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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

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

For the transition period from _____to_____.

Commission File Number: 001-40366

WEREWOLF THERAPEUTICS, INC.
(Exact name of registrant as specified in its charter)

Delaware	**82-3523180**
(State or other jurisdiction of incorporation or organization)	**(I.R.S. Employer Identification No.)**
200 Talcott Ave, 2nd Floor Watertown, Massachusetts	**02472**
(Address of principal executive offices)	**(Zip Code)**

Registrant's telephone number, including area code: (617) 952-0555

(Former name, former address and former fiscal year, if changed since last report)

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, $0.0001 par value per share	HOWL	The Nasdaq Global Select 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 registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes ☒ No ☐

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

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

Large accelerated filer	☐	Accelerated filer	☐
Non-accelerated filer	☒	Smaller reporting company	☒
		Emerging growth company	☒

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

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

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

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

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

As of June 28, 2024, the last business day of the registrant's most recently completed second fiscal quarter, the aggregate market value of the registrant's Common Stock held by non-affiliates of the registrant was approximately $69,689,962, based upon the closing price of the registrant's Common Stock on June 28, 2024.

As of March 5, 2025, there were 44,827,159 shares of common stock, $0.0001 par value per share, outstanding.

Documents Incorporated by Reference

Portions of the registrant's Definitive Proxy Statement on Schedule 14A relating to its 2025 Annual Meeting of Stockholders to be filed within 120 days of the registrant's fiscal year ended December 31, 2024 are incorporated by reference into Part III of this Annual Report on Form 10-K to the extent stated herein.

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References to Werewolf

Throughout this Annual Report on Form 10-K, or Annual Report, the "Company," "Werewolf," "Werewolf Therapeutics," "we," "us," "our," and similar references, except where the context requires otherwise, refer to Werewolf Therapeutics, Inc. and its consolidated subsidiary, and "board of directors" refers to the board of directors of Werewolf Therapeutics, Inc.

Cautionary Note Regarding Forward-Looking Statements and Industry Data

This Annual Report contains forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Securities Exchange Act of 1934, or the Exchange Act, that involve substantial risks and uncertainties. All statements other than statements of historical facts contained in this Annual Report, including statements regarding our strategy, future operations, future financial position, future revenue, projected costs, prospects, plans, objectives of management and expected market growth, are forward-looking statements.

The words "aim," "anticipate," "believe," "contemplate," "continue," "could," "design," "designed to," "engineered," "estimate," "expect," "goal," "intend," "may," "might," "objective," "ongoing," "plan," "potential," "predict," "promise," "project," "should," "target," "will," "would," or the negative of these words or other similar expressions are intended to identify forward-looking statements, although not all forward-looking statements contain these identifying words. These forward-looking statements include, among other things, statements about:

- the initiation, timing, progress and results of our research and development programs, preclinical studies and ongoing and planned clinical trials, including the anticipated timing of data announcements;
- our estimates regarding expenses, capital requirements, need for additional financing and the period over which we believe our existing cash and cash equivalents will be sufficient to fund our operating expenses and capital expenditure requirements;
- our plans to develop and, if approved, subsequently commercialize product candidates;
- the timing of and our ability to submit applications and obtain and maintain regulatory approvals for product candidates;
- the potential advantages of our PREDATOR platform and our ability to use our platform to identify and develop future product candidates;
- our estimates regarding the potential market opportunities for our product candidates;
- our commercialization, marketing and manufacturing capabilities and strategy;
- our intellectual property position and our expectations regarding our ability to obtain and maintain intellectual property protection;
- our ability to identify additional products, product candidates or technologies with significant commercial potential that are consistent with our commercial objectives;
- the impact of government laws and regulations;
- our competitive position and expectations regarding developments and projections relating to our competitors and any competing therapies that are or become available; and
- developments and expectations regarding developments and projections relating to our competitors and our industry.

There are a number of important risks and uncertainties that could cause our actual results to differ materially from those indicated by forward-looking statements. We may not actually achieve the plans, intentions or expectations disclosed in our forward-looking statements, and you should not place undue reliance on our forward-looking statements. Actual results or events could differ materially from the plans, intentions and expectations disclosed in the forward-looking statements we make. We have included important factors in the cautionary statements included in this Annual Report, particularly in Part I, Item 1A. "Risk Factors", that we believe could cause actual results or events to differ materially from the forward-looking statements that we make. New risk factors and uncertainties may emerge from time to time, and it is not possible for management to predict all risk factors and uncertainties, nor can we assess the impact of all factors on our business or the extent to which any factor, or combination of factors, may cause actual results to differ materially from those contained in any forward-looking statements we make. Our forward-looking statements do not reflect the potential impact of any future acquisitions, mergers, dispositions, collaborations, joint ventures or investments that we may make or enter into.

You should read this Annual Report and the documents that we have filed or incorporated by reference as exhibits to this Annual Report completely and with the understanding that our actual future results may be materially different from what we expect. The forward-looking statements contained in this Annual Report are made as of the date of this Annual Report, and we

do not assume any obligation to update any forward-looking statements, whether as a result of new information, future events or otherwise, except as required by applicable law.

In addition, statements that "we believe" and similar statements reflect our beliefs and opinions on the relevant subject. These statements are based upon information available to us as of the date of this Annual Report, and while we believe such information forms a reasonable basis for such statements, such information may be limited or incomplete. Our statements should not be read to indicate that we have conducted an exhaustive inquiry into, or review of, all potentially available relevant information. These statements are inherently uncertain, and you are cautioned not to unduly rely on these statements.

Trademarks and Trade names

We own or have rights to trademarks, service marks and trade names that we use in connection with the operation of our business, including our corporate name, logos and website names. The service marks and trademarks that we own include the marks PREDATOR® and INDUKINE™. Other trademarks, service marks and trade names appearing in this Annual Report are the property of their respective owners. Solely for convenience, some of the trademarks, service marks and trade names referred to in this Annual Report are listed without the ® and ™ symbols, but we will assert, to the fullest extent under applicable law, our rights to our trademarks, service marks and trade names.

Risk Factor Summary

Our business is subject to numerous risks that, if realized, could materially and adversely affect our business, financial condition, results of operations and future growth prospects. These risks are discussed more fully in Part I, Item 1A. Risk Factors in this Annual Report. These risks include, but are not limited to, the following:

- We have a limited operating history, have incurred significant operating losses since our inception and expect to incur significant losses for the foreseeable future.
- We have no products approved for commercial sale and have not generated any revenue from product sales. We may never generate any revenue from product sales or become profitable or, if we achieve profitability, we may not be able to sustain it.
- We will need to obtain substantial additional funding to finance our operations and complete the development and any commercialization of WTX-124, WTX-330 and any future product candidates.
- We are early in our development efforts and our current product candidates will require successful completion of preclinical and clinical development before we can seek regulatory approval for any product candidates.
- Our business is highly dependent on the success of our initial INDUKINE molecules, which are in the early stages of development and will require significant additional preclinical and clinical development before we can seek regulatory approval for and launch a product commercially.
- Our approach to the discovery and development of product candidates based on our PREDATOR platform is unproven, and we do not know whether we will be able to develop any products of commercial value.
- Manufacturing INDUKINE molecules is subject to risk since they are a novel class of multi-domain biologics that include protease cleavable linkers, and they have never been produced on a commercial scale. We may be unable to manufacture INDUKINE molecules at the scale needed for clinical development and commercial production on a timely basis or at all.
- Preclinical studies and clinical trials are expensive, time-consuming and difficult to design and implement, and involve uncertain outcomes.
- We may encounter substantial delays in the commencement or completion, or termination or suspension, of our clinical trials, which could result in increased costs to us, delay or limit our ability to generate revenue and adversely affect our commercial prospects.
- If we experience delays or difficulties in the enrollment of patients in clinical trials, our clinical development activities could be delayed or otherwise adversely affected.
- We are developing WTX-124, and could potentially develop WTX-330 and future product candidates, in combination with third-party drugs, some of which may still be in development, and we will have limited or no control over the safety, supply, regulatory status or regulatory approval of such drugs.
- We face substantial competition, which may result in others discovering, developing or commercializing products before or more successfully than we do.

- We rely, and expect to continue to rely, on third parties to conduct our preclinical studies and clinical trials. If these third parties do not successfully carry out their contractual duties or meet expected deadlines or comply with regulatory requirements, we may not be able to obtain regulatory approval of or commercialize any product candidates.
- The manufacturing of biologics is complex, and we do not have our own clinical manufacturing capabilities. We will rely on third parties to produce preclinical, clinical and commercial supplies of all current and any future product candidates.
- We rely on our license agreement with Harpoon Therapeutics, Inc. for patent rights with respect to our product candidates and may in the future acquire additional third-party intellectual property rights on which we may similarly rely. We face risks with respect to such reliance, including the risk that we could lose these rights that are important to our business if we fail to comply with our obligations under these licenses.
- Our proprietary position in part depends upon patents that are manufacturing, formulation or method-of-use patents, which may not prevent a competitor or other third party from using the same product candidate for another use.
- In the past, we have identified material weaknesses in our internal control over financial reporting, and if we are unable to implement and maintain effective internal control over financial reporting in the future, investors may lose confidence in the accuracy and completeness of our financial reports, and the market price of our common stock may be materially adversely affected.

