529 |
| Accounts receivable - related party | 75 | 26 |
| Prepaid and other current assets | 2,368 | 781 |
| Total current assets | 54,407 | 27,956 |
| Property and equipment, net | 151 | 236 |
| Operating lease right-of-use asset | 1,177 | 1,149 |
| Investment in Angel Pharmaceuticals | 12,540 | 16,123 |
| Other assets | 632 | 89 |
| Total assets | $ 68,907 | $ 45,553 |
| | | |
| **Liabilities and Stockholders' Equity** | | |
| Current liabilities: | | |
| Accounts payable | $ 2,582 | $ 1,525 |
| Operating lease liability | 185 | 1,374 |
| Accrued and other liabilities | 3,725 | 3,970 |
| Warrant liability | 28,910 | — |
| Total current liabilities | 35,402 | 6,869 |
| Operating lease liability | 937 | — |
| Total liabilities | 36,339 | 6,869 |
| Commitments and contingencies *(Note 15)* | | |
| Stockholders' equity: | | |
| Preferred stock: $0.0001 par value; 10,000,000 shares authorized at December 31, 2024 and December 31, 2023; 0 shares issued and outstanding at each of December 31, 2024 and December 31, 2023 | — | — |
| Common stock: $0.0001 par value; 290,000,000 shares authorized at December 31, 2024 and December 31, 2023; 67,899,779 and 49,038,582 shares issued and outstanding at December 31, 2024 and December 31, 2023, respectively | 7 | 5 |
| Additional paid-in capital | 430,859 | 374,363 |
| Accumulated other comprehensive loss | (1,288) | (967) |
| Accumulated deficit | (397,010) | (334,717) |
| Total stockholders' equity | 32,568 | 38,684 |
| Total liabilities and stockholders' equity | $ 68,907 | $ 45,553 |

The accompanying notes are an integral part of these consolidated financial statements.

**CORVUS PHARMACEUTICALS, INC.**

**CONSOLIDATED STATEMENTS OF OPERATIONS AND COMPREHENSIVE LOSS**

**(in thousands, except share and per share data)**

| | Year Ended December 31, | | |
|---|---|---|---|
| | 2024 | 2023 | 2022 |
| Operating expenses: | | | |
| Research and development | $ 19,385 | $ 16,526 | $ 24,468 |
| General and administrative | 8,163 | 6,881 | 8,097 |
| Total operating expenses | 27,548 | 23,407 | 32,565 |
| Loss from operations | (27,548) | (23,407) | (32,565) |
| Interest income and other expense, net | 1,824 | 1,584 | 654 |
| Gain from sale of property and equipment | 5 | — | 22 |
| Change in fair value of warrant liability | (33,377) | — | — |
| Sublease income - related party | — | 78 | 587 |
| Loss before equity method investment | (59,096) | (21,745) | (31,302) |
| Loss from equity method investment | (3,197) | (5,284) | (10,005) |
| Net loss | $ (62,293) | $ (27,029) | $ (41,307) |
| Net loss per share, basic and diluted | $ (1.02) | $ (0.56) | $ (0.89) |
| Shares used to compute net loss per share, basic and diluted | 60,985,165 | 48,025,274 | 46,553,511 |
| Other comprehensive loss: | | | |
| Unrealized gain on marketable securities | 65 | 66 | (48) |
| Cumulative foreign currency translation adjustment | (386) | (470) | (2,384) |
| Comprehensive loss | $ (62,614) | $ (27,433) | $ (43,739) |

The accompanying notes are an integral part of these consolidated financial statements.

**CORVUS PHARMACEUTICALS, INC.**

**CONSOLIDATED STATEMENTS OF CHANGES IN STOCKHOLDERS' EQUITY**

**(in thousands, except share data)**

| | Common Stock | | Additional Paid-in Capital | Accumulated Other Comprehensive Income (Loss) | Accumulated Deficit | Total Stockholders' Equity |
|---|---|---|---|---|---|---|
| | Shares | Amount | | | | |
| **Balance at December 31, 2021** | 46,553,511 | $ 5 | $ 361,669 | $ 1,869 | $ (266,381) | $ 97,162 |
| Stock-based compensation expense | — | — | 2,692 | — | — | 2,692 |
| Unrealized loss on marketable securities | — | — | — | (48) | — | (48) |
| Foreign currency translation adjustment | — | — | — | (2,384) | — | (2,384) |
| Net loss | — | — | — | — | (41,307) | (41,307) |
| **Balance at December 31, 2022** | 46,553,511 | $ 5 | $ 364,361 | $ (563) | $ (307,688) | $ 56,115 |
| Issuance of common stock in connection with at-the-market offering, net | 2,461,903 | — | 7,843 | — | — | 7,843 |
| Common stock issued on exercise of stock options | 23,168 | — | 12 | — | — | 12 |
| Stock-based compensation expense | — | — | 2,147 | — | — | 2,147 |
| Unrealized loss on marketable securities | — | — | — | 66 | — | 66 |
| Foreign currency translation adjustment | — | — | — | (470) | — | (470) |
| Net loss | — | — | — | — | (27,029) | (27,029) |
| **Balance at December 31, 2023** | 49,038,582 | $ 5 | $ 374,363 | $ (967) | $ (334,717) | $ 38,684 |
| Common stock issued in connection with registered direct offering, net | 13,512,699 | 1 | 16,404 | — | — | 16,405 |
| Pre-funded warrants issued in connection with registered direct offering, net | — | — | 5,031 | — | — | 5,031 |
| Issuance of common stock upon exercise of common stock warrants | 5,311,198 | 1 | 31,990 | — | — | 31,991 |
| Common stock issued on exercise of stock options | 37,300 | — | 68 | — | — | 68 |
| Stock-based compensation expense | — | — | 3,003 | — | — | 3,003 |
| Unrealized gain on marketable securities | — | — | — | 65 | — | 65 |
| Foreign currency translation adjustment | — | — | — | (386) | — | (386) |
| Net loss | — | — | — | — | (62,293) | (62,293) |
| **Balance at December 31, 2024** | 67,899,779 | $ 7 | $ 430,859 | $ (1,288) | $ (397,010) | $ 32,568 |

The accompanying notes are an integral part of these consolidated financial statements.

**CORVUS PHARMACEUTICALS, INC.**

**CONSOLIDATED STATEMENTS OF CASH FLOWS**

**(in thousands)**

| | Year Ended December 31, | | |
|---|---|---|---|
| | 2024 | 2023 | 2022 |
| **Cash flows from operating activities** | | | |
| Net loss | $ (62,293) | $ (27,029) | $ (41,307) |
| Adjustments to reconcile net loss to net cash used in operating activities: | | | |
| Depreciation and amortization | 85 | 151 | 367 |
| Accretion related to marketable securities | (1,141) | (894) | (170) |
| Stock-based compensation | 3,003 | 2,147 | 2,692 |
| Gain from sale of property and equipment | (5) | — | (22) |
| Change in fair value of warrant liability | 33,377 | — | — |
| Loss from equity method investment | 3,197 | 5,284 | 10,005 |
| Changes in operating assets and liabilities: | | | |
| Accounts receivable - related party | (49) | 562 | (81) |
| Prepaid and other current assets | (1,587) | (8) | 581 |
| Operating lease right-of-use asset | (28) | 1,068 | 973 |
| Other assets | (543) | 40 | 107 |
| Accounts payable | 1,057 | (451) | 411 |
| Accrued and other liabilities | (245) | (3,578) | 467 |
| Operating lease liability | (252) | (1,227) | (1,046) |
| Net cash used in operating activities | (25,424) | (23,935) | (27,023) |
| **Cash flows from investing activities** | | | |
| Purchases of marketable securities | (70,119) | (47,048) | (66,191) |
| Maturities of marketable securities | 42,630 | 62,623 | 43,162 |
| Purchases of property and equipment | — | (34) | (269) |
| Proceeds from sale of property and equipment | 5 | – | 22 |
| Net cash (used in) provided by investing activities | (27,484) | 15,541 | (23,276) |
| **Cash flows from financing activities** | | | |
| Proceeds from issuance of common stock, net (includes $1,794 in aggregate gross proceeds from related parties) | 16,405 | — | — |
| Proceeds from issuance of pre-funded warrants, net (includes $1,769 in aggregate gross proceeds from related parties) | 5,031 | — | — |
| Proceeds from issuance of common warrants (includes $1,472 in aggregate gross proceeds from related parties) | 8,934 | — | — |
| Proceeds from the exercise of common stock warrants | 18,590 | — | — |
| Proceeds from issuance of common stock in connection with at-the-market offering, net | — | 7,843 | — |
| Proceeds from exercise of common stock options | 68 | 12 | — |
| Net cash provided by financing activities | 49,028 | 7,855 | 0 |
| Net decrease in cash and cash equivalents | (3,880) | (539) | (50,299) |
| Cash and cash equivalents at beginning of the period | 12,620 | 13,159 | 63,458 |
| Cash and cash equivalents at end of the period | $ 8,740 | $ 12,620 | $ 13,159 |
| **Supplemental disclosures of cash flow information** | | | |
| Reclassification of common stock warrant liability into additional paid-in capital upon exercise of common stock warrants | $ 13,401 | $ — | $ — |

The accompanying notes are an integral part of these consolidated financial statements.

**CORVUS PHARMACEUTICALS, INC.**

**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS**

**1. Organization**

Corvus Pharmaceuticals, Inc. ("Corvus" or the "Company") was incorporated in Delaware on January 27, 2014 and commenced operations in November 2014. Corvus is a clinical-stage biopharmaceutical company. The Company's operations are located in South San Francisco, California.

***Presentation***

The consolidated financial statements include the accounts of the Company and its wholly-owned subsidiaries, Corvus Biopharmaceuticals, Ltd. and Corvus Hong Kong Limited. All intercompany accounts and transactions have been eliminated from the consolidated financial statements.

***Initial Public Offering***

On March 22, 2016, the Company's registration statement on Form S-1 (File No. 333-208850) relating to its initial public offering ("IPO") of its common stock was declared effective by the Securities and Exchange Commission ("SEC") and the shares of its common stock began trading on the Nasdaq Global Market on March 23, 2016. The public offering price of the shares sold in the IPO was $15.00 per share. The IPO closed on March 29, 2016, pursuant to which the Company sold 4,700,000 shares of its common stock. On April 26, 2016, the Company sold an additional 502,618 shares of its common stock to the underwriters upon partial exercise of their over-allotment option, at the initial offering price of $15.00 per share. The Company received aggregate net proceeds of approximately $70.6 million, after underwriting discounts, commissions and offering expenses. Immediately prior to the consummation of the IPO, all outstanding shares of convertible preferred stock were converted into common stock.

***Follow-on Public Offering***

In March 2018, the Company completed a follow-on public offering in which the Company sold 8,117,647 shares of common stock at a price of $8.50 per share, which included 1,058,823 shares issued pursuant to the underwriters' exercise of their option to purchase additional shares of common stock. The aggregate net proceeds received by the Company from the offering were approximately $64.9 million, net of underwriting discounts and commissions and offering expenses payable by the Company.

In February 2021, the Company completed a follow-on public offering in which the Company sold 9,783,660 shares of common stock at a price of $3.50 per share, which included 1,212,231 shares issued pursuant to the underwriters' exercise of their option to purchase additional shares of common stock. The aggregate net proceeds received by the Company from the offering were approximately $32.0 million, net of underwriting discounts and commissions and offering expenses.