PART I

Item 1. Business

Company Overview

We are an innovative biopharmaceutical company pioneering the development of therapeutics engineered to stimulate the body's immune system for the treatment of cancer and other immune-mediated conditions. We are leveraging our proprietary PREDATOR platform to design conditionally activated molecules that stimulate both adaptive and innate immunity with the goal of addressing the limitations of conventional proinflammatory immune therapies. Our molecules, which we refer to as INDUKINE molecules, are intended to activate selectively in the tumor microenvironment, or TME. Our most advanced product candidates, WTX-124 and WTX-330, are systemically delivered, conditionally activated Interleukin-2 (IL-2) and Interleukin-12 (IL-12), respectively, INDUKINE molecules for the treatment of multiple tumor types.

We are currently evaluating WTX-124 in a Phase 1/1b clinical trial as a monotherapy and in combination with Merck & Co., Inc.'s anti-PD-1 therapy KEYTRUDA (pembrolizumab) in patients with immunotherapy sensitive advanced or metastatic solid tumors who have failed standard of care treatment, including checkpoint inhibitor therapy. In November 2023, we announced preliminary first-in-human clinical data from the initial monotherapy dose-escalation cohorts in the Phase 1/1b clinical trial establishing proof of mechanism for WTX-124 and proof of concept for our INDUKINE design, and included assessments of safety and tolerability, pharmacokinetics, relevant biomarkers and preliminary antitumor activity. In June 2024, we reported updated interim data from the monotherapy dose-escalation arms of the Phase 1/1b clinical trial, selected a recommended dose for expansion and initiated monotherapy dose expansion arms, and reported initial data from the combination dose escalation cohorts of the Phase 1/1b clinical trial. We completed the dose-escalation phase of our Phase 1/1b clinical trial and continue to enroll patients in the monotherapy and combination expansion arms of the Phase 1/1b clinical trial. We have targeted full enrollment in the monotherapy dose expansion arm in the first half of 2025 and in the combination arm in the second half of 2025. We plan to meet with regulatory authorities to discuss potential registrational pathways in the second half of 2025 and to release a monotherapy and combination therapy clinical data update in the fourth quarter of 2025.

We have evaluated WTX-330 in a Phase 1 clinical trial for the treatment of immunotherapy resistant advanced or metastatic solid tumors or lymphoma. We reported initial data from the Phase 1 clinical trial in June 2024 and presented updated interim safety and efficacy data from the Phase 1 clinical trial at the Society for Immunotherapy of Cancer Annual Meeting held in November 2024, highlighting the tolerability profile and monotherapy efficacy signals of WTX-330. Guided by these data, we expect to initiate a Phase 1/2 dose and regimen-finding clinical trial of WTX-330 in the first quarter of 2025 in patients with selected advanced or metastatic solid tumors.

We have licensed the worldwide right to develop and commercialize JZP898, formerly WTX-613, a differentiated, conditionally activated interferon alpha, or IFNα, INDUKINE molecule, to Jazz Pharmaceuticals Ireland Limited, or Jazz.

We continue to further the development of our preclinical product candidates, WTX-712, WTX-518, and WTX-921. WTX-712 is a systemically delivered, conditionally activated Interleukin-21 (IL-21) INDUKINE molecule that is being developed to minimize the severe toxicities that have been observed with recombinant IL-21 therapy and maximize clinical benefit when administered as monotherapy or in combination with checkpoint inhibitors in refractory and/or immunologically unresponsive

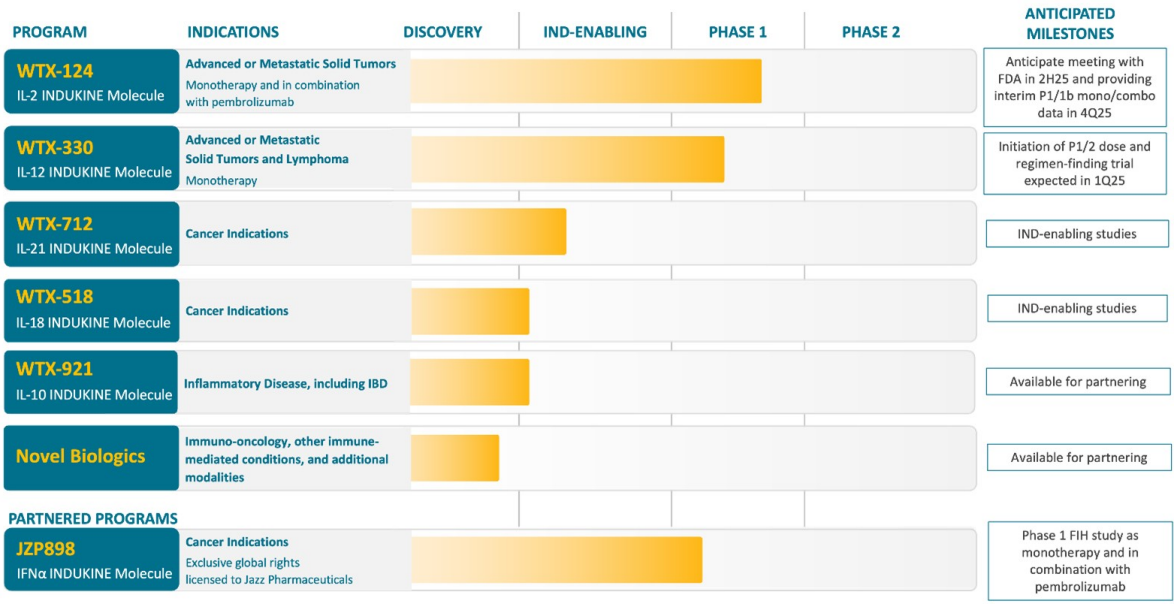
tumors. In April 2024, we presented preclinical data for WTX-712 at the American Association for Cancer Research, or AACR, annual meeting demonstrating that WTX-712 acts through a unique mechanism that robustly activates tumor-specific T lymphocytes with an expanded therapeutic window through its selective release of wild-type IL-21 in the TME. WTX-518 is a systemically delivered, conditionally activated Interleukin-18 (IL-18) INDUKINE molecule in development for the treatment of cancer and is designed to promote activation of immune cells in the TME, resulting in antitumor immunity. In April 2024, we also presented preclinical data for WTX-518 at the AACR Annual Meeting demonstrating that WTX-518 exhibits remarkable tumor-selective activation, resistance to IL-18BP and robust immune activation. WTX-921 is a systemically delivered, conditionally activated Interleukin-10 (IL-10) INDUKINE molecule in development for the treatment of inflammatory bowel disease, or IBD, and potentially other inflammatory diseases.

We continue to build our PREDATOR platform to generate a pipeline of innovative therapeutics that cover a diversity of immune stimulating mechanisms with the potential to address significant unmet medical need in therapeutic areas including new immuno-oncology, autoimmune, and inflammatory diseases. Our PREDATOR platform consists of our protein engineering technologies and our know-how, which we use to generate INDUKINE molecules with multiple functional domains rationally engineered into a single protein to achieve the desired pharmaceutical profile. Each of our lead INDUKINE molecules consists of four components: a cytokine, an inactivation domain, a half-life extension domain and a proprietary protease-cleavable linker. Our INDUKINE molecules for oncology contain cytokines that mediate pro-inflammatory, anti-cancer mechanisms within the TME, with full potency and functionality observed in preclinical studies. The inactivation domain physically blocks the cytokine portion of the INDUKINE molecule in non-tumor tissue throughout the body, or the periphery, preventing it from binding to its receptor until it is cleaved and thereby activated in the TME. The half-life extension domain enables high systemic and tumor tissue exposure for the INDUKINE molecule prior to its cleavage in the tumor. After cleavage in the tumor, the half-life extension domain is removed, and the cytokine is released to activate immune cells. We select the proprietary protease-cleavable linker to enable conditional release of the cytokine portion of the INDUKINE molecule within tumor tissue. This selection is based on our extensive screening in preclinical studies to identify protease-cleavable linkers that are efficiently cleaved by a broad array of human tumor tissues with minimal cleavage in non-tumor tissues.

Our Pipeline

We are leveraging our novel PREDATOR platform to engineer conditionally activated proinflammatory immunomodulators, or INDUKINE molecules, which are delivered systemically but activated only in the TME, with the goal of generating potent antitumor response while minimizing toxicities. Except for JZP898, which we have licensed to Jazz, we have worldwide rights to our PREDATOR platform and our portfolio of INDUKINE product candidates, all of which we have developed internally. We believe our approach has the potential to overcome current limitations of systemic proinflammatory immunomodulatory

therapies, such as cytokines, for the treatment of cancer and other immune-mediated conditions. Our current pipeline is summarized below:



Using our PREDATOR platform, we have identified and are continuing to develop five initial product candidates: WTX-124, WTX-330, WTX-712, WTX-518, and WTX-921. In addition to these product candidates, we are pursuing additional immuno-oncology discovery programs in which we are applying our novel engineering approach to other targets. We are also expanding our technology to other disease areas, such as inflammatory diseases.

Our Strategy

Our goal is to utilize our proprietary PREDATOR platform to redefine the cancer treatment landscape with therapies to transform the lives of cancer patients, as well as to continue to develop our preclinical portfolio for the treatment of inflammatory bowel disease and potentially other inflammatory diseases. Key elements of our strategy include:

- Advancing our lead product candidate, WTX-124, through clinical development in selected solid tumor indications.
- Advancing WTX-330 through clinical development in selected solid tumors and lymphoma.
- Advancing WTX-712, WTX-518, and WTX-921 through preclinical development.
- Establishing a leading position in protein engineering and developing optimized conditionally activated molecules.
- Selectively entering into strategic partnerships while retaining key rights to our programs and platform in major pharmaceutical markets.

Traditional Cancer Therapy, Immunotherapy and the Need for New Treatment Options

The treatment of certain cancers has improved markedly over the past decade. Whereas many cancer treatments were historically limited to surgical removal, chemotherapy and radiation, recent advances target specific genetic changes in individual tumors or redirect the patient's immune system to eliminate tumors and improve patient outcomes.

The latter approach, referred to as immunotherapy, represents one of the fastest growing segments in cancer treatment. The goal of immunotherapy is to harness an individual's immune system to better enable it to identify, attack and kill tumor cells and to form long-term immunologic memory against tumors. The immune system is generally divided into the innate and adaptive arms, which are responsible for driving immediate and lasting antitumor responses, respectively. The innate immune system involves a diverse set of cells, including natural killer, or NK, cells, mast cells, eosinophils, basophils, neutrophils, macrophages and dendritic cells, or DCs, all of which generate a rapid local response to a foreign body, pathogen or tumor cell and release signals to activate and recruit cells, specifically lymphocytes, from the adaptive immune system. The adaptive immune system is the line of defense that is specific to a pathogen or tumor antigen and is composed of T cells and B cells, which work in concert to kill cells directly, produce antibodies and form immunologic memory. The latter is critical for the

body's immune response upon re-exposure to the initial antigen or pathogen. Many of the recent advances in immuno-oncology, such as immune checkpoint inhibitors, have focused on improving the function of T cells.

The development of immune checkpoint inhibitors, in particular programmed cell death protein 1, or PD-1, and programmed death-ligand 1, or PD-L1, inhibitors, revolutionized the treatment of many cancers. The efficacy of these T cell targeted immunomodulators, both as single agents or in combination with standard of care therapies, including chemotherapy, has resulted in many of these regimens moving up the treatment paradigm to become first- or second-line treatment options in numerous cancer types, and the landscape for immunotherapy continues to rapidly evolve. However, features of the tumor cells or the TME play a role in the efficacy of immune checkpoint inhibitors, leaving many patients with advanced or metastatic disease either ineligible for or unresponsive to treatment with immune checkpoint inhibitors. The majority of patients who do respond to these therapies ultimately develop resistance and experience disease progression. As a result, many patients are still underserved and could benefit from novel approaches to immunotherapy that complement and/or enhance checkpoint inhibition, whether as monotherapy or in combination. We believe that the best way to improve outcomes for cancer patients is to stimulate additional or *de novo* immune cell responses within the innate and adaptive arms of the immune system to complement immune checkpoint inhibitor therapy.

Leveraging our PREDATOR platform and drug development capabilities, we are creating a portfolio of conditionally activated proinflammatory immunomodulators, including cytokines, designed to be optimized for the treatment of cancer, and suppressive immunomodulators for the treatment of immune mediated diseases. Cytokines are small biologically active proteins that play an essential role in immune cell function of both the innate and adaptive arms of the immune system. These proteins regulate immune responses by acting as chemical messengers for the body's immune cells through receptor site binding. Interleukins, such as IL-2 and IL-12, IFNα, IL-21, IL-18, and IL-10 are specific types of cytokines, produced primarily by cells of the immune system to signal and organize the immune response. In cancer, cytokines facilitate the ability of the immune system to recognize tumor cells as abnormal and harmful to the host. Cytokines further increase the proliferation of, enhance the survival of and direct a variety of immune cell types to infiltrate the TME and promote potent antitumor immune responses resulting in tumor cell killing and tumor clearance. Three cytokine therapies have received U.S. Food and Drug Administration, or FDA, approval for cancer treatment: (1) aldesleukin for the treatment of metastatic renal cell carcinoma, or RCC, and metastatic melanoma; (2) interferon alfa-2b for the treatment of several malignancies, including advanced melanoma; and most recently (3) nogapendekin alfa inbakicept (IL-15 receptor agonist) for non-muscle invasive bladder cancer.

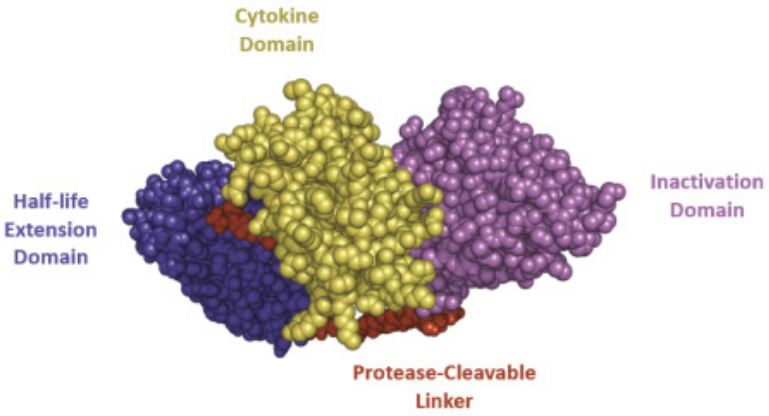
However, despite promising antitumor activity, the clinical utility of approved cytokine therapies is limited due to toxicity and poor pharmaceutical properties, such as short half-life, reduced exposure of active drug in the tumor and the requirement for frequent administration. The efficacy observed is often accompanied by side effects that can be severe and can make treatment difficult for many patients to tolerate, which limits the ability of patients to remain on therapy long-term. The need to improve the pharmaceutical properties of cytokines to achieve increased therapeutic indexes provides an opportunity to address a large unmet need for safer, and potentially more efficacious, cytokine therapeutics for the treatment of cancer. Our PREDATOR platform allows us to engineer cytokines that can be delivered systemically and have activity selectively upon reaching the TME, thus potentially limiting systemic toxicity. We believe this unique profile will help overcome the limitations seen with other cytokine approaches.

Our Solution

Our PREDATOR Platform

We designed our PREDATOR platform to overcome the current limitations of systemic proinflammatory therapies. We use our PREDATOR platform to design molecules with superior tolerability and optimal pharmaceutical properties when administered systemically as inactive prodrugs. They then undergo transformation to an active state upon reaching the TME, thereby delivering the full biological potency of antitumor immune modulation for maximum therapeutic potential.

Our PREDATOR platform is based on protein engineering to combine four critical components into a single INDUKINE molecule, as shown in the figure below.