***Registered Direct Offering***

On May 6, 2024, the Company completed a registered direct offering which resulted in gross proceeds of approximately $30.6 million. The financing consisted of the sale of 13,512,699 shares of common stock and accompanying common stock warrants to purchase 13,078,509 shares of common stock (or pre-funded warrants in lieu thereof) at a combined offering price of $1.7312 per share, and the sale of pre-funded warrants to purchase 4,144,085 shares of common stock and accompanying common warrants to purchase 4,010,927 shares of common stock (or pre-funded warrants in lieu thereof) at a combined offering price of $1.7311 per share. The common warrants have an exercise price of $3.50 per share of common stock (or $3.4999 per pre-funded warrant in lieu thereof), are exercisable at any time after the date of issuance, subject to certain ownership limitations, and expire on June 30, 2025. The pre-funded warrants have an exercise price of $0.0001 and are exercisable any time after the date of the issuance, subject to certain

ownership limitations. During the year ended December 31, 2024, 5,311,198 of common stock warrants were exercised, resulting in aggregate proceeds of approximately $18.6 million received by the Company.

***Liquidity***

The Company is subject to risks and uncertainties common to early-stage companies in the biotechnology industry, including, but not limited to, development by competitors of new technological innovations, protection of proprietary technology, dependence on key personnel, contract manufacturer and contract research organizations, compliance with government regulations and the need to obtain additional financing to fund operations. Since commencing operations in 2014, the majority of the Company's efforts have been focused on the research and development of soquelitinib, ciforadenant and mupadolimab. The Company believes that it will continue to expend substantial resources for the foreseeable future as it continues clinical development of, seek regulatory approval for and, if approved, prepare for the commercialization of soquelitinib, ciforadenant and mupadolimab, as well as product candidates under the Company's other development programs. These expenditures will include costs associated with research and development, conducting preclinical studies and clinical trials, obtaining regulatory approvals, manufacturing and supply, sales and marketing and general operations. In addition, other unanticipated costs may arise. Because the outcome of any clinical trial and/or regulatory approval process is highly uncertain, the Company may not be able to accurately estimate the actual amounts necessary to successfully complete the development, regulatory approval process and commercialization of soquelitinib, ciforadenant and mupadolimab or any other product candidates.

The Company has incurred significant losses and negative cash flows from operations in all periods since inception and had an accumulated deficit of $397.0 million as of December 31, 2024. To date, none of the Company's product candidates have been approved for sale and therefore the Company has not generated any revenue from sales of commercial products. Management expects operating losses to continue for the foreseeable future. The Company has funded its operations to date primarily through the sale of redeemable convertible preferred stock and common stock. As of December 31, 2024, the Company had cash, cash equivalents and marketable securities of $52.0 million. The Company's cash, cash equivalents and marketable securities are not sufficient to fund the Company's planned operations for a period of at least 12 months from the date these consolidated financial statements are issued. To fund the Company's planned operations, the Company will need to raise additional capital. The Company intends to raise additional capital through private and public equity offerings, including its "at-the-market" offering program, debt financings, the potential exercise of common warrants outstanding with an exercise price of $3.50 per share and potential future collaboration, license and development agreements. However, there can be no assurance that the Company will be successful in acquiring additional funding at levels sufficient to fund its operations or on terms acceptable to the Company or at all. If the Company is unsuccessful in its efforts to raise additional capital or if sufficient funds on acceptable terms are not available when needed, the Company could be required to significantly reduce operating expenses and delay, reduce the scope of or eliminate one or more of its development programs, out-license intellectual property rights to its product candidates and sell unsecured assets, or a combination of the above, any of which may have a material adverse effect on the Company's business, results of operations, financial condition and/or its ability to fund its obligations on a timely basis or at all. Failure to manage discretionary spending or raise additional capital, as needed, may adversely impact the Company's ability to achieve its intended business objectives. These conditions raise substantial doubt about the Company's ability to continue as a going concern for a period of one year from the date of the issuance of these consolidated financial statements.

The accompanying consolidated financial statements have been prepared assuming that the Company will continue as a going concern, which contemplates the realization of assets and the settlement of liabilities and commitments in the normal course of business. The consolidated financial statements do not reflect any adjustments relating to the recoverability and classification of assets or the amounts and classification of liabilities that might be necessary if the Company is unable to continue as a going concern.

**2. Summary of Significant Accounting Policies**

***Basis of Presentation***

The accompanying consolidated financial statements have been prepared in conformity with accounting principles generally accepted in the United States of America ("U.S. GAAP"). The Company's functional and reporting currency is the U.S. dollar, except for its investment in its equity method investee which is the Chinese renminbi (RMB). The accompanying consolidated financial statements have been prepared on a going-concern basis, which contemplates the realization of assets and discharge of liabilities in the normal course of business.

***Use of Estimates***

The preparation of the Company's consolidated financial statements in conformity with U.S. GAAP requires management to make estimates and assumptions that affect the amounts reported in the consolidated financial statements and accompanying notes. Actual results could differ from such estimates.

***Concentrations of Credit Risk and Other Risks and Uncertainties***

Substantially all of the Company's cash and cash equivalents are deposited in accounts with two financial institutions that management believes are of high credit quality. Such deposits may, at times, exceed federally insured limits. The Company maintains its cash with an accredited financial institution and accordingly, such funds are subject to minimal credit risk. The Company's marketable securities consist of investments in U.S. Treasury securities and U.S. government agency securities, which can be subject to certain credit risks. However, the Company mitigates the risks by investing in high-grade instruments, limiting its exposure to any one issuer, and monitoring the ongoing creditworthiness of the financial institutions and issuers. The Company has not experienced any losses on its deposits of cash, cash equivalents or marketable securities.

The Company is subject to a number of risks similar to other early stage biopharmaceutical companies, including, but not limited to, the need to obtain adequate additional funding, possible failure of preclinical testing or clinical trials, its reliance on third parties to conduct its clinical trials, the need to obtain marketing approval for its product candidates, competitors developing new technological innovations, the need to successfully commercialize and gain market acceptance of the Company's product candidates, its right to develop and commercialize its product candidates pursuant to the terms and conditions of the licenses granted to the Company, and protection of proprietary technology. If the Company does not successfully commercialize or partner any of its product candidates, it will be unable to generate product revenue or achieve profitability.

***Segments***

Operating segments are identified as components of an enterprise about which separate discrete financial information is available for evaluation by the chief operating decision-maker ("CODM") in making decisions regarding resource allocation and assessing performance. The Company views its operations and manages its business in one operating segment, that of the development and commercialization of drugs and antibodies that target critical elements of the immune system. See Note 4 Segments for further details.

***Cash, Cash Equivalents and Marketable Securities***

The Company considers all highly liquid investment securities with remaining maturities at the date of purchase of three months or less to be cash equivalents.

Investments with remaining maturities, at the date of purchase, greater than three months are classified as "available-for-sale" and are carried at fair value with unrealized gains and losses, if any, included as a component of accumulated other comprehensive income (loss) in stockholders' equity. Interest and realized gains and losses are included in interest income. Realized gains and losses are recognized based on the specific identification model.

***Fair Value Measurements***

Fair value accounting is applied for all financial assets and liabilities and non-financial assets and liabilities that are recognized or disclosed at fair value in the consolidated financial statements on a recurring basis (at least annually). The carrying amount of the Company's financial instruments, including cash equivalents, accounts payable and accrued liabilities, approximate fair value due to their short-term maturities.

***Warrants***

The Company accounts for warrants as either equity-classified or liability-classified instruments based on an assessment of the warrant's specific terms and applicable authoritative guidance included in Accounting Standards Codification ("ASC") 480, Distinguishing Liabilities from Equity ("ASC 480") and ASC 815, Derivatives and Hedging ("ASC 815"). The assessment considers whether the warrants are freestanding financial instruments pursuant to ASC 480, whether the warrants meet the definition of a liability pursuant to ASC 480, and whether the warrants meet all of the requirements for equity classification under ASC 815. This assessment, which requires the use of professional judgment, is conducted at the time of warrant issuance and as of each subsequent reporting period end date while the warrants are outstanding.

Warrants that meet all of the criteria for equity classification are required to be recorded as a component of additional paid-in capital at the time of issuance, or when the conditions for equity classification are met, and are not remeasured. Warrants that do not meet the required criteria for equity classification are classified as liabilities. The Company adjusts such warrants to fair value at each reporting period until the warrants are exercised or expire. Any change in fair value is recognized in the Company's statements of operations and comprehensive loss.

***Investments in Equity Securities***

The Company uses the equity method of accounting for its equity investment if the investment provides the ability to exercise significant influence, but not control, over operating and financial policies of the investee.

The Company's proportionate share of the net income (loss) resulting from the equity method investment is reported under the line item captioned "loss from equity method investment" in the Consolidated Statements of Operations and Comprehensive Loss and the carrying value of the equity method investments is reported under the line captioned "Investment in Angel" in the Consolidated Balance Sheets. The Company's equity method investments are reported at cost and adjusted each period for the Company's share of the investee's income or loss and the foreign currency translation adjustment as applicable.

For equity method investees with a functional currency different than the Company's reporting currency, the Company follows the guidance under ASC 830-10-15-5, pursuant to which, the foreign currency financial statements of a foreign investee accounted for by the equity method should be translated to the reporting entity's reporting currency.

The Company evaluates equity method investments for impairment whenever events or changes in circumstances indicate that the carrying amount of the investment might not be recoverable. Factors considered by the Company when reviewing an equity method investment for impairment include the length of time (duration) and the extent (severity) to which the fair value of the equity method investment has been less than cost, the investee's financial condition and near-term prospects and the intent and ability to hold the investment for a period of time sufficient to allow for anticipated recovery. An impairment that is other-than-temporary is recognized in the period identified.

See Note 6 Equity Method Investment, for further information.

***Property and Equipment, Net***

Property and equipment are stated at cost and depreciated using the straight-line method over the estimated useful lives of the respective assets:

| | |
|---|---|
| Laboratory equipment | 5 years |
| Computer equipment and purchased software | 3 years |
| Leasehold improvements | Shorter of asset's useful life or remaining term of lease |

Maintenance and repairs that do not extend the life or improve the asset are expensed when incurred. When assets are retired or otherwise disposed of, the cost and accumulated depreciation or amortization are removed from the balance sheet and any resulting gain or loss is reflected in operations.

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

The Company regularly reviews the carrying value and estimated lives of all of its long-lived assets, including property and equipment, to determine whether indicators of impairment may exist which warrant adjustments to carrying values or estimated useful lives. Recoverability of assets to be held and used is measured by a comparison of the carrying amount of an asset group to future undiscounted net cash flows expected to be generated by the asset or asset group. Should impairment exist, the impairment loss to be recognized is measured by the amount by which the carrying amount of the asset exceeds the projected discounted future net cash flows arising from the asset. All long-lived assets are maintained in the United States of America.

***Research and Development Expenses***

The Company records research and development expenses as incurred. The Company accounts for nonrefundable advance payments for goods and services that will be used in future research and development activities as expenses when the goods have been received or when the service has been performed rather than when the payment is made. Research and development expenses consist of costs incurred by the Company for the discovery and development of the Company's product candidates and include:

- employee-related expenses, including salaries, benefits, travel and non-cash stock-based compensation expense;
- external research and development expenses incurred under arrangements with third parties, such as contract research organizations, contract manufacturing organizations, academic and non-profit institutions and consultants;
- costs to acquire technologies to be used in research and development that have not reached technological feasibility and have no alternative future use;
- license fees; and
- other expenses, which include direct and allocated expenses for laboratory, facilities and other costs.