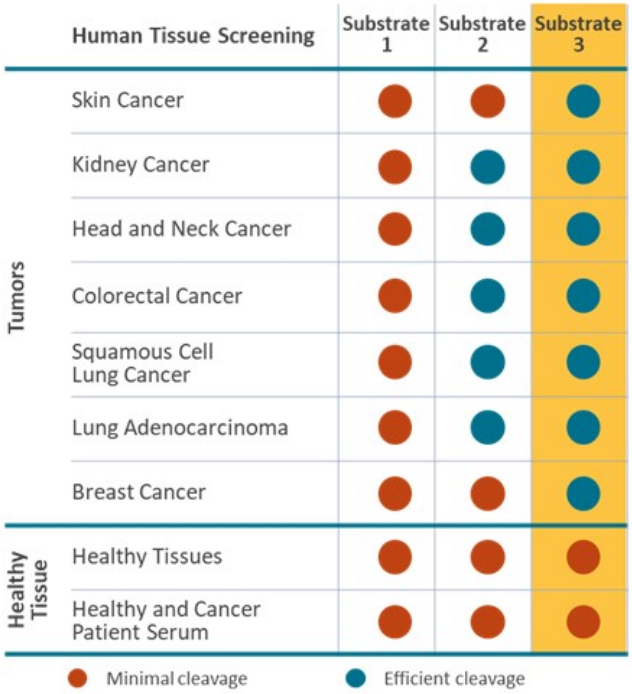
- **Cytokine Domain**: An immunostimulatory molecule. Upon tumor specific conditional activation, the released cytokine works as a fully potent agonist, displaying the expected pro-inflammatory mechanism and pharmacology.
- **Inactivation Domain**: A domain that blocks the activity of the immunostimulatory molecule outside of the tumor, for which we have identified and optimized multiple formats with high affinity blockade to achieve minimal off-tumor toxicity and low peripheral target receptor-mediated clearance.
- **Half-Life Extension Domain**: A domain that imparts a longer half-life to the INDUKINE molecule thereby increasing systemic and tumor tissue exposure. Following cleavage within the tumor, half-life extension domain is removed and the immunostimulatory cytokine is released. We have selected multiple domain formats to enable our INDUKINE product candidates to maintain high systemic and tumor tissue exposure.
- **Protease-Cleavable Linker**: A novel, proprietary protease-cleavable linker substrate with optimal tumor selectivity that is used to impart conditional activation of the INDUKINE molecule through its cleavage, which releases the active cytokine. We have observed high stability of these proprietary protease-cleavable linker substrates in rodents and non-human primates, or NHPs, with minimal non-tumor tissue cleavage.

Linker Selection

A key challenge in the design of tumor-selective conditionally activated immunomodulators is the heterogeneity of tumor protease profiles. There is no single protease that is uniquely dysregulated in human tumors. Therefore, the identification of a linker substrate with the optimal profile cannot be achieved by biasing the linker sequence towards any single protease or protease family.

To ensure INDUKINE molecules are broadly activated across multiple tumor types, the linker substrate must be efficiently cleaved in the TME of many different tumors while remaining stable in circulation and in normal non-tumor tissues. We achieve this by utilizing a differentiated approach for linker identification and let the tumors select the substrate, rather than screening for linkers sensitive to cleavage by a single protease. Our process begins with a novel proprietary library of peptide sequences designed to target the universe of protease families known to be dysregulated in tumors. We initially screen these libraries for a high efficiency of cleavage and, based on the result, generate additional libraries to optimize the sequence motifs. We then screen the prioritized linker sequences that we have identified from the initial novel proprietary library of peptide sequences for cleavage by a panel of primary human tumor specimens and for stability when incubated with human serum or normal tissues. Leveraging this screening process, we initially screened several thousand linker sequences for optimal biochemical properties, and then screened the lead sequences for cleavage by a panel of primary human tumor specimens and normal non-tumor tissues. Linker sequences that were not efficiently cleaved by human tumor samples (for example, the linker shown as Linker 1 in the diagram below) were eliminated in the screening and those that were efficiently cleaved by human tumors but not cleaved by normal serum or tissues (for example, the linker shown as Linker 3 in the diagram below) were selected for incorporation into our INDUKINE molecules to confirm their activity *in vitro* and *in vivo*. We have selected linkers for our INDUKINE molecules with characteristics similar to those of Linker 3 in the table below.

Human Tissue Screening for Selection of Optimized Linker Candidates



We seek to protect aspects of our PREDATOR platform technology by obtaining patent protection in the United States and internationally. Currently, our patent portfolio for our PREDATOR platform technology includes two families of pending patent applications, which disclose and claim protease cleavable linkers and libraries of protease cleavable linkers, as well as polypeptides that contain such linkers, methods of making libraries and methods of screening libraries to identify linkers with desired properties. These patent families were recently filed, and no patents have been granted. For more information see "Intellectual Property" described in this Part I, Item 1.

INDUKINE Molecules

We have rationally engineered INDUKINE molecules to have four key characteristics that we believe provide our product candidates with a unique profile and potential advantages in clinical settings when compared to other cytokines currently approved or in development:

- **Optimized Antitumor Activity**: The active portion of our INDUKINE molecules consists of a fully potent and functional cytokine molecule delivered directly into the tumor. We believe that delivery of a cytokine molecule into the TME will enable our product candidates to capture the full proinflammatory and immunomodulatory potential of cytokines and potentially result in optimal antitumor activity.
- **Enhanced Tolerability**: To improve tolerability, our INDUKINE molecules are designed to be administered as inactive prodrugs that employ a tailored, high affinity blockade to minimize off-target toxicity. We aim to prevent peripheral pathway activation, as well as target-mediated disposition in normal tissues, with the goal of minimizing potential toxicity.
- **Optimized Pharmaceutical Properties**: We design INDUKINE molecules to be stable in the bloodstream and periphery and to have a long serum half-life to achieve efficacy without requiring the frequent dosing that is a limiting requirement of approved recombinant cytokines, such as aldesleukin, a recombinant human IL-2, or rhIL-2, therapy. Our design allows us to achieve high, biologically relevant tumor tissue exposure with our INDUKINE molecules. Once our molecules are cleaved within the tumor, the cytokine is released for either intratumoral target binding or rapid systemic clearance.
- **Conditional Activation**: Upon reaching the TME, INDUKINE molecules are activated via cleavage of our proprietary linkers by tumor-specific proteases which results in release of the cytokines in the tumor. We select our linkers to be

specifically cleaved in the tumor and be stable in circulation and normal non-tumor tissues, with the goal enhancing the tolerability profile of our INDUKINE molecules.

Our Programs

WTX-124: Our IL-2 INDUKINE Molecule

Overview

Our lead product candidate, WTX-124, is a systemically delivered, conditionally activated IL-2 INDUKINE molecule that we are developing to minimize the severe toxicities observed with rhIL-2 therapy and maximize clinical benefit when administered as monotherapy or in combination with immune checkpoint inhibitors in patients with immunotherapy sensitive advanced or metastatic solid tumors. We believe that these properties will also allow WTX-124 to have potential applicability in indications beyond those for which rhIL-2 therapy is currently approved. Key features of WTX-124 include preservation of full IL-2 potency and function as observed in preclinical studies, high affinity blockade of IL2—IL2R interaction in systemic circulation and non-tumor tissues, half-life extension for optimal tumor exposure and conditional protease activation within the TME due to our proprietary linker.

We designed WTX-124 to address the limitations of next generation IL-2 therapies in development by blocking the binding of IL-2 to the IL-2R in the periphery, thereby inhibiting IL-2 signaling and potentially minimizing toxicities, while maintaining binding to the high affinity IL-2Ra/ß/g in tumors to ensure the full pharmacology of IL-2.

WTX-124 consists of wild-type human IL-2, an IL-2Rß blockade element that eliminates binding to both high and medium affinity IL-2Rs expressed in normal tissues to neutralize IL-2 activity in the periphery, an antibody fragment that extends the circulation half-life and a proprietary linker for cleavage in the TME. As a prodrug, WTX-124 is conditionally activated in the TME to release an IL-2 cytokine to stimulate an antitumor immune response but with reduced peripheral toxicities. In preclinical studies, WTX-124 exhibited favorable pharmacokinetic and tolerability profile with robust antitumor activity driven by the differentiation, activation and expansion of T effector and memory lymphocyte immune responses.

Market Opportunity

We are initially developing WTX-124 in tumor types known to be responsive to IL-2 and/or PD-1 targeting therapies including melanoma, RCC and non-small cell lung cancer. These are aggressive tumor types and many patients will eventually progress following treatment with standard of care. As a result, we believe there is a need for new therapies to improve response and durability. If successfully developed and approved, we believe WTX-124 represents a promising therapeutic option for patients with life-threatening diseases with high unmet medical need, either as monotherapy or in combination with immune checkpoint inhibitors or current or potential future standard of care agents. We have the opportunity to potentially expand upon the patient populations and indications beyond those for which Proleukin (aldesleukin) is approved. We intend to develop WTX-124 as monotherapy and in combination with pembrolizumab, and eventually in combination with other standard of care therapeutics across different lines of therapy.

According to the Checkpoint Inhibitors Global Market Report 2024, the global checkpoint inhibitors market is expected to grow to $55.64 billion in 2028 at a CAGR of 10.1%.

WTX-124 Clinical Development Plan and Interim Results

We are currently evaluating WTX-124 in a Phase 1/1b clinical trial as a monotherapy and in combination with Merck & Co., Inc.'s anti-PD-1 therapy KEYTRUDA (pembrolizumab) in patients with immunotherapy sensitive advanced or metastatic solid tumors who have failed standard of care treatment, including checkpoint inhibitor therapy. In November 2023, we announced preliminary first-in-human clinical data from the initial monotherapy dose-escalation cohorts in the Phase 1/1b clinical trial. The preliminary data established proof of mechanism for WTX-124 and proof of concept for our INDUKINE design, and included assessments of safety and tolerability, pharmacokinetics, relevant biomarkers and preliminary antitumor activity. In June 2024, at the American Society of Clinical Oncology, or ASCO, Annual Meeting, we presented updated interim data from dose escalation, both monotherapy and combination therapy with pembrolizumab, in the Phase 1/1b clinical trial, and announced our recommended dose for expansion, or RDE, of 18 mg for monotherapy, and opening of monotherapy expansion arms. As of May 1, 2024, 47 patients had been treated with at least one dose of WTX-124, 35 in monotherapy and 12 in combination dose escalation. The data continued to demonstrate that WTX-124 was generally well-tolerated in the outpatient setting at monotherapy doses up to 28 mg and combination doses up to 12 mg, with no new safety signals in combination with pembrolizumab. WTX-124 as a monotherapy produced objective clinical responses, including a durable confirmed complete response, or CR, and two partial responses, or PRs, at the active dose levels of 12 and 18 mg. Both PRs were confirmed subsequent to the data cutoff, and one remained progression-free as of November 7, 2024. Increased T cell activation signature for the combination suggested a potential for improved efficacy by combining WTX-124 with pembrolizumab. Of the two previously disclosed PRs in combination therapy, one PR improved to a CR, and both combination responses remain ongoing at greater than eight months.

We have targeted full enrollment in the monotherapy dose expansion arm in the first half of 2025 and in the combination arm in the second half of 2025. We plan to meet with regulatory authorities to discuss potential registrational pathways in the second half of 2025 and to release a monotherapy and combination therapy clinical data update in the fourth quarter of 2025.

The rationale for our clinical development strategy is as follows:

- **IL-2 has been shown to have single agent activity in some cancers**. Aldesleukin is approved for the treatment of metastatic RCC and metastatic melanoma. However, due to the toxicity associated with aldesleukin, which is noted in a black box warning, the drug is used infrequently. We believe, based on the mechanism of action of WTX-124, that it may be able to achieve higher intratumoral exposures of IL-2 than aldesleukin with minimal systemic toxicity, leading to monotherapy antitumor immune responses in patients with historically immunotherapy-sensitive tumor types who have progressed on, or subsequent to, immune checkpoint inhibitor therapy. Our preclinical data with WTX-124 show that WTX-124 has single agent antitumor activity in mouse tumor models and was well-tolerated. WTX-124 was also tolerated in NHPs at doses greater than predicted to be required for antitumor activity based on modeling the mouse tumor data. The data in our Phase 1/1b clinical trial has demonstrated monotherapy antitumor activity at doses safely delivered in the outpatient setting. Single agent activity with competitor IL-2 compounds has been limited, potentially affording an opportunity for us to pursue an expedited clinical development and regulatory strategy for WTX-124 if we can continue to show positive single arm efficacy data in a relapsed or refractory tumor type with high unmet medical need.
- **IL-2 agonists and immune checkpoint inhibitors may act synergistically to enhance antitumor immune response**. Clinical results have shown that aldesleukin induces responses as a single agent in patients who have progressed on immune checkpoint inhibitors. Our preclinical data with WTX-124 highlight the potential benefit of WTX-124 when combined with an anti-PD-1 antibody. These results suggest that combining novel IL-2 therapies with checkpoint inhibitors merits further evaluation as a regimen for treating cancer.

WTX-330: Our IL-12 INDUKINE Molecule

Overview

Our second product candidate, WTX-330, is a systemically delivered, conditionally activated IL-12 INDUKINE molecule that we are developing to minimize the severe toxicities observed with recombinant human IL-12, or rhIL-12, therapy and maximize clinical benefit when administered as monotherapy or in combination with standard of care therapies including checkpoint inhibitors in relapsed or refractory advanced or metastatic solid tumors or lymphoma.

IL-12 is a potent, pleiotropic cytokine for immune-mediated killing of cancer cells, whose mechanism of action includes stimulation of both innate and adaptive immune responses. IL-12 is a heterodimeric cytokine (p70) containing two subunits (p35 and p40). A subset of antigen-presenting cells, such as DCs, produce IL-12 upon activation, during the antigen presentation process. Binding of IL-12 to the IL-12R expressed on multiple immune cell populations activates the JAK/STAT signaling pathway resulting in helper T cell differentiation, activation of cytotoxic NK and T cells, and inhibition or reprogramming of immunosuppressive cells such as tumor-associated macrophages or myeloid-derived suppressor cells. IL-12 also increases the expression of antigen-presentation machinery, which is necessary to initiate an immune response in tumors that have not naturally stimulated an antitumor immune response, also referred to as "cold" tumors. IL-12 induces the production of interferon gamma, or IFNγ, a potent proinflammatory mediator of the downstream activities of IL-12 signaling. IFNγ, in turn, increases the production of IL-12 by mature DCs aiding in their antigen presentation capacity and driving activation of effector T cells. Numerous studies conducted by others have demonstrated that IL-12 treatment has significant antitumor activity in a range of preclinical models, with the induction of a long-lasting antitumor immune memory.

Due to the robust antitumor activity seen in preclinical studies, there has been significant interest in developing rhIL-12 therapy for advanced solid tumors. In early clinical trials conducted by a third party, the use of systemically administered rhIL-12 produced evidence of clinical activity in several tumor types, including RCC, melanoma and non-Hodgkin's lymphoma. However, the systemic administration of rhIL-12 was shown to be toxic, resulting in the death of two patients in one Phase 2 trial and multiple hospitalizations. Additional trials at tolerated doses yielded modest clinical activity, potentially due to a lack of sufficient and durable exposure of rhIL-12 in the TME at lower doses.

WTX-330 is designed to improve the pharmacological properties of IL-12 and require less frequent systemic administration. The prodrug is designed to remain inactive while circulating in the periphery and is activated preferentially in the TME to release an IL-12 cytokine. We believe activation of WTX-330 in the TME has the potential to stimulate a robust antitumor immune response while minimizing the peripheral toxicities that have been associated with systemic administration of rhIL-12 therapy. Key features of WTX-330 include high affinity blockade of IL-12 – IL-12R interaction in systemic circulation and non-tumor tissues, half-life extension for optimal tumor exposure and conditional protease activation due to our proprietary linker. In preclinical studies, we have observed high antitumor activity of an IL-12 INDUKINE surrogate molecule across a broad range of preclinical tumor models and that it has a favorable pharmacokinetic and tolerability profile.

WTX-330 Clinical Development Plan

We have evaluated WTX-330 in a Phase 1 clinical trial for the treatment of immunotherapy resistant advanced or metastatic solid tumors or lymphoma, followed by expansion arms in relapsed/refractory tumors following treatment with checkpoint inhibitors or tumors for which checkpoint inhibitors are not approved. In November 2024, at the 39th Annual Meeting of the Society for Immunotherapy Cancer, or SITC, we presented preliminary first-in-human clinical data from the Phase 1 clinical trial of WTX-330. The preliminary data established proof of mechanism for WTX-330 and proof of concept for our second INDUKINE molecule, and included assessments of safety and tolerability, pharmacokinetics, relevant biomarkers and preliminary antitumor activity. The preliminary data, collected as of October 7, 2024, was generated from 25 heavily pretreated patients from three dose escalation cohorts (0.016, 0.024, and 0.032 mg/kg) and two expansion arms at 0.024 mg/kg in patients resistant to checkpoint inhibitors or for whom checkpoint inhibitors were not indicated. WTX-330 was generally well-tolerated, with the most common adverse events expected for IL-12 therapy, including cytokine release syndrome, pyrexia, and liver function test elevations. WTX-330 delivered 22-fold more IL-12 than rhIL-12 therapy at its maximal tolerated dose. Anti-tumor activity was noted, including one confirmed PR in metastatic melanoma and stable disease in patients with less immunosensitive tumors. Biomarker data, including NanoString, showed pleiotropic immune activation in the TME, consistent with the mechanism of action of IL-12.

We expect to initiate a Phase 1/2 dose and regimen-finding clinical trial of WTX-330 in the first quarter of 2025 in patients with selected advanced or metastatic solid tumors.

WTX-712: Our IL-21 INDUKINE Molecule

WTX-712 is a systemically delivered, conditionally activated IL-21 INDUKINE molecule. IL-21 is a pluripotent cytokine that activates antitumor T cell responses, induces B cell activation, and promotes generation and maintenance of germinal centers and tertiary lymphoid structures. A member of the common g-chain family of cytokines, IL-21 acts on a broader range of cells than IL-2 and does not induce vascular leak syndrome. Despite being a potent inducer of immune activation, IL-21 development has been hampered by poor PK properties and adverse events at dose levels associated with antitumor activity. WTX-712 is being developed to minimize the severe toxicities that have been observed with recombinant IL-21 therapy and maximize clinical benefit. In April 2024, we presented preclinical data for WTX-712 at the AACR annual meeting demonstrating that WTX-712 acts through a unique mechanism that robustly activates tumor-specific T lymphocytes with an expanded therapeutic window through its selective release of wild-type IL-21 in the TME.