***Clinical Trial Accruals***

Costs for preclinical studies and clinical trial activities are recognized based on an evaluation of the vendors' progress towards completion of specific tasks. The Company applies significant judgment in developing estimates for clinical trial accruals based on assumptions related to vendors' progress towards completion. In developing these estimates, management estimates vendors' progress towards completion using data such as clinical site activations, patient enrollment or information provided to the Company by its vendors regarding their actual costs incurred. Payments for these activities are based on the terms of individual contracts and payment timing may differ significantly

from the period in which the services are performed. The Company determines accrual estimates through reports from and discussions with applicable personnel and outside service providers as to the progress or state of completion, or the services completed. The Company's estimates of accrued expenses as of each balance sheet date are based on the facts and circumstances known at the time.

***Stock-Based Compensation***

The Company maintains incentive plans under which incentive stock options and nonqualified stock options may be granted to employees and non-employee service providers.

The Company accounts for stock-based employee compensation arrangements in accordance with the provisions of ASC 718, "Compensation—Stock Compensation." For stock options granted to employees, the Company recognizes compensation expense for all stock-based awards based on the grant-date estimated fair values. The value of the award is recognized as an expense ratably over the requisite service period. The fair value of stock options is determined using the Black-Scholes option pricing model. Forfeitures are accounted for when they occur.

Stock-based compensation expense related to stock options granted to non-employees is recognized based on the fair value of the stock options, determined using the Black-Scholes option pricing model. The awards generally vest over the time period the Company expects to receive service from the non-employee.

***Income Taxes***

The Company accounts for income taxes under the asset and liability method. The Company estimates actual current tax exposure together with assessing temporary differences resulting from differences in accounting for reporting purposes and tax purposes for certain items, such as accruals and allowances not currently deductible for tax purposes. These temporary differences result in deferred tax assets and liabilities, which are included in the Company's balance sheets. In general, deferred tax assets represent future tax benefits to be received when certain expenses previously recognized in the Company's statements of operations and comprehensive loss become deductible expenses, under applicable income tax laws or when net operating loss or credit carryforwards are utilized. Accordingly, realization of the Company's deferred tax assets is dependent on future taxable income against which these deductions, losses and credits can be utilized.

The Company must assess the likelihood that the Company's deferred tax assets will be recovered from future taxable income and a valuation allowance is recorded when it is more likely than not that the deferred tax asset will not be recovered. The Company applies judgment in the determination of the financial statement recognition and measurement of a tax position taken or expected to be taken in a tax return. Based on the available evidence, the Company is unable, at this time, to support the determination that it is more likely than not that its deferred tax assets will be utilized in the future. Accordingly, the Company recorded a full valuation allowance for all periods presented. The Company intends to maintain a valuation allowance until sufficient evidence exists to support its reversal.

The Company recognizes benefits of uncertain tax positions if it is more likely than not such positions will be sustained upon examination based solely on their technical merits as the largest amount of benefit that is more likely than not to be realized upon the ultimate settlement. The Company recognizes any material interest and penalties related to unrecognized tax benefits in income tax expense. The Company is required to file income tax returns in the U.S. federal jurisdiction. The Company currently is not under examination by the Internal Revenue Service or other jurisdictions for any tax years.

***Comprehensive Loss***

Comprehensive loss includes net loss as well as other changes in stockholders' equity that result from transactions and economic events other than those with stockholders. The Company's elements of other comprehensive loss in any period presented were unrealized gains and losses on available-for-sale marketable securities and cumulative foreign currency translation adjustments.

***Net Loss per Share***

Basic net loss per share is calculated by dividing the net loss by the weighted average number of common shares outstanding and Exchange Warrants outstanding during the period, without consideration of potentially dilutive securities. In accordance with Accounting Standards Codification Topic 260, *Earnings Per Share*, the Prefunded Warrants are included in the computation of basic net loss per share because the exercise price is negligible and they are fully vested and exercisable at any time after the original issuance date. Diluted net loss per share is computed by dividing the net loss by the weighted average number of common shares, Prefunded Warrants, and potentially dilutive securities outstanding for the period. Diluted net loss per share is the same as basic net loss per share for all periods presented since the effect of potentially dilutive securities is anti-dilutive given the net loss of the Company.

***Recent Accounting Pronouncements***

In October 2023, the FASB issued ASU 2023-06, Disclosure Improvements: Codification Amendments in Response to the SEC's Disclosure Update and Simplification Initiative, which modifies the disclosure or presentation requirements related to variety of FASB Accounting Standard Codification topics. The effective date for each amendment will be the date on which the SEC's removal of that related disclosure from Regulation S-X or Regulation S-K is effective. If by June 30, 2027, the SEC has not removed the applicable requirement from Regulation S-X or Regulation S-K, the pending content of the associated amendment will be removed from the Codification and will not become effective for any entities. The Company is currently evaluating the effect of adopting this ASU.

In November 2023, the FASB issued ASU 2023-07, Segment Reporting (Topic 280), Improvements to Reportable Segment Disclosures. This ASU requires disclosures to include significant segment expenses that are regularly provided to the CODM, a description of other segment items by reportable segment, and any additional measures of a segment's profit or loss used by the CODM when deciding how to allocate resources. The amendments in this update are effective for fiscal years beginning after December 15, 2023 and interim periods within fiscal years beginning after December 15, 2024. The Company adopted this update effective December 31, 2024, on a retrospective basis. Refer to Note 4 Segments for further details.

In December 2023, the FASB issued ASU 2023-09, Improvements to Income Tax Disclosures, which amends the guidance in ASC 740, Income Taxes. The ASU is intended to improve the transparency of income tax disclosures by requiring (1) consistent categories and greater disaggregation of information in the rate reconciliation and (2) income taxes paid disaggregated by jurisdiction. It also includes certain other amendments to improve the effectiveness of income tax disclosures. The ASU's amendments are effective for public business entities for annual periods beginning after December 15, 2024. Entities are permitted to early adopt the standard "for annual financial statements that have not yet been issued or made available for issuance." As adoption is either prospectively or retrospectively, the Company will adopt this ASU on a prospective basis. The Company is currently evaluating the impact of this ASU but does not expect any material impacts upon adoption.

In November 2024, the FASB issued ASU 2024-03, Disaggregation of Income Statement Expense. This update requires entities to disaggregate operating expenses into specific categories, such as salaries and wages, depreciation, and amortization, to provide enhanced transparency into the nature and function of expenses. ASU 2024-03 is effective for fiscal years beginning after December 15, 2026, with early adoption permitted. ASU 2024-03 may be applied retrospectively or prospectively. The Company is currently evaluating the impact of ASU 2024-03 on its financial statement presentation and disclosures.

**3. Net Loss per Share**

The following table shows the calculation of net loss per share (in thousands, except share and per share data):

| | Year Ended December 31, | | |
|---|---|---|---|
| | 2024 | 2023 | 2022 |
| Numerator: | | | |
| Net loss - basic and diluted | $ (62,293) | $ (27,029) | $ (41,307) |
| Denominator: | | | |
| Weighted average common shares and prefunded warrants outstanding used to compute basic and diluted net loss per share | 60,985,165 | 48,025,274 | 46,553,511 |
| Net loss per share, basic and diluted | $ (1.02) | $ (0.56) | $ (0.89) |

The amounts in the table below were excluded from the calculation of diluted net loss per share, due to their anti-dilutive effect:

| | Year Ended December 31, | | |
|---|---|---|---|
| | 2024 | 2023 | 2022 |
| Common warrants (1) | 11,778,238 | — | — |
| Outstanding options | 11,935,100 | 9,244,150 | 7,006,250 |
| Total shares of common stock equivalents | 23,713,338 | 9,244,150 | 7,006,250 |

(1) Based on the treasury stock method, such common warrants that are in-the-money should be included in the calculation of diluted earnings per share ("EPS") if the impact is not anti-dilutive. Therefore, as the Company was in a net loss position for the year ended December 31, 2024 and other expense from the revaluation of the common warrants was $33.4 million for the year ended December 31, 2024, respectively, the impact of including the common warrants in calculating diluted EPS would be antidilutive and the Company has excluded the common warrants from the calculation of diluted net loss per share.

**4. Segments**

The Company views its operations and manages its business in one operating segment, that of the development and commercialization of drugs and antibodies that target critical elements of the immune system. The Company's CODM is made up of the Chief Executive Officer and Chief Financial Officer. The CODM assesses performance for the segment and decides how to allocate resources based on consolidated net loss that is reported on the consolidated statement of operations and comprehensive loss. The measure of segment assets is reported on the balance sheet as total consolidated assets. Managing and allocating resources on a consolidated basis enables the CODM to assess the overall level of resources available and how to best deploy these resources across functions and programs that are in line with the Company's long-term company-wide strategic goals.

The following table presents reportable segment net loss, including significant expense categories, attributable to the Company's reportable segment for the years ended December 31, 2024, 2023 and 2022 (in thousands):

| | Year Ended December 31, | | |
|---|---|---|---|
| | 2024 | 2023 | 2022 |
| Compensation and benefits, excluding stock-based compensation | $ 7,438 | $ 6,737 | $ 7,239 |
| Stock-based compensation | 3,003 | 2,148 | 2,691 |
| Drug manufacturing | 2,485 | 2,195 | 11,213 |
| Clinical trial | 4,148 | 2,716 | 3,159 |
| Outside general and administrative | 3,101 | 2,703 | 2,978 |
| Facilities and insurance | 3,219 | 3,160 | 3,342 |
| Other segment items (1) | 4,154 | 3,748 | 1,943 |
| Total segment expense | 27,548 | 23,407 | 32,565 |
| Non-operating income and expense, net | 34,745 | 3,622 | 8,742 |
| Net loss | $ 62,293 | $ 27,029 | $ 41,307 |

(1) Includes consulting, non-clinical research and laboratory supplies.

**5. Fair Value Measurements**

Financial assets and liabilities are measured and recorded at fair value. The Company is required to disclose information on all assets and liabilities reported at fair value that enables an assessment of the inputs used in determining the reported fair values. The fair value hierarchy prioritizes valuation inputs based on the observable nature of those inputs. The fair value hierarchy applies only to the valuation inputs used in determining the reported fair value of the investments and is not a measure of the investment credit quality. The hierarchy defines three levels of valuation inputs:

- Level 1—Quoted prices in active markets for identical assets or liabilities
- Level 2—Inputs other than quoted prices included within Level 1 that are observable for the asset or liability, either directly or indirectly
- Level 3—Unobservable inputs that reflect the Company’s own assumptions about the assumptions market participants would use in pricing the asset or liability

There have been no transfers of assets and liabilities between levels of hierarchy.

The Company’s Level 2 investments are valued using third-party pricing sources. The pricing services utilize industry standard valuation models, including both income and market-based approaches, for which all significant inputs are observable, either directly or indirectly, to estimate fair value. These inputs include reported trades of and broker/dealer quotes on the same or similar investments, issuer credit spreads, benchmark investments, prepayment/default projections based on historical data and other observable inputs.

***Financial Assets***

The following tables present information as of December 31, 2024 and 2023 about the Company's assets that are measured at fair value on a recurring basis and indicate the level of the fair value hierarchy the Company utilized to determine such fair values (in thousands):

| | December 31, 2024 | | | |
|---|---|---|---|---|
| | Fair Value Measured Using | | | Total |
| | (Level 1) | (Level 2) | (Level 3) | Balance |
| **Assets** | | | | |
| Cash equivalents | $ 8,333 | $ — | $ — | $ 8,333 |
| Marketable securities | 37,764 | 5,460 | — | 43,224 |
| | $ 46,097 | $ 5,460 | $ — | $ 51,557 |

| | December 31, 2023 | | | |
|---|---|---|---|---|
| | Fair Value Measured Using | | | Total |
| | (Level 1) | (Level 2) | (Level 3) | Balance |
| **Assets** | | | | |
| Cash equivalents | $ 12,280 | $ — | $ — | $ 12,280 |
| Marketable securities | 10,356 | 4,173 | — | 14,529 |
| | $ 22,636 | $ 4,173 | $ — | $ 26,809 |

As of December 31, 2024, marketable securities had a maximum remaining maturity of less than two years.

As of December 31, 2024 and 2023, the fair value of available for sale marketable securities by type of security were as follows (in thousands):

| | December 31, 2024 | | | |
|---|---|---|---|---|
| | Amortized Cost | Gross Unrealized Gains | Gross Unrealized Losses | Fair Value |
| U.S. Treasury securities | $ 37,688 | $ 76 | $ — | $ 37,764 |
| U.S. Government agency securities | 5,456 | 4 | — | 5,460 |
| | $ 43,144 | $ 80 | $ — | $ 43,224 |

| | December 31, 2023 | | | |
|---|---|---|---|---|
| | Amortized Cost | Gross Unrealized Gains | Gross Unrealized Losses | Fair Value |
| U.S. Treasury securities | $ 10,348 | $ 8 | $ — | $ 10,356 |
| U.S. Government agency securities | 4,166 | 7 | — | 4,173 |
| | $ 14,514 | $ 15 | $ — | $ 14,529 |

***Financial Liabilities***

The following tables present information as of December 31, 2024 about the Company's liabilities that are measured at fair value on a recurring basis and indicate the level of the fair value hierarchy the Company utilized to determine such fair values (in thousands):

| | December 31, 2024 | | | |
|---|---|---|---|---|
| | Fair Value Measured Using | | | Total |
| | (Level 1) | (Level 2) | (Level 3) | Balance |
| Warrant liability | $ — | $ — | $ 28,910 | $ 28,910 |

The Company had no liabilities measured at fair value on a recurring basis as of December 31, 2023.

During the year ended December 31, 2024, the changes in the Company's warrant liability were as follows (in thousands):

| | Warrants |
|---|---|
| Warrant liability balance as of December 31, 2023 | $ — |
| Issuance of warrants | 8,934 |
| Change in fair value | 33,377 |
| Exercise of warrants | (13,401) |
| Warrant liability balance as of December 31, 2024 | $ 28,910 |

The Company uses the Black-Scholes pricing model to determine the fair value of its warrant liabilities using Level 3 inputs. Inputs used to determine estimated fair value of the warrant liabilities include the fair value of the underlying stock at the valuation date, the term of the warrants, and the expected volatility of the underlying stock. The significant unobservable input used in the fair value measurement of the warrant liabilities is the estimated term of the warrants.

The key inputs into valuation models used to estimate the fair value of the warrant liabilities as of May 6, 2024, the issuance date, and as of December 31, 2024 were as follows:

| | December 31, 2024 | May 6, 2024 (Date of Issuance) |
|---|---|---|
| Risk-free interest rate | 4.2 % | 5.1 % |
| Expected volatility | 106.6 % | 104.4 % |
| Expected term (in years) | 0.50 | 1.15 |
| Share price | $ 5.35 | $ 1.91 |

**6. Equity Method Investment**

In August 2020, the Company established Angel Pharmaceuticals Co. Ltd. ("Angel"), a wholly-owned corporate venture in the People's Republic of China ("China") designed to develop, manufacture, and commercialize soquelitinib, ciforadenant and mupadolimab compounds for distribution within the countries of China, Taiwan, Macao, and Hong Kong (collectively, the "Territories") based on intellectual property licenses to be contributed to Angel by the Company.

In October 2020, Angel raised financing from third-party investors, the licenses were entered into and the Company's ownership interest was reduced to 53.2%. Under the license agreements, the Company is required to provide manufacturing supply services for future supply of drug products for use in clinical trials, research and development, operational support, and participate in the joint steering committee which oversees the development and commercialization of the compounds. Angel is not required to make any payments to the Company regarding the licensed compounds or the additional services outlined in the agreement. Pursuant to the terms of the agreement, during ta 7-year exclusive grant back period, Angel grants to Corvus an exclusive, fully paid-up and sublicensable license for sole and jointly owned IP. After the 7-year exclusive grant back period, the licenses for sole and jointly owned IP that Angel grants to the Company will be non-exclusive, fully paid, and sublicensable.

As a result of the financing, the Company reassessed its interest in Angel and determined that while Angel is a Variable Interest Entity ("VIE"), the Company is not considered the primary beneficiary of such VIE since Corvus does not have the power, through voting or similar rights and the license agreements, to direct the activities of Angel that most significantly impact Angel's economic performance. Further, the Company determined that as it has a significant influence over Angel, and, therefore, it shall account for its investment in Angel using the equity method starting in October 2020, the date it lost control over Angel. At the date of loss of control, the Company derecognized all of

Angel's assets and liabilities from its balance sheet, recognized the retained equity interest at its fair value of $37.5 million, and recognized a gain of $37.5 million, which is included in gain on deconsolidation of Angel Pharmaceuticals on the consolidated statement of operations for the year ended December 31, 2020.

As of December 31, 2024, the Company's ownership interest in Angel was approximately 49.7%, excluding 7% of Angel's equity reserved for issuance under the Angel's Employee Stock Ownership Plan. The Company recognized its share of losses in Angel for the total amount of $3.2 million, $5.3 million and $10.0 million as loss from equity method investment on the consolidated statement of operations for the years ended December 31, 2024, 2023 and 2022, respectively. Since inception through December 31, 2024, Angel has not recorded any revenue.

The Company evaluates its equity method investment in Angel for impairment whenever events or changes in circumstances indicate that the carrying amount of the investment might not be recoverable. For further discussion of the Company's impairment policy, see Note 2.

**Summary Financial Information**

Summary financial information for Angel is as follows:

| Balance Sheet Data | As of December 31, 2024 | As of December 31, 2023 |
|---|---|---|
| | (in thousands) | |
| Current assets | $ 12,957 | $ 17,628 |
| Non-current assets | 1,316 | 1,427 |
| Current liabilities | 1,202 | 1,725 |
| Non-current liabilities | 593 | 648 |
| Stockholders' equity | 12,478 | 16,682 |

| Statement of Operations Data | Year Ended December 31, 2024 | 2023 | 2022 |
|---|---|---|---|
| | | (in thousands) | |
| Revenue | $ — | $ — | $ — |
| Gross Profit | — | — | — |
| Net income (loss) | (3,783) | (6,213) | (11,846) |
| Share of loss from investments accounted for using the equity method | (3,197) | (5,284) | (10,005) |

**7. License and Collaboration Agreements**

***Scripps Licensing Agreement***

In December 2014, the Company entered into a license agreement with The Scripps Research Institute ("Scripps"), pursuant to which it was granted a non-exclusive, world-wide license for all fields of use under Scripps' rights in certain know-how and technology related to a mouse hybridoma clone expressing an anti-human CD73 antibody, and to progeny, mutants or unmodified derivatives of such hybridoma and any antibodies expressed by such hybridoma, from which we developed CPI-006. Scripps also granted the Company the right to grant sublicenses in conjunction with other proprietary rights the Company holds, or to others collaborating with or performing services for the Company. Under this license agreement, Scripps has agreed not to grant any additional commercial licenses with respect to such materials, other than march-in rights granted to the U.S. government.

Upon execution of the agreement, the Company made a one-time cash payment to Scripps of $10,000 in 2015 and is also obligated to pay a minimum annual fee to Scripps of $25,000. The one-time cash payment was recorded as research and development expense as technological feasibility of the asset had not been established and there was no alternative future use. A minimum annual fee payment is due on each anniversary of the effective date of the agreement

for the term of the agreement. The Company is also required to make performance-based cash payments upon successful completion of clinical and sales milestones. The aggregate potential milestone payments are $2.5 million. The Company is also required to pay royalties on net sales of licensed products (including CPI-006) sold by it, its affiliates and its sublicensees at a rate in the low-single digits. In addition, should the Company sublicense the rights licensed under the agreement, it has agreed to pay a percentage of sublicense revenue received at specified rates that start at double digit percentages and decrease to single digit percentages based on the elapsed time from the effective date of the agreement and the time of entry into such sublicense. To date, no milestone payments have been made.

The Company's license agreement with Scripps will terminate upon expiration of its obligation to pay royalties to Scripps under the license agreement. The Company's license agreement with Scripps is terminable by the consent of the parties, at will by the Company upon providing 90 days written notice to Scripps, or by Scripps for certain material breaches, or if the Company undergoes a bankruptcy event. In addition, Scripps may terminate the license on a product-by-product basis, or the entire agreement, if the Company fails to meet specified diligence obligations related to the development and commercialization of licensed products. Scripps may also terminate the agreement after the third anniversary of the effective date of the agreement if it reasonably believes, based on reports the Company provides to Scripps, that the Company has not used commercially reasonable efforts as required under the agreement, subject to a specified notice and cure period.

***Vernalis Licensing Agreement***

In February 2015, the Company entered into a license agreement with Vernalis (R&D) Limited ("Vernalis"), which was subsequently amended as of November 5, 2015, and, pursuant to which the Company was granted an exclusive, worldwide license under certain patent rights and know-how, including a limited right to grant sublicenses, for all fields of use to develop, manufacture and commercialize products containing certain adenosine receptor antagonists, including ciforadenant. Pursuant to this agreement, the Company made a one-time cash payment to Vernalis in the amount of $1.0 million, which was recorded as research and development expense as technological feasibility of the asset had not been established and there was no alternative future use. The Company is also required to make cash milestone payments to Vernalis upon the successful completion of clinical and regulatory milestones for licensed products depending on the indications for which such licensed products are developed and upon achievement of certain sales milestones. In February 2017, the Company made a milestone payment of $3.0 million to Vernalis following the expansion of a cohort of patients with renal cell cancer treated with single agent ciforadenant in the Company's Phase 1/1b clinical trial. During the year ended December 31, 2024, no clinical or regulatory milestones were completed or paid to Vernalis and the aggregate potential milestone payments were approximately $220 million for all indications as of December 31, 2024. The Company has also agreed to pay Vernalis tiered incremental royalties based on the annual net sales of licensed products containing ciforadenant on a product-by-product and country-by-country basis, subject to certain offsets and reductions. The tiered royalty rates for products containing ciforadenant range from the mid-single digits up to the low-double digits on a country-by-country net sales basis. The royalties on other licensed products that do not include ciforadenant also increase with the amount of net sales on a product-by-product and country-by-country basis and range from the low-single digits up to the mid-single digits on a country-by-country net sales basis. The Company is also obligated to pay to Vernalis certain sales milestones as indicated above when worldwide net sales reach specified levels over an agreed upon time period.

The agreement will expire on a product-by-product and country-by-country basis upon the expiration of the Company's payment obligations to Vernalis in respect of a particular product and country. Both parties have the right to terminate the agreement for an uncured material breach by the other party. The Company may also terminate the agreement at its convenience by providing 90 days written notice, provided that the Company has not received notice of its own default under the agreement at the time the Company exercises such termination right. Vernalis may also terminate the agreement if the Company challenges a licensed patent or undergoes a bankruptcy event.

***Monash License Agreement***

In April 2017, the Company entered into a license agreement with Monash University ("Monash"), pursuant to which the Company was granted an exclusive, sublicensable worldwide license under certain know-how, patent rights and other intellectual property rights controlled by Monash to research, develop, and commercialize certain antibodies directed to CXCR2 for the treatment of human diseases.