WTX-518: Our IL-18 INDUKINE Molecule

WTX-518 is a systemically delivered, conditionally activated IL-18 INDUKINE molecule in development for the treatment of cancer and is designed to promote activation of immune cells in the TME, resulting in antitumor immunity. In April 2024, we presented preclinical data for WTX-518 at the AACR annual meeting demonstrating that WTX-518 exhibits remarkable tumor-selective activation, resistance to IL-18BP and robust immune activation.

WTX-921: Our IL-10 INDUKINE Molecule

WTX-921 is a systemically delivered, conditionally activated IL-10 INDUKINE molecule for the treatment of inflammatory bowel disease and potentially other inflammatory diseases. We have generated an IND-enabling data package, and WTX-921 is available for partnering opportunities.

Our Early Stage Programs

In addition to IL-2, IL-12, IFNα, IL-21, IL-18, and IL-10 INDUKINE molecules, we are also applying our novel engineering approach to other modalities with a focus on conditionally activated immune cell engagers. We believe that our PREDATOR platform protein engineering principles can be extended to conditionally activated immune cell engagers, optimizing how immune cell engagers leverage the immune system to fight cancer.

Our goal is to better understand how the localized tumor delivery of immunomodulatory molecules might contribute to disease control while reducing the toxicity that in many cases accompany the systemic delivery of molecules such as cytokines or immune cell engagers.

Our Partnered Programs

JZP898: IFNα INDUKINE Molecule Licensed Globally to Jazz Pharmaceuticals

JZP898 (formerly WTX-613) is a systemically delivered, conditionally activated IFNα INDUKINE molecule that we are collaborating with Jazz to develop to minimize the severe toxicities that have been observed with recombinant human IFNα, or rhIFNα, therapy and maximize clinical benefit when administered as monotherapy or in combination with checkpoint inhibitors or other standard of care therapy.

IFNα is a member of the type-I IFN family and a proinflammatory cytokine that exerts dual mechanisms of inhibiting tumor cell growth through both cytotoxic effects directly on tumor cells as well as driving antitumor immune responses. While IFNα can inhibit proliferation and induce direct cell apoptosis of some cancer cell types, this mechanism by itself is unlikely to be sufficient to fully control tumor growth. The additional ability of IFNα to activate and engage different cells of the immune system makes IFNα a potentially effective antitumor agent. IFNα activation of the immune response can occur directly by engagement of IFNARs on immune cells or indirectly by the induction of chemokines that attract immune cells to the tumor site. IFNα can activate NK cells, enhance their ability to kill and increase their production of IFNγ. Furthermore, it can increase macrophage activation and support differentiation and activation of DCs. Lastly, IFNα can have a direct effect on B lymphocytes as well as T lymphocytes where IFNα favors the differentiation of naïve CD4+ T cells into helper T cells and directly activates CD8+ T cells, augmenting their IFNγ production and survival.

IFNα was one of the first cytokines clinically tested as a therapy for patients with cancer. Encouraging clinical benefit, although limited, resulted in regulatory approvals for the treatment of several hematological malignancies and solid tumors, such as chronic myelogenous leukemia, lymphoma and malignant melanoma. Widespread use of IFNα for hematologic and oncologic indications has unfortunately been hampered by adverse events linked to the on-target, off-tumor activity and its use in clinical practice has been supplanted by other therapies. In our preclinical studies, we observed the potential benefit of IFNα treatment in syngeneic mouse tumor models using colon, melanoma and breast tumor cell lines and the superior response obtained by the INDUKINE molecule format when compared to the dosing of recombinant cytokine.

In April 2022, we entered into a global collaboration and license agreement, or the Collaboration Agreement, with Jazz under which Jazz acquired exclusive global development and commercialization rights to WTX-613, which has subsequently been designated JZP898, as well as products containing certain isolated recombinant polypeptides comprising IFNα that meet specified criteria (each such product, a Licensed Product). Pursuant to the terms of the Collaboration Agreement, we are responsible for certain preclinical development activities with respect to JZP898 and other development activities specified in mutually agreed upon development plans. Jazz will generally reimburse us for the cost of such activities. Jazz will be responsible for all other development and commercialization activities conducted to exploit the Licensed Products. In June 2024, we executed a transfer agreement, or the Transfer Agreement, to assign our rights in a development agreement with a contract manufacturer of our interferon alpha INDUKINE molecule JZP898 to Jazz. The execution of this Transfer Agreement was the last material performance obligation required of us under the Collaboration Agreement. As of the execution of the Transfer Agreement, we no longer have any material performance obligations under the Collaboration Agreement.

Competition

The pharmaceutical industry is characterized by rapidly advancing technologies, intense competition and a strong emphasis on proprietary drugs. While we believe that our technology, knowledge, experience and scientific resources provide us with certain competitive advantages, we face potential competition from many different sources, including major pharmaceutical, specialty pharmaceutical and biotechnology companies; academic institutions; governmental agencies; and public and private research institutions. Any product candidates that we successfully develop and commercialize will compete with existing treatments and new treatments that may become available in the future.

We compete with other companies working to develop immunotherapies for the treatment of cancer including divisions of large pharmaceutical and biotechnology companies of various sizes. These companies are developing cytokines as immunotherapies using different modalities, including monoclonal antibodies, cell therapies, oncolytic viruses and vaccines.

Our lead product candidate, WTX-124, if approved, may face competition from other IL-2 based cancer therapies. Proleukin (aldesleukin) has been approved and is marketed for the treatment of both metastatic RCC and metastatic melanoma. In addition, we are aware of numerous clinical and preclinical IL-2 molecules using different platforms being developed for oncology indications, including programs from Anaveon AG, Anwita Biosciences, Inc., Ascendis Pharma A/S, Asher Biotherapeutics, Inc., Aulos Bioscience, Inc., BioNTech SE, Cue Biopharma, Inc., DEKA Biosciences, Inc., Merck & Co., Inc., Medicenna Therapeutics Corp., Mural Oncology PLC, F. Hoffmann-La Roche AG, Synthekine, Inc., and Xilio Therapeutics, Inc.

There are no approved IL-12 therapies currently on the market for the treatment of cancer. However, if approved, WTX-330 may face competition from other IL-12 cytokine programs in clinical and preclinical development for oncology indications, including programs from Sanofi S.A. (Amunix), DEKA Biosciences, Inc., DragonFly Therapeutics, Inc., Juno Therapeutics, Inc. (Bristol-Myers Squibb Company), Mural Oncology, OncoSec Medical Incorporated, Philogen S.p.A., Sonnet BioTherapeutics, Inc., Turnstone Biologics Corp. (partnered with Takeda Pharmaceutical Company Limited), Xilio Therapeutics, Inc., and Zymeworks Inc.

We are developing WTX-124 and WTX-330 as potential monotherapies in relapsed or refractory tumor types or in combination with checkpoint inhibitors or other standard of care therapies in advanced or metastatic malignancies with high unmet medical need. Standard of care therapies include chemotherapy, targeted therapy, and more recently, immunotherapies, including

monoclonal antibodies and bispecific formats, antibody drug conjugates, adoptive cellular therapies, and cytokines. In addition, there are numerous investigational agents in clinical development. Combining agents to improve patient outcomes and prevent emergence of resistance has become the paradigm for treatment of cancer.

Many of our competitors, either alone or with their collaboration partners, have significantly greater financial resources and expertise in research and development, preclinical testing, clinical trials, manufacturing and marketing than we do. Future collaborations and mergers and acquisitions may result in further resource concentration among a smaller number of competitors. Smaller or early-stage companies may also prove to be significant competitors, particularly through collaborative arrangements with large and established companies. These competitors will also compete with us in recruiting and retaining qualified scientific and management personnel and establishing clinical trial sites and subject registration for clinical trials, as well as in acquiring technologies complementary to, or that may be necessary for, our programs.

Our commercial potential could be reduced or eliminated if our competitors develop and commercialize products that are safer, more effective, have fewer or less severe side effects, are more convenient or are less expensive than products that we may develop. Our competitors also may obtain FDA or other regulatory approval for their products more rapidly than we may obtain approval for ours, which could result in our competitors establishing a strong market position before we are able to enter the market or make our development more complicated. The key competitive factors affecting the success of all of our programs are likely to be efficacy, safety and convenience.