Upon execution of the agreement, the Company made a one-time cash payment to Monash of $275,000 and reimbursed Monash for certain patent prosecution costs incurred prior to execution of the agreement. The Company recorded these payments as research and development expenses for the year ended December 31, 2017. The Company is also obligated to pay an annual license maintenance fee to Monash of $25,000 until a certain development milestone is met with respect to the licensed product, after which no further maintenance fee will be due. The Company is also required to make development and sales milestone payments to Monash with respect to the licensed products. During the year ended December 31, 2024, no development or sales milestones were completed or paid to Monash and the aggregate potential milestones were $45.1 million as of December 31, 2024. The Company is also required to pay to Monash tiered royalties on net sales of licensed products sold by it, its affiliates and its sublicensees at a rate ranging in the low-single digits. In addition, should the Company sublicense its rights under the agreement, the Company has agreed to pay a percentage of sublicense revenue received at specified rates that are currently at low double digit percentages and decrease to single digit percentages based on the achievement of development milestones.

The term of the Company's agreement with Monash continues until the expiration of its obligation to pay royalties to Monash thereunder. The license agreement is terminable at will by the Company upon providing 30 days written notice to Monash, or by either party for material breaches by the other party. In addition, Monash may terminate the entire agreement or convert the license to a non-exclusive license if the Company has materially breached its obligation to use commercially reasonable efforts to develop and commercialize a licensed product, subject to a specified notice and cure mechanism.

**8. Balance Sheet Components (in thousands):**

| | December 31, | |
|---|---|---|
| | **2024** | **2023** |
| ***Prepaid and Other Current Assets*** | | |
| Interest receivable | $ 141 | $ 37 |
| Prepaid research and development manufacturing expenses | 1,209 | 149 |
| Prepaid facility expenses | 308 | 196 |
| Prepaid insurance | 162 | 179 |
| Other | 548 | 220 |
| | $ 2,368 | $ 781 |
| ***Property and Equipment*** | | |
| Laboratory equipment | $ 2,522 | $ 2,678 |
| Computer equipment and purchased software | 171 | 171 |
| Leasehold improvements | 2,084 | 2,084 |
| | 4,777 | 4,933 |
| Less: accumulated depreciation and amortization | (4,626) | (4,697) |
| | $ 151 | $ 236 |
| ***Accrued and Other Liabilities*** | | |
| Accrued clinical trial expense | $ 1,672 | $ 2,302 |
| Accrued manufacturing expense | 679 | 675 |
| Personnel related | 820 | 684 |
| Accrued legal and accounting | 265 | 64 |
| Other | 289 | 245 |
| | $ 3,725 | $ 3,970 |

During the years ended December 31, 2024, 2023, and 2022, the Company recorded $0.1 million, $0.2 million and $0.4 million in depreciation expense, respectively.

**9. Warrants**

On May 6, 2024, the Company completed a registered direct offering in which the Company sold an aggregate of 13,512,699 shares of common stock and common warrants to purchase up to 13,078,509 shares of common stock (or pre-funded warrants in lieu thereof) at a combined offering price of $1.7312 per share and common warrant, and pre-funded warrants to purchase up to 4,144,085 shares of common stock and common warrants to purchase up to 4,010,927 shares of common stock (or pre-funded warrants in lieu thereof), at a combined offering price of $1.7311 per share underlying each pre-funded warrant and common warrant, which equals the offering price per share and common warrant less the $0.0001 exercise price per share of the pre-funded warrants.

The pre-funded warrants have an exercise price per share of common stock equal to $0.0001 per share. The exercise price and the number of shares of common stock issuable upon exercise of the pre-funded warrants are subject to appropriate adjustments in the event of certain stock dividends and distributions, stock splits, stock combinations, reclassifications or similar events affecting the common stock. The pre-funded warrants are exercisable at any time after the date of issuance. In accordance with accounting guidance discussed in Note 2, the Company recorded $5.0 million to additional paid-in capital upon issuance of the pre-funded warrants on May 6, 2024. As of December 31, 2024, none of the pre-funded warrants have been exercised.

The common warrants have an exercise price per share of common stock equal to $3.50 per share (or $3.4999 per pre-funded warrant). The exercise price and the number of shares of common stock (or pre-funded warrants in lieu thereof) issuable upon exercise of the common warrants are subject to appropriate adjustments in the event of certain stock dividends and distributions, stock splits, stock combinations, reclassifications or similar events affecting the common stock. The common warrants are exercisable at any time after the date of issuance and will expire on June 30, 2025. In accordance with accounting guidance discussed in Note 2, the Company recorded $8.9 million to warrant liability upon issuance of the common warrants on May 6, 2024 and recorded a change in fair value of warrant liability of $33.4 million to other income in its consolidated statement of operations and comprehensive loss for the year ended December 31, 2024, respectively. The value of the common warrants upon issuance on May 6, 2024 has been included within the consolidated statement of cash flows from financing activities. During the year ended December 31, 2024, 5,311,198 of the common warrants were exercised, resulting in proceeds of $18.6 million. As of December 31, 2024, 11,778,238 of the common warrants are outstanding and the Company's warrant liability was $28.9 million.

**10. Common Stock**

As of December 31, 2024, the amended and restated certificate of incorporation authorizes the Company to issue 290 million shares of common stock and 10 million shares of preferred stock.

Each share of common stock is entitled to one vote. Common stockholders are entitled to dividends if and when declared by the board of directors. As of December 31, 2024, no dividends on common stock had been declared.

On August 6, 2024, the Company entered into an open market sale agreement (the "2024 Sales Agreement") with Jefferies LLC ("Jefferies") to sell shares of the Company's common stock, from time-to-time, with aggregate gross sales proceeds of up to $100.0 million, through an at-the-market equity offering program under which Jefferies will act as its sales agent. The issuance and sale of shares of common stock by the Company pursuant to the 2024 Sales Agreement are deemed an "at-the-market" offering under the Securities Act of 1933, as amended. Jefferies is entitled to compensation for its services up to 3.0% of the gross proceeds of any shares of common stock sold through Jefferies under the 2024 Sales Agreement.

During the year ended December 31, 2024, the Company did not sell any shares of common stock under its at-the-market offering program. As of December 31, 2024, $100.0 million remained available for sale under the 2024 Sales Agreement.

The Company has reserved shares of common stock, for issuance as follows:

| | December 31, | | |
|---|---|---|---|
| | 2024 | 2023 | 2022 |
| Pre-funded warrants | 4,144,085 | — | — |
| Outstanding common warrants | 11,778,238 | — | — |
| Shares available for future option grants | 2,850,693 | 3,617,943 | 4,017,011 |
| Outstanding options | 11,935,100 | 9,244,150 | 7,006,250 |
| Shares reserved for employee stock purchase plan | 400,000 | 400,000 | 400,000 |
| Total | 31,108,116 | 13,262,093 | 11,423,261 |

**11. Stock Option Plans**

In February 2014, the Company adopted the 2014 Equity Incentive Plan (the "2014 Plan"), which was subsequently amended in November 2014, July 2015 and September 2015, under which it granted incentive stock options ("ISOs") or non-qualified stock options ("NSOs"). Terms of stock agreements, including vesting requirements, are determined by the board of directors or a committee authorized by the board of directors, subject to the provisions of the 2014 Plan. In general, awards granted by the Company vest over four years and have maximum exercise term of 10 years. The 2014 Plan provides that grants must be at an exercise price of 100% of fair market value of the Company's common stock as determined by the board of directors on the date of the grant.

In connection with the consummation of the IPO in March 2016, the 2016 Equity Incentive Award Plan (the "2016 Plan") became effective. Under the 2016 Plan, incentive stock options, non-statutory stock options, stock purchase rights and other stock-based awards may be granted. Terms of stock agreements, including vesting requirements, are determined by the board of directors or a committee authorized by the board of directors, subject to the provisions of the 2016 Plan. In general, awards granted by the Company vest over four years and have a maximum exercise term of 10 years. The 2016 Plan provides that grants must be at an exercise price of 100% of fair market value of the Company's common stock as determined by the board of directors on the date of the grant. In conjunction with adopting the 2016 Plan, the 2014 Plan was terminated and no further awards will be granted under the 2014 Plan. Options outstanding under the 2014 Plan as of the effective date of the 2016 Plan that are forfeited or lapse unexercised may be re-issued under the 2016 Plan, up to a maximum of 1,136,229 shares.

Activity under the Company's stock option plans is set forth below:

| | | Options Outstanding | |
|---|---|---|---|
| | Shares Available for Grant | Number of Options | Weighted-Average Exercise Price |
| Balance at December 31, 2023 | 3,617,943 | 9,244,150 | $ 4.17 |
| Additional shares authorized | 1,961,000 | — | — |
| Options granted | (2,807,000) | 2,807,000 | 4.45 |
| Options exercised | — | (37,300) | 1.87 |
| Options forfeited | 78,750 | (78,750) | 1.84 |
| Balance at December 31, 2024 | 2,850,693 | 11,935,100 | $ 4.26 |

The weighted average grant date fair value of options granted for the years ended December 31, 2024, 2023 and 2022, was $3.60, $1.12 and $0.69, respectively.

Options outstanding that had vested or were expected to vest at December 31, 2024 were as follows:

| | Number of shares | Weighted Average Exercise Price | Weighted Average Remaining Contractual Life (years) | Aggregate Intrinsic Value (in thousands) |
|---|---|---|---|---|
| Vested | 7,171,370 | $ 4.98 | 5.55 | $ 15,294 |
| Expected to vest | 4,763,730 | $ 3.19 | 9.13 | $ 10,348 |

In the table above, aggregate intrinsic value represents the difference between the exercise price of the options to purchase common stock and the fair value of the Company's common stock of $5.35 per share as of December 31, 2024.

The aggregate intrinsic value of stock options exercised in the years ended December 31, 2024, 2023 and 2022, was less than $0.1 million, $1.0 million and $0.0 million, respectively.

The total fair value of options that vested in the year ended December 31, 2024, 2023 and 2022, was $2.6 million, $2.1 million, and $2.8 million, respectively.

**12. Stock-Based Compensation**

The Company's results of operations include expenses relating to stock-based awards as follows (in thousands):

| | Year Ended December 31, | | |
|---|---|---|---|
| | 2024 | 2023 | 2022 |
| Research and development | $ 1,016 | $ 755 | $ 1,039 |
| General and administrative | 1,987 | 1,392 | 1,653 |
| Total | $ 3,003 | $ 2,147 | $ 2,692 |

***Valuation Assumptions***

The Company estimated the fair value of employee stock options using the Black-Scholes valuation model. The fair value of employee stock options is being amortized on a straight-line basis over the requisite service period of the awards. The fair value of employee stock options were estimated using the following assumptions for the years ended December 31, 2024, 2023 and 2022:

| | Year Ended December 31, | | |
|---|---|---|---|
| | 2024 | 2023 | 2022 |
| Risk-free interest rate | 4.3 % | 3.9 % | 3.0 % |
| Expected volatility | 102.3 % | 97.1 % | 83.8 % |
| Expected term (in years) | 5.8 | 5.7 | 5.5 |
| Expected dividend yield | 0 % | 0 % | 0 % |

**Risk-free Interest Rate:** The risk-free interest rate is estimated based on the U.S. Treasury securities with maturity dates commensurate with the expected term of the equity award.

**Volatility:** The expected volatility in 2024 and 2023 was determined based on the Company's historical stock price volatility. In 2022, the Company utilized the average historical stock price volatility of a peer group of publicly traded companies to represent its expected future stock price volatility, due to the insufficient trading history of the Company's common stock. For purposes of identifying these peer companies, the Company considered the industry, stage of development, size and financial leverage of potential comparable companies. For each grant, the Company measured historical volatility over a period equivalent to the expected term.

**Expected Term:** The Company uses the simplified method prescribed in the ASC 718, Compensation—Stock Compensation, to calculate the expected term of options granted to employees and directors.

**Expected Dividends:** The Company has not paid and does not anticipate paying any dividends in the near future.

At December 31, 2024 and 2023, the unrecognized compensation expense associated with respect to options granted to employees was $11.8 million and $4.5 million, respectively, and is expected to be recognized on a straight-line basis over 2.71 and 2.27 years, respectively.