Manufacturing

To date, we have produced limited quantities of our product candidates at our own facilities for preclinical evaluation. We do not own manufacturing facilities capable of producing drug product for clinical trials or at clinical scale. We must manufacture drug product for clinical trial use in compliance with current Good Manufacturing Practices, or cGMPs, or similar foreign standards. The cGMP regulations include requirements relating to organization of personnel, buildings and facilities, equipment, control of components and drug product containers and closures, production and process controls, packaging and labeling controls, holding and distribution, laboratory controls, records and reports, and returned or salvaged products. We do not have and we do not currently plan to acquire or develop the facilities or capabilities to manufacture cGMP drug substance or filled drug product for use in human clinical trials. As a result, we rely on third-party contract manufacturers to manufacture some of our preclinical product candidate supplies and rely on third-party contract manufacturers to manufacture all of our clinical trial product supplies. We will also contract with additional third parties for the filling, labeling, packaging, storage and distribution of our product candidates investigational drug products.

The manufacturing facilities for our product candidates must meet cGMP requirements and FDA certification before any product is approved and we can manufacture commercial products. Our third-party manufacturers will also be subject to periodic inspections of facilities by the FDA and other authorities, including procedures and operations used in the testing and manufacture of our products to assess our compliance with applicable regulations. In March 2024, we received alignment from the U.S. Food and Drug Administration, or the FDA, on the comparability path for WTX-330 for an improved manufacturing process.

Commercialization Plan

We intend to retain significant development and commercial rights to our product candidates and, if marketing approval is obtained, to commercialize our product candidates on our own, or potentially with a partner, in the United States and other major pharmaceutical markets. We currently have no sales, marketing or commercial product distribution capabilities and have no experience as a company commercializing products. We intend to build the necessary infrastructure and capabilities over time for the United States, and potentially other regions, following further advancement of our product candidates. Clinical data, the size of the addressable patient population, the size of the commercial infrastructure and manufacturing needs may all influence or alter our commercialization plans.

Intellectual Property

Our intellectual property is critical to our business, and we strive to protect it, including by seeking to obtain and maintaining patent protection in the United States and internationally to cover our product candidates, their methods of use and processes for their manufacture and any other inventions that are commercially important to the development of our business. We also rely on trade secrets and proprietary know-how to protect aspects of our business that are not amenable to, or that we do not consider appropriate for, patent protection.

Our patent portfolio includes patents and patent applications with composition of matter and method of use claims with respect to our product candidates, WTX-124, WTX-330, JZP898, WTX-712, WTX-518, and WTX-921, and claims directed to our PREDATOR platform technology. For our product candidates, we will, in general, initially pursue patent protection covering compositions of matter and methods of use. Throughout the development of our product candidates, we will seek to identify

additional opportunities for obtaining patent protection that would potentially enhance commercial success, including through additional methods of use, processes for manufacture, formulation and dosing regimen-related claims.

Our commercial success depends in part on our ability to obtain and maintain proprietary protection for our current and future product candidates, platform technologies, novel discoveries, product development technologies and know-how, to operate without infringing on the proprietary rights of others and to prevent others from infringing our proprietary rights. We seek to protect our proprietary position by, among other methods, filing or in-licensing U.S. and foreign patents and patent applications related to technology, inventions and improvements that are important to the development and implementation of our business. We also rely on or may rely in the future on trademarks, trade secrets, copyright protection, know-how, continuing technological innovation and confidential information to develop and maintain our proprietary position. For the product candidates we develop and plan to commercialize, as a normal course of business, we have been granted and intend to continue to pursue composition and method of manufacture and use, including therapeutic use, patents, as well as novel indications for our product candidates. We also have obtained and will continue to seek patent protection with respect to novel discoveries. We have sought and plan to continue to seek patent protection, either alone or jointly with our collaborators, as our agreements may dictate.

In some instances, we submit patent applications directly with the United States Patent and Trademark Office, or USPTO, as provisional patent applications. Provisional applications for patents were designed to provide a lower-cost first patent filing in the United States. Corresponding non-provisional patent applications must be filed not later than 12 months after the provisional application filing date. The corresponding non-provisional application benefits in that the priority date(s) of the patent application is/are the earlier provisional application filing date(s), and the patent term of the finally issued patent is calculated from the later non-provisional application filing date. This system allows us to obtain an early priority date, add material to the patent application(s) during the priority year, obtain a later start to the patent term and to delay prosecution costs, which may be useful in the event that we decide not to pursue examination in an application. While we intend to timely file non-provisional patent applications relating to our provisional patent applications, we cannot predict whether any such patent applications will result in the issuance of patents that provide us with any competitive advantage.

We file U.S. non-provisional applications and Patent Cooperation Treaty, or PCT, applications that claim the benefit of the priority date of earlier filed provisional applications, when applicable. The PCT system allows a single application to be filed within 12 months of the original priority date of the patent application, and to designate all of the PCT member states in which national patent applications can later be pursued based on the international patent application filed under the PCT. The PCT searching authority performs a patentability search and issues a non-binding patentability opinion, which can be used to evaluate the chances of success for the national applications in foreign countries prior to having to incur the filing fees. Although a PCT application does not issue as a patent, it allows the applicant to seek protection in any of the member states through national-phase applications.

At the end of the period of two and a half years from the first priority date of the patent application, separate patent applications can be pursued in any of the PCT member states either by direct national filing or, in some cases by filing through a regional patent organization, such as the European Patent Organization. The PCT system delays expenses, allows a limited evaluation of the chances of success for national/regional patent applications and enables substantial savings where applications are abandoned within the first two and a half years of filing.

For all patent applications, we determine claiming strategy on a case-by-case basis. Advice of counsel and our business model and needs are always considered. We file patent applications containing claims for protection of all useful applications of our proprietary technologies and any products, as well as all new applications and/or uses we discover for existing technologies and products, assuming these are strategically valuable. We continuously reassess the number and type of patent applications, as well as the existing patent claims to ensure that maximum coverage and value are obtained for our processes and compositions, given existing patent office rules and regulations. Further, claims may be modified during patent prosecution to meet our intellectual property and business needs.

We recognize that the ability to obtain patent protection and the degree of such protection depends on a number of factors, including the extent of the prior art, the novelty and non-obviousness of the invention and the ability to satisfy the enablement requirement of the patent laws. The patent positions of therapeutic polypeptide companies like ours are generally uncertain and involve complex legal, scientific and factual questions. In addition, the coverage claimed in a patent application can be significantly reduced before the patent is issued, and its scope can be reinterpreted or further altered even after patent issuance. Consequently, we may not obtain or maintain adequate patent protection for any of our future product candidates or for our platform technology. We cannot predict whether the patent applications we are currently pursuing will issue as patents in any particular jurisdiction or whether the claims of any issued patents will provide sufficient proprietary protection from competitors. Any patents that we hold may be challenged, circumvented or invalidated by third parties.

Regardless of the coverage we seek under our existing patent applications, there is always a risk that an alteration to the product or process may provide sufficient basis for a competitor to avoid infringement claims. In addition, the coverage claimed in a

patent application can be significantly reduced before a patent is issued, and courts can reinterpret patent scope after issuance. Moreover, many jurisdictions, including the United States, permit third parties to challenge allowed or issued patents in administrative proceedings, which may result in further narrowing or even cancellation of patent claims. Moreover, we cannot provide any assurance that any patents will be issued from our pending or any future applications or that any current or future issued patents will adequately protect our products.

Our patent portfolio, including patents and patent applications that we own and comprises about 23 patent families that are in various stages of the patent application filing and examination process in various jurisdictions worldwide, and include claims to our product candidates and claims directed to our PREDATOR platform technology for potential products and developments. The status of our patent portfolio changes frequently in the ordinary course of patent prosecution. As of February 5, 2025, our patent portfolio included approximately eight (8) issued patents in the United States, approximately forty (40) pending U.S. provisional or non-provisional patent applications, eight (8) pending international patent applications filed under the PCT and approximately one hundred nine (109) pending foreign patent applications, including pending applications in Australia, Brazil, Canada, China, European Patent Office, Hong Kong, India, Israel, Japan, Republic of Korea, Mexico, Russian Federation, Singapore, South Africa and Taiwan. These patent applications, if issued, are expected to expire on various dates from 2039 through about 2045, in each case without taking into account any possible patent term extension that may be available.

Our patent portfolio on our PREDATOR platform technology includes three patent families directed to protease cleavable linkers and libraries of protease cleavable linkers, as well as polypeptides that contain such linkers and methods of making libraries and screening libraries to identify linkers with desired properties. One of the patent families includes one issued U.S. patent with claims directed to protease cleavable linkers, and pending applications in the United States, Australia, Brazil, Canada, China, European Patent Office, Hong Kong, Israel, India, Japan, Republic of Korea, Mexico and Singapore. The 20-year term for patents in this family runs through 2040, excluding any extension of patent term that may be available. The second patent family currently consists of a pending U.S. non-provisional application. The 20-year term for patents in this family runs through 2044. The third patent family currently consists of a pending U.S. provisional application. We plan to file an international patent application under the PCT based on this provisional application before the applicable deadlines.