**13. Income Taxes**

The components of loss before income tax is as follows (in thousands):

| | December 31, | | |
|---|---|---|---|
| | 2024 | 2023 | 2022 |
| Domestic | $ (62,293) | $ (27,029) | $ (41,307) |
| Foreign | — | — | — |
| | $ (62,293) | $ (27,029) | $ (41,307) |

During the years ended December 31, 2024, 2023 and 2022, the Company recorded no income tax benefits for the net operating losses ("NOLs") incurred due to the uncertainty of realizing a benefit from those items.

A reconciliation of the Company's effective tax rate to the U.S. Federal statutory rate is as follows:

| | December 31, | | |
|---|---|---|---|
| | 2024 | 2023 | 2022 |
| Federal tax benefit at statutory rate | 21 % | 21 % | 21 % |
| State tax, net of Federal benefit | 7 % | 8 % | 8 % |
| Change in valuation allowance | (12)% | (25)% | (22)% |
| Research and development tax credits | 2 % | 3 % | 2 % |
| Share based Compensation | — % | (1)% | (1)% |
| 162(m) covered employees compensation limitation | (1)% | — % | — |
| FIN48 Reserve | — % | (1)% | — % |
| Investment in Angel | (1)% | (5)% | (7) |
| Warrant liability | (15)% | — % | — % |
| Other | (1)% | — | (1) |
| Effective income tax rate | 0 % | 0 % | 0 % |

The effective tax rate is different from the federal statutory tax rate primarily due to a foreign rate differential and a valuation allowance against deferred tax assets as a result of the Company's history of losses.

The principal components of the Company's net deferred tax assets are as follows (in thousands)

| | December 31, | | |
|---|---|---|---|
| | 2024 | 2023 | 2022 |
| **Deferred tax assets** | | | |
| Net operating loss carryforwards | $ 64,080 | $ 59,314 | $ 56,030 |
| Tax credit carryforwards | 11,953 | 10,752 | 9,888 |
| Capitalized tax assets | 118 | 138 | 155 |
| Accruals | 135 | 116 | 124 |
| Stock compensation | 5,898 | 5,883 | 5,487 |
| Operating lease liability | 314 | 384 | 728 |
| IRC 174 capitalization | 8,387 | 6,713 | 4,518 |
| Other | — | — | 21 |
| Total deferred tax assets | $ 90,885 | $ 83,300 | $ 76,951 |
| **Deferred tax liabilities** | | | |
| Operating lease right-of-use asset | $ (330) | $ (322) | $ (620) |
| Other | (22) | — | — |
| Valuation allowance | (90,533) | (82,978) | (76,331) |
| Net deferred tax assets | $ — | $ — | $ — |

The Company recorded a valuation allowance against its deferred tax assets at December 31, 2024, 2023 and 2022 because Company management believed that it was more likely than not that these assets would not be fully realized in the future. The valuation allowance increased by approximately $7.6 million, $6.6 million and $9.2 million for the years ended December 31, 2024, 2023 and 2022, respectively. Changes in the valuation allowance for deferred tax assets relate primarily to the increase in the Company's net operating loss carryforward.

As of December 31, 2024, the Company had federal NOL carryforwards of approximately $243.8 million and state NOL carryforwards of approximately $317.8 million which are available to reduce future taxable income. The NOLs will begin to expire in 2034, if not utilized. Utilization of the net operating loss carryforwards are subject to various limitations due to the ownership change limitations provided by Internal Revenue Code ("IRC") Section 382 and similar state provisions.

As of December 31, 2024, the Company also had $10.2 million of federal research and development tax credit, $0.5 million of federal orphan drug credit, and $5.4 million of state research and development tax credit carryforwards available to reduce future income taxes. The federal research and development tax credits will begin to expire 2036, if not utilized. The state research and development tax credits have no expiration date.

U.S. income and foreign withholding taxes have not been recognized on the excess of the amount for financial reporting over the tax basis of investments in foreign subsidiaries that are essentially permanent in duration. This excess totaled approximately $12.5 million as of December 31, 2024, which will be indefinitely reinvested; deferred income taxes have not been provided on such investments in foreign subsidiaries.

As of December 31, 2024, the Company had unrecognized tax benefits ("UTBs") of approximately $13.1 million. All of the deferred tax assets associated with these UTBs are fully offset by a valuation allowance. The following table summarizes the activity related to UTBs:

| | December 31, | | |
|---|---|---|---|
| | 2024 | 2023 | 2022 |
| Unrecognized tax benefits beginning of the period | $ 12,823 | $ 12,720 | $ 12,504 |
| Decrease related to the prior year | 17 | (119) | — |
| Increased related to the current year | 296 | 222 | 216 |
| Unrecognized tax benefits, end of the period | $ 13,136 | $ 12,823 | $ 12,720 |

The Company follows the provisions of ASC 740, Accounting for Income Taxes, and the accounting guidance

related to accounting for uncertainty in income taxes. 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 or positions is more likely than not to be sustained upon examination by the relevant income tax authorities. None of the Company's unrecognized tax benefits that, if recognized, would affect its effective tax rate. The Company does not anticipate the total amounts of unrecognized tax benefits will significantly increase or decrease in the next 12 months. The Company will recognize both accrued interest and penalties related to unrecognized benefits in income tax expense. Management determined that no accrual for interest or penalties was required as of December 31, 2024, 2023 and 2022.

The Company currently has no federal or state tax examinations in progress nor has it had any federal or state examinations since inception. As a result of the Company's net operating loss carryforwards, all of its tax years are subject to federal, state and foreign tax examinations.

**14. Facility Leases**

As of December 31, 2024, the Company had entered into two operating lease agreements and records rent expense on a straight-line basis over the effective term of each lease, including any free rent periods and incentives. As the interest rate implicit in lease arrangements is typically not readily available, in calculating the present value of the lease payments, the Company has utilized its incremental borrowing rate, which is determined based on the prevailing market rates for collateralized debt with maturity dates commensurate with the term of its leases.

***Burlingame Lease***

In January 2015, the Company signed an initial operating lease (the "Burlingame Lease"), effective February 1, 2015 for 8,138 square feet of office and laboratory space with a one year term located at 863 Mitten Road, Burlingame, California. Between January 2015 and September 2021, the Company entered into a series of lease amendments to increase the amount of leased space to 27,280 square feet and extend the expiration of the Burlingame Lease to January 2025. The lease agreement includes annual rent escalations. Under the Burlingame Lease and subsequent amendments, the landlord provided approximately $1.9 million in free rent and lease incentives. The Burlingame Lease is a net lease, as the non-lease components (i.e. common area maintenance) are paid separately from rent based on actual costs incurred. Therefore, the non-lease components were not included in the right-of-use asset and liability and are reflected as an expense in the period incurred.

As of December 31, 2024, all noncancelable rent payments under the Burlingame Lease had been made and no right-of-use asset under this operating lease remained. As of December 31, 2023, the right-of-use asset under operating lease was $1.1 million. The elements of lease expense under the Burlingame Lease were as follows (in thousands):

| | Statements of operations and comprehensive loss location | Year Ended December 31, 2024 | 2023 | 2022 |
|---|---|---|---|---|
| **Costs of operating lease** | | | | |
| Operating lease costs | Research and development, General and administrative | $ 1,273 | $ 1,224 | $ 1,051 |
| Costs of non-lease components (previously common area maintenance) | Research and development, General and administrative | 471 | 420 | 351 |
| Total operating lease cost | | $ 1,744 | $ 1,644 | $ 1,402 |
| **Other Information** | | | | |
| Operating cash flows used for operating lease | | $ 1,892 | $ 1,839 | $ 1,695 |
| Remaining lease term | | 0.1 years | 1.1 years | 2.1 years |
| Discount rate | | 8.0% | 8.0% | 8.0% |

As of December 31, 2023, minimum rental commitments under the Burlingame Lease were as follows (in thousands):

| Year Ended December 31 (in thousands) | |
|---|---|
| 2024 | $ 1,434 |
| Total lease payments | 1,434 |
| Less: imputed interest | (60) |
| Total | $ 1,374 |

***South San Francisco Lease***

On October 22, 2024, the Company entered into a sub-sublease agreement (the "South San Francisco Lease"), pursuant to which the Company sub-leased approximately 20,916 square feet of office and lab space. The sub-sublease has a term of three years commencing on February 21, 2025 with an option to extend at fair market value for an

additional 27 months.

The Company's obligation for the payment of base rent for the Premises begins on the commencement date and will initially be $33,833 per month, up to monthly base rent of $47,200 during the third year of the sub-sublease. In addition to base rent, the Company is obligated to pay its proportionate share of taxes, insurance and operating expenses. In November 2024, the Company paid the Sublandlord $231,235 in prepaid rent, which shall be applied to the monthly base rent and the Company's proportionate share of additional expenses for the first three months of the term of the sub-sublease.

Although the non-cancellable lease term commences on February 1, 2025, for purposes of determining the right-of-use asset balance, in accordance with ASC Topic 842, the Company used November 25, 2024 as the commencement date, the date on which the sublandlord granted the Company access to the premises. The sub-sublease is a net lease, as the non-lease components (i.e. common area maintenance) are paid separately from rent based on actual costs incurred. Therefore, the non-lease components were not included in the right-of-use asset and liability and are reflected as an expense in the period incurred.

As of December 31, 2024, the right-of-use asset under South San Francisco Lease was $1.1 million. The elements of lease expense under the South San Francisco Lease were as follows (in thousands):

| | Statements of operations and comprehensive loss location | Year Ended December 31, 2024 |
|---|---|---|
| **Costs of operating lease** | | |
| Operating lease costs | Research and development, General and administrative | $ 46 |
| Costs of non-lease components (previously common area maintenance) | Research and development, General and administrative | — |
| Total operating lease cost | | $ 46 |
| **Other Information** | | |
| Operating cash flows used for operating lease | | $ 153 |
| Remaining lease term | | 3 years |
| Discount rate | | 11.7% |

As of December 31, 2024, minimum rental commitments under the South San Francisco Lease were as follows (in thousands):

| Year Ended December 31 (in thousands) | |
|---|---|
| 2025 | $ 305 |
| 2026 | 486 |
| 2027 | $ 566 |
| Total lease payments | 1,357 |
| Less: imputed interest | (235) |
| Total | $ 1,122 |

**15. Commitments and Contingencies**

In August 2015, the Company entered into an agreement for a line of credit of $0.1 million for the purpose of issuing its landlord a letter of credit of $0.1 million as a security deposit under the Burlingame Lease. The Company pledged money market funds and marketable securities as collateral for the line of credit. For further discussion of the Company's facility lease agreement, see Note 14.

Pursuant to the Company's license agreements with each of Vernalis, Scripps and Monash, it has obligations to make future milestone and royalty payments to these parties, respectively. However, because these amounts are

contingent, they have not been included on the Company's balance sheet until probable. For further discussion of the Vernalis, Scripps and Monash licensing agreements, see Note 7.

***Indemnifications***

In the ordinary course of business, the Company enters into agreements that may include indemnification provisions. Pursuant to such agreements, the Company may indemnify, hold harmless and defend an indemnified party for losses suffered or incurred by the indemnified party. Some of the provisions will limit losses to those arising from third-party actions. In some cases, the indemnification will continue after the termination of the agreement. The maximum potential amount of future payments the Company could be required to make under these provisions is not determinable. The Company has never incurred material costs to defend lawsuits or settle claims related to these indemnification provisions. The Company has also entered into indemnification agreements with its directors and officers that may require the Company to indemnify its directors and officers against liabilities that may arise by reason of their status or service as directors or officers to the fullest extent permitted by Delaware law. There have been no claims to date and the Company has a directors and officers insurance policy that may enable it to recover a portion of any amounts paid for future claims.

***Legal Proceedings***

The Company is not a party to any material legal proceedings.

**16. Related Party Transactions**

On May 6, 2024, the Company closed a registered direct offering which resulted in gross proceeds of approximately $30.6 million. The financing consisted of the sale of 13,512,699 shares of common stock and accompanying common stock warrants to purchase 13,078,509 shares of common stock (or pre-funded warrants in lieu thereof) at a combined offering price of $1.7312 per share, and the sale of pre-funded warrants to purchase 4,144,085 shares of common stock and accompanying common warrants to purchase 4,010,927 shares of common stock (or pre-funded warrants in lieu thereof) at a combined offering price of $1.7311 per share. The common warrants have an exercise price of $3.50 per share of common stock (or $3.4999 per pre-funded warrant in lieu thereof), are exercisable at any time after the date of issuance, subject to certain ownership limitations, and expire on June 30, 2025. The pre-funded warrants have an exercise price of $0.0001 and are exercisable any time after the date of the issuance, subject to certain ownership limitations.

As part of the registered direct offering, the following number of shares of common stock, pre-funded warrants and common warrants were sold to related parties:

| | Number of Shares of Common Stock | Number of Pre-Funded Warrants | Number of Common Warrants | Aggregate Purchase Price |
|---|---|---|---|---|
| OrbiMed Advisors LLC (1) | — | 1,444,085 | 1,397,684 | $ 2,499,856 |
| Puissance Capital Management (2) | 866,451 | — | 838,610 | 1,500,000 |
| Richard A. Miller, M.D. (3) | 577,634 | — | 559,073 | 1,000,000 |
| William B. Jones, Ph.D. (4) | 20,001 | — | 19,358 | 34,624 |

(2) Peter Thompson, M.D., a member of our Board of Directors since November 2014, is a Member of OrbiMed Advisors, LLC.

(3) Ted Wang, Ph.D., a Co-Founder, General Manager and Director of Angel Pharmaceuticals, of which the Company holds a 49.7% ownership interest, is the founder of Puissance Capital Management.

(4) Richard A. Miller, M.D. is the Company's President, Chief Executive Officer and Chairman of the Board.

(5) William B. Jones, Ph.D. is the Company's Senior Vice President, Pharmaceutical Development.

The Company holds a 49.7% ownership in Angel and, in connection with intellectual property licensing agreements between the Company and Angel Pharmaceuticals, the Company provides operational support and clinical

drug supplies to Angel. Third-party and internal personnel costs incurred by the Company are billed to Angel in the period incurred and recorded as an offset to expenses. During the years ended December 31, 2024 and 2023, there were no internal personnel costs billed to Angel and during the year ended December 31, 2022, the Company billed Angel for approximately $0.1 million in internal personnel costs. During the years ended December 31, 2024, 2023 and 2022 the Company billed Angel for approximately $0.0 million, $0.1 million and $1.3 million in third-party costs, respectively. Of the third-party costs billed to Angel in the year ending December 31, 2022, approximately $0.5 million were associated with clinical drug supply manufactured and expensed in prior years. The remaining $0.1 million and $0.8 million in third-party costs were primarily associated with clinical drug supply passthrough costs incurred during the years ended December 31, 2023 and 2022, respectively, and did not have an impact on the Company's consolidated statements of operations.

In addition to the provision of clinical supplies to Angel, Angel may provide clinical supplies and research services to the Company on an as needed basis. These transactions are recorded as research and development expense. During the years ended December 31, 2023 and 2022, Angel billed the Company for approximately $0.2 million and $0.2 million, respectively, associated with clinical drug supply and research services provided to the Company. There were no clinical supplies or research services billed by Angel to the Company during the year ended December 31, 2024.

In August 2021, the Company entered into an agreement to sublease 7,585 square feet of its office and laboratory space in Burlingame, California to Angel. Pursuant to the sublease, rent is due monthly and is subject to scheduled annual increases and Angel is responsible for certain operating expenses and taxes throughout the life of the sublease. The sublease expired in January 2023. Sublease income is recognized on a straight-line basis as other income in our consolidated statements of operations. For the years ended December 31, 2023 and 2022, the Company recognized $0.1 million and $0.6 million of sublease income, respectively.

In July 2021, Linda S. Grais, M.D., J.D., a member of the Company's Board of Directors, was appointed as a non-executive member of the Board of Directors of ICON plc ("ICON"), effective upon completion of ICON's acquisition of PRA Health Sciences, Inc. ICON is a clinical research organization and provides services to support the Company's clinical trials. During the years ended December 31, 2024, 2023 and 2022, the Company recorded approximately $351,000, $254,000 and $429,000, respectively, in clinical trial expenses under its agreements with ICON.

**Item 9. Changes in and Disagreements with Accountants on Accounting and Financial Disclosure**

None.

**Item 9A. Controls and Procedures**

**Evaluation of Disclosure Controls and Procedures.**

The term "disclosure controls and procedures," as defined in Rules 13a-15(e) and 15d-15(e) under the Securities Exchange Act of 1934, as amended (the "Exchange Act") refers to controls and procedures that are designed to ensure that information required to be disclosed by a company in the reports that it files or submits under the Exchange Act is recorded, processed, summarized and reported, within the time periods specified in the SEC's rules and forms. Disclosure controls and procedures include, without limitation, controls and procedures designed to ensure that information required to be disclosed by a company in the reports that it files or submits under the Exchange Act is accumulated and communicated to the company's management, including its principal executive and principal financial officers, or persons performing similar functions, as appropriate to allow timely decisions regarding required disclosure. Our management recognizes that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving their objectives and our management necessarily applies its judgment in evaluating the cost-benefit relationship of possible controls and procedures. Due to the inherent limitations of control systems, not all misstatements may be detected. These inherent limitations include the realities that judgments in decision-making can be faulty and that breakdowns can occur because of a simple error or mistake. Our disclosure controls and procedures are designed to provide reasonable assurance of achieving their control objectives.

Our management, with the participation of our Chief Executive Officer and Chief Financial Officer, has evaluated the effectiveness of our disclosure controls and procedures as of December 31, 2024, the end of the period covered by this Annual Report on Form 10-K. Based upon such evaluation, our Chief Executive Officer and Chief Financial Officer have concluded that our disclosure controls and procedures were effective at the reasonable assurance level as of such date.

**Management's Annual Report on Internal Control Over Financial Reporting**

Our management is responsible for establishing and maintaining adequate internal control over financial reporting (as defined in Rule 13a-15(f) and 15d-15(f) of the Exchange Act). Internal control over financial reporting is 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 generally accepted accounting principles and includes those policies and procedures that:

- Pertain to the maintenance of records that accurately and fairly reflect in reasonable detail the transactions and dispositions of the assets of our company;
- Provide reasonable assurance that transactions are recorded as necessary to permit preparation of financial statements in accordance with generally accepted accounting principles, and that our receipts and expenditures are being made only in accordance with authorizations of our management and directors; and
- Provide reasonable assurances regarding prevention or timely detection of unauthorized acquisition, use or disposition of our assets that could have a material effect on our financial statements.

Under the supervision and with the participation of our management, including our Chief Executive Officer and Chief Financial Officer, we conducted an evaluation of the effectiveness of our internal control over financial reporting as of December 31, 2024 based on the criteria established in *Internal Control - Integrated Framework* issued by the Committee of Sponsoring Organizations of the Treadway Commission, or COSO 2013. Based on our evaluation under the criteria set forth in *Internal Control - Integrated Framework* issued by the COSO, our management concluded our internal control over financial reporting was effective as of December 31, 2024.

Internal control over financial reporting has inherent limitations. Internal control over financial reporting is a process that involves human diligence and compliance and is subject to lapses in judgment and breakdowns resulting from human failures. Internal control over financial reporting also can be circumvented by collusion or improper management override. Because of such limitations, there is a risk that material misstatements will not be prevented or detected on a timely basis by internal control over financial reporting. However, these inherent limitations are known features of the financial reporting process. Therefore, it is possible to design into the process safeguards to reduce, though not eliminate, this risk.

**Changes in Internal Control Over Financial Reporting**

There were no changes in our internal control over financial reporting that occurred during the quarter ended December 31, 2024 that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

**Item 9B. Other Information**

During the quarter ended December 31, 2024, no director or officer (as defined in Rule 16a-1(f) under the Exchange Act) of the Company adopted or terminated a "Rule 10b5-1 trading arrangement" or "non-Rule 10b5-1 trading arrangement," as each term is defined in Item 408(a) of Regulation S-K.

**Item 9C. Disclosure Regarding Foreign Jurisdictions that Prevent Inspections**

Not applicable.

## PART III

**Item 10. Directors, Executive Officers and Corporate Governance**

The information required by this Item will be set forth in the Company's proxy statement to be filed with the SEC within 120 days after the Company's fiscal year end and is incorporated herein by reference.

We have adopted a code of business conduct and ethics that applies to all employees, including our principal executive officer, principal financial officer, principal accounting officer or controller, or persons performing similar functions. The code of business conduct and ethics is available on our website at http://corvuspharma.com. Amendments to, and waivers from, the code of business conduct and ethics that apply to any director, executive officer or persons performing similar functions will be disclosed at the website address provided above and, to the extent required by applicable regulations, on a Current Report on Form 8-K filed with the SEC.

We have adopted an insider trading policy governing the purchase, sale and other dispositions of our securities by our directors, officers and employees that we believe is reasonably designed to promote compliance with insider trading laws, rules and regulations, and any applicable listing standards. A copy of our insider trading policy is filed as Exhibit 19 to this Annual Report on Form 10-K.

**Item 11. Executive Compensation**

The information required by this Item will be set forth in the Company's proxy statement to be filed with the SEC within 120 days after the Company's 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 Company's proxy statement to be filed with the SEC within 120 days after the Company's 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 Company's proxy statement to be filed with the SEC within 120 days after the Company's 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 Company's proxy statement to be filed with the SEC within 120 days after the Company's fiscal year end and is incorporated herein by reference.

## PART IV

### Item 15. Exhibits and Financial Statement Schedules

(1) Financial Statements:

The consolidated financial statements required by Item 15(a) are filed as part of this Annual Report on Form 10-K under Item 8 "Consolidated Financial Statements and Supplementary Data."

(2) Financial Statement Schedules:

All schedules are omitted because they are either not required, not applicable, or the required information is shown in the consolidated financial statements or notes thereto.

(3) Exhibits.

**EXHIBIT INDEX**

| Exhibit Number | Exhibit Description | Incorporated by Reference | | | Filed Herewith |
|---|---|---|---|---|---|
| | | Form | Date | Number | |
| 3.1 | Amended and Restated Certificate of Incorporation. | 8-K | 3/29/2016 | 3.1 | |
| 3.2 | Amended and Restated Bylaws. | 8-K | 3/29/2016 | 3.2 | |
| 4.1 | Reference is made to Exhibits 3.1 through 3.2. | | | | |
| 4.2 | Form of Common Stock Certificate. | S-1 | 1/4/2016 | 4.2 | |
| 4.3 | Amended and Restated Investors' Rights Agreement, dated September 16, 2015, by and among Corvus Pharmaceuticals, Inc. and the investors listed therein. | S-1/A | 2/8/2016 | 4.3 | |
| 4.4 | Form of Warrant | 8-K | 11/12/2019 | 4.1 | |
| 4.5 | Form of Pre-Funded Warrant | 8-K | 5/6/2024 | 4.1 | |
| 4.6 | Form of Common Warrant | 8-K | 5/6/2024 | 4.2 | |
| 4.7 | Description of Registrant's Securities Registered Pursuant to Section 12 of the Securities Exchange Act of 1934 | | | | X |
| 10.1(a) | Office Lease, dated as of January 27, 2015, by and between Corvus Pharmaceuticals, Inc. and ARE-819/863 Mitten Road, LLC. | S-1 | 1/4/2016 | 10.2(a) | |
| 10.1(b) | First Amendment to Office Lease, dated as of March 19, 2015, by and between Corvus Pharmaceuticals, Inc. and ARE-819/863 Mitten Road, LLC. | S-1 | 1/4/2016 | 10.2(b) | |
| 10.1(c) | Second Amendment to Office Lease, dated as of August 20, 2015, by and between Corvus Pharmaceuticals, Inc. and ARE-819/863 Mitten Road, LLC | S-1 | 1/4/2016 | 10.2(c) | |
| 10.1(d) | Third Amendment to Office Lease, dated as of June 27, 2016, by and between Corvus Pharmaceuticals, Inc. and ARE-819/863 Mitten Road, LLC. | 10-Q | 8/4/2016 | 10.1(d) | |
| 10.1(e) | Fourth Amendment to Office Lease, dated as of August 15, 2016, by and between Corvus Pharmaceuticals, Inc. and ARE-819/863 Mitten Road, LLC. | 10-Q | 11/3/2016 | 10.1(e) | |
| 10.1(f) | Fifth Amendment to Office Lease, dated as of March 2, 2018, by and between Corvus Pharmaceuticals, Inc. and ARE-819/863 Mitten Road, LLC. | 10-Q | 5/3/2018 | 10.3 | |
| 10.1(g) | Sixth Amendment to Office Lease, dated as of April 5, 2018, by and between Corvus Pharmaceuticals, Inc. and ARE-819/863 Mitten Road, LLC. | 10-Q | 8/2/2018 | 10.2 | |
| 10.1(h) | Seventh Amendment to Office Lease, dated as of October 11, 2018, by and between Corvus Pharmaceuticals, Inc. and ARE-819/863 Mitten Road, LLC. | 10-K | 3/7/2019 | 10.1(h) | |
| 10.1(i) | Eighth Amendment to Office Lease, dated as of September 13, 2021, by and between Corvus Pharmaceuticals, Inc. and ARE 819/863 Mitten Road, LLC. | 10-Q | 11/1/2021 | 10.2 | |
| 10.2 | Sublease agreement, dated August 1, 2021, by and between Corvus Pharmaceuticals, Inc. and Angel Pharmaceuticals US Inc. | 10-Q | 11/1/2021 | 10.1 | |
| 10.3 | Sub-Sublease agreement, dated as of October 22, 2024, by and between Corvus Pharmaceuticals, Inc. and NewLimit, Inc. | 8-K | 10/23/2024 | 10.1 | |
| 10.4(a)# | 2014 Equity Incentive Plan. | S-1 | 1/4/2016 | 10.4(a) | |
| 10.4(b)# | Amendment to the 2014 Equity Incentive Plan, dated November 26, 2014. | S-1 | 1/4/2016 | 10.4(b) | |
| 10.4(c)# | Amendment to the 2014 Equity Incentive Plan, dated July 24, 2015. | S-1 | 1/4/2016 | 10.4(c) | |

| Exhibit Number | Exhibit Description | Incorporated by Reference | | | Filed Herewith |
|---|---|---|---|---|---|
| | | Form | Date | Number | |
| 10.4(d)# | Amendment to the 2014 Equity Incentive Plan, dated September 14, 2015. | S-1 | 1/4/2016 | 10.4(d) | |
| 10.4(e)# | Form of Stock Option Grant Notice and Stock Option Agreement under the 2014 Equity Incentive Award Plan. | S-1 | 1/4/2016 | 10.4(e) | |
| 10.4(f)# | Form of Restricted Stock Purchase Right Grant Notice and Restricted Stock Purchase Agreement under the 2014 Equity Incentive Plan. | S-1 | 1/4/2016 | 10.4(f) | |
| 10.5(a)# | 2016 Equity Incentive Award Plan. | S-8 | 3/29/2016 | 99.2(a) | |
| 10.5(b)# | Form of Stock Option Grant Notice and Stock Option Agreement under the 2016 Equity Incentive Award Plan. | S-1 | 1/4/2016 | 10.5(b) | |
| 10.5(c)# | Form of Restricted Stock Award Agreement and Restricted Stock Award Grant Notice under the 2016 Equity Incentive Award Plan. | S-1 | 1/4/2016 | 10.5(c) | |
| 10.5(d)# | Form of Restricted Stock Unit Award Agreement and Restricted Stock Unit Award Grant Notice under the 2016 Equity Incentive Award Plan. | S-1 | 1/4/2016 | 10.5(d) | |
| 10.6# | Form of Indemnification Agreement for directors and officers. | S-1 | 1/4/2016 | 10.6 | |
| 10.7(a)# | Amended and Restated Employment Agreement, dated as of December 22, 2015, by and between Corvus Pharmaceuticals, Inc. and Richard A. Miller. | S-1 | 1/4/2016 | 10.7 | |
| 10.7(b)# | Amendment to Amended and Restated Employment Agreement, dated as of March 31, 2023, by and between Corvus Pharmaceuticals, Inc. and Richard A. Miller. | 10-Q | 8/8/2023 | 10.2 | |
| 10.8# | Amended and Restated Employment Agreement, dated as of December 22, 2015, by and between Corvus Pharmaceuticals, Inc. and Leiv Lea. | S-1 | 1/4/2016 | 10.8 | |
| 10.9(a)# | Offer Letter, dated as of November 27, 2014, by and between Corvus Pharmaceuticals, Inc. and William B. Jones. | S-1 | 1/4/2016 | 10.9(a) | |
| 10.9(b)# | Change in Control and Severance Agreement, dated December 23, 2015, by and between Corvus Pharmaceuticals, Inc. and William B. Jones. | S-1 | 1/4/2016 | 10.9(b) | |
| 10.10# | Employment Agreement, dated as of February 2, 2024 by and between Corvus Pharmaceuticals, Inc. and Jeffrey S. Arcara. | 10-Q | 5/7/2024 | 10.1 | |
| 10.11# | Corvus Pharmaceuticals, Inc. 2016 Employee Stock Purchase Plan. | S-8 | 3/29/2016 | 99.3 | |
| 10.12# | Non-Employee Director Compensation Program. | S-1 | 1/4/2016 | 10.12 | |
| 10.13(a)† | License Agreement, dated February 25, 2015, by and between Corvus Pharmaceuticals, Inc. and Vernalis (R&D) Limited. | S-1/A | 3/10/2016 | 10.13(a) | |
| 10.13(b)† | Amendment to License Agreement dated November 5, 2015, by and between Corvus Pharmaceuticals, Inc. and Vernalis (R&D) Limited. | S-1 | 1/4/2016 | 10.13(b) | |
| 10.14† | License Agreement, dated December 20, 2014, by and between Corvus Pharmaceuticals, Inc. and The Scripps Research Institute | S-1 | 1/4/2016 | 10.14 | |
| 10.15†† | Exclusive License Agreement dated April 21, 2017, by and between Corvus Pharmaceuticals, Inc. and Monash University. | 10-K | 3/9/2020 | 10.18 | |
| 10.16 | Framework Agreement, dated as of October 5, 2020, by and between Corvus Hong Kong Limited, Jiaxing Puissance Angel Equity Investment Partnership (Limited Partnership) and AP BIOTECH DEVELOPMENT CORP. | 8-K | 10/5/2020 | 2.1 | |
| 10.17 | Open Market Sale Agreement, dated August 6, 2024, by and between Corvus Pharmaceuticals, Inc. and Jefferies LLC. | S-3 | 8/6/2024 | 1.2 | |

| Exhibit Number | Exhibit Description | Incorporated by Reference | | | Filed Herewith |
|---|---|---|---|---|---|
| | | Form | Date | Number | |
| 10.18 | Securities Purchase Agreement, dated May 1, 2024, between the Company and the Investors. | 8-K | 5/6/2024 | 10.1 | |
| 19.1 | Insider Trading Policy | | | | X |
| 21.1 | List of subsidiaries | | | | X |
| 23.1 | Consent of Independent Registered Public Accounting Firm. | | | | X |
| 24.1 | Power of Attorney (included on signature page) | | | | X |
| 31.1 | Certification by Chief Executive Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002. | | | | X |
| 31.2 | Certification by Chief Financial Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002. | | | | X |
| 32.1** | Certification of Chief Executive Officer and Chief Financial Officer pursuant to 18 USC Section 1350 as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002. | | | | X |
| 97.1 | Policy Relating to Recovery of Erroneously Awarded Compensation | 10-K | 3/19/2024 | 97.1 | |
| 101.INS | Inline XBRL Instance Document. | | | | X |
| 101.SCH | Inline XBRL Taxonomy Extension Schema Document. | | | | X |
| 101.CAL | Inline XBRL Taxonomy Extension Calculation Linkbase Document. | | | | X |
| 101.DEF | Inline XBRL Taxonomy Extension Definition Linkbase Document. | | | | X |
| 101.LAB | Inline XBRL Taxonomy Extension Label Linkbase Document. | | | | X |
| 101.PRE | Inline XBRL Taxonomy Extension Presentation Linkbase Document. | | | | X |
| 104 | The cover page of Corvus Pharmaceuticals, Inc.'s Annual Report on Form 10-K for the year ended December 31, 2024, formatted in Inline XBRL (contained in Exhibit 101) | | | | X |

† Confidential treatment has been granted for a portion of this exhibit.

†† Portions of this exhibit have been omitted in accordance with Item 601(b)(10) of Regulation S-K.

# Indicates management contract or compensatory plan.

** The certification attached as Exhibit 32.1 that accompanies this Annual Report on Form 10-K is not deemed filed with the Securities and Exchange Commission and is not to be incorporated by reference into any filing of Corvus Pharmaceuticals, Inc. under the Securities Act of 1933, as amended, or the Securities Exchange Act of 1934, as amended, whether made before or after the date of this Annual Report on Form 10-K, irrespective of any general incorporation language contained in such filing.

**Item 16. Form 10-K Summary**

Registrants may voluntarily include a summary of information required by Form 10-K under this Item 16. We have elected not to include such summary.

**SIGNATURES**

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned thereunto duly authorized.

**CORVUS PHARMACEUTICALS, INC.**

Date: March 25, 2025

By: /s/ RICHARD. A. MILLER
Richard A. Miller, M.D.
*President, Chief Executive Officer and Director*
*(Principal Executive Officer)*

Date: March 25, 2025

By: /s/ LEIV LEA
Leiv Lea
*Chief Financial Officer*
*(Principal Financial and Accounting Officer)*

**POWER OF ATTORNEY**

Each person whose individual signature appears below hereby authorizes and appoints Richard A. Miller, M.D. and Leiv Lea 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/ RICHARD A. MILLER, M.D.<br>Richard A. Miller, M.D. | President, Chief Executive Officer and Director<br>(Principal Executive Officer) | March 25, 2025 |
| /s/ LEIV LEA<br>Leiv Lea | Chief Financial Officer<br>(Principal Financial and Accounting Officer) | March 25, 2025 |
| /s/ IAN T. CLARK<br>Ian T. Clark | Director | March 25, 2025 |
| /s/ TERRY GOULD<br>Elisha P. (Terry) Gould III | Director | March 25, 2025 |
| /s/ LINDA S. GRAIS, M.D., J.D.<br>Linda S. Grais, M.D., J.D. | Director | March 25, 2025 |
| /s/ SCOTT W. MORRISON<br>Scott W. Morrison | Director | March 25, 2025 |
| /s/ PETER THOMPSON, M.D.<br>Peter Thompson, M.D. | Director | March 25, 2025 |