Our platform technology patent portfolio also includes a patent family directed to conditionally activated immune cell engagers. The patent family currently consists of a pending U.S. provisional application. We plan to file an international patent application under the PCT based on this provisional application before the applicable deadlines.

Our patent portfolio also includes patent and patent applications that we license from Harpoon Therapeutics, Inc., or Harpoon.

Our patent portfolio for each of the product candidates is summarized below.

WTX-124

We own seven patent families directed to IL-2 INDUKINE molecules and our WTX-124 product candidate. One of the families includes patents issued in the U.S. (four patents), Australia, Europe, Hong Kong, Japan, and Russian Federation with certain composition of matter claims with respect to IL-2 INDUKINE molecules and WTX-124. We have also filed pending U.S. applications and pending foreign patent applications in Australia, Brazil, Canada, China, European Patent Office, Hong Kong, India, Israel, Japan, Republic of Korea, Mexico, Russian Federation, Singapore and South Africa that claim certain compositions of matter and methods of use with respect to IL-2 INDUKINE molecules and WTX-124. The 20-year term for patents in this family runs through 2039, excluding any extension of patent term that may be available. A second patent family currently includes patents issued in the U.S. (two patents), and pending applications in U.S., Australia, Brazil, Canada, China, European Patent Office, India, Israel, Japan, Republic of Korea, Mexico, Russian Federation, Singapore and South Africa with claims direct to certain compositions of matter and methods of use with respect to IL-2 INDUKINE molecules and WTX-124. These applications also claim certain compositions of matter and method of use with respect to INF-a INDUKINE molecules and WTX-613. The 20-year term for patents in this family runs through to 2040, excluding any extension of patent term that may be available. A third patent family that we co-own currently includes pending applications in the U.S., Australia, Canada, China, Europe, Japan, and Republic of Korea that claim certain pharmaceutical compositions and methods of use of IL-2 INDUKINE molecules and our WTX-124 product candidate. The 20-year term for patents in this family will run through to 2042, excluding any extension of patent term that may be available. A fourth patent family currently includes pending applications in the U.S., Canada, Europe, Japan, and Republic of Korea that claims certain methods of use of IL-2 INDUKINE molecules and our WTX-124 product candidate. The 20-year term for patents in this family will run through to 2042, excluding any extension of patent term that may be available. Our fifth patent family also includes pending applications in the U.S., Australia, Canada, Europe, Japan, Taiwan, and the U.S. that claim certain methods of use with respect our IL-2 INDUKINE molecules and our WTX-124 product candidate. This family also claims certain methods of use with respect to IL-12 INDUKINE molecules and our WTX-330 product candidate, and INF-a INDUKINE molecules and WTX-613.The 20-year term for patents in this family will run through to 2042, excluding any extension of patent term that may be available. A fifth patent family includes a pending U.S. provisional application that claims certain compositions of matter and method of use with respect to IL-2 INDUKINE molecules and our WTX-124 product candidate. The 20-year term for patents in this family will run

through 2045, excluding any extension of patent term that may be available. We plan to file an international patent application under the PCT based on this provisional application before the applicable deadlines. A sixth patent family includes a pending U.S. provisional application that claims certain compositions of matter and methods of use with respect to IL-2 INDUKINE molecules and our WTX-124 product candidate. This family also claims certain compositions of matter and methods of use with respect to IL-12 INDUKINE molecules and our WTX-330 product candidate, and INF-a INDUKINE molecules and WTX-613. The 20-year term for patents in this family will run through 2045, excluding any extension of patent term that may be available. We plan to file an international patent application under the PCT based on this provisional application before the applicable deadlines. Our seventh patent family includes a pending U.S. provisional application that claims certain methods of use with respect to our IL-2 INDUKINE molecules and our WTX-124 product candidate. The 20-year term for patents in this family will run through 2045, excluding any extension of patent term that may be available. We plan to file an international patent application under the PCT based on this provisional application before the applicable deadlines.

WTX-330

We own seven families directed to IL-12 INDUKINE molecules and our WTX-330 product candidate. One of the families includes patents issued in the U.S. (two patents), Australia, Japan, and Russian Federation with certain composition of matter claims with respect to IL-12 INDUKINE molecules. We have also filed a pending U.S. application and pending foreign applications in Australia, Brazil, Canada, China, European Patent Office, Hong Kong, India, Israel, Japan, Republic of Korea, Mexico, Russian Federation, Singapore and South Africa that claim certain compositions of matter and methods of use with respect to IL-12 INDUKINE molecules and WTX-330. The 20-year term for patents in this family runs through 2039, excluding any extension of patent term that may be available. A second patent family currently includes pending patent applications in the U.S., Australia, Brazil, Canada, China, European Patent Office, Hong Kong, India, Israel, Japan, Republic of Korea, Mexico, Russian Federation, Singapore and South Africa with claims directed to certain compositions of matter and methods of use with respect to IL-12 INDUKINE molecules and WTX-330. The 20-year term for patents in this family runs through to 2041, excluding any extension of patent term that may be available. Our third patent family includes pending applications in the U.S., Australia, Canada, European Patent Office, Japan, and Republic of Korea that claim certain methods of use with respect to IL-12 INDUKINE molecules and our WTX-330 product candidate. The 20-year term for patents based on this international application will run through 2043, excluding any extension of patent term that may be available. Our fourth patent family currently includes a pending PCT application and pending applications in the U.S., Australia, Canada, European Patent Office, Japan, and Taiwan, that claim certain methods of use of IL-12 INDUKINE molecules and our WTX-330 product candidate. This family also claims certain methods of use with respect to INF-a INDUKINE molecules and WTX-613, and IL-2 INDUKINE molecules and our WTX-124 product candidate. The 20-year term for patents in this family will run through to 2042, excluding any extension of patent term that may be available. A fifth patent family includes a pending PCT application that claims certain methods of use of our IL-12 INDUKINE molecules and WTX-330 product candidate. We intend to file national applications in other jurisdictions based on the PCT application before the applicable deadlines. The 20-year term for patents in this family will run through 2044, excluding any extension of patent term that may be available. A sixth patent family includes a pending U.S. provisional application that claims certain methods of use of our IL-12 INDUKINE molecules and WTX-330 product candidate. We plan to file an international patent application under the PCT based on this provisional application before the applicable deadlines. The 20-year term for patents in this family will run through 2045, excluding any extension of patent term that may be available. A seventh patent family includes a pending U.S. provisional application that claims certain compositions of matter and methods of use with respect to IL-12 INDUKINE molecules and our WTX-330 product candidate. This family also claims certain compositions of matter and methods of use with respect to IL-2 INDUKINE molecules and our WTX-124 product candidate, and INF-a INDUKINE molecules and WTX-613. The 20-year term for patents in this family will run through 2045, excluding any extension of patent term that may be available. We plan to file an international patent application under the PCT based on this provisional application before the applicable deadlines.

WTX-613

We own five patent families directed to our INF-a INDUKINE molecules and our WTX-613 product candidate. We own a first patent family that includes pending foreign applications in the United States, Australia, Brazil, Canada, China, European Patent Office, Hong Kong, India, Israel, Japan, Republic of Korea, Mexico, Russian Federation, Singapore and South Africa that claim certain compositions of matter and methods of use with respect to INF-a INDUKINE molecules and WTX-613. The 20-year term for patents in this family runs through 2039, excluding any extension of patent term that may be available. A second patent family currently includes patents issued in the U.S. (two patents), and pending patent applications in the U.S., Australia, Brazil, Canada, China, European Patent Office, Hong-Kong, India, Israel, Japan, Republic of Korea, Mexico, Russian Federation, Singapore and South Africa with claims directed to certain compositions of matter and methods of use with respect to WTX-613. These applications also claim certain compositions of matter and method of use with respect to IL-2 INDUKINE molecules and our WTX-124 product candidate. The 20-year term for patents in this family runs through 2040, excluding any extension of patent term that may be available. We filed a pending application in the United States that combined the disclosures of the first and second families and claims compositions of matter and certain methods of use with respect to

WTX-613. The 20-year term for patents based on the pending U.S. application will run through to 2039 or 2040, depending on the particular claims, excluding any extension of patent term that may be available. Our third patent family includes pending applications in the U.S., Canada, China, European Patent Office, Japan, and Taiwan. that claim certain compositions of matter and methods of use with respect our INF-a INDUKINE molecules. The 20-year term for patents in this family will run through to 2042, excluding any extension of patent term that may be available. Our fourth patent family also includes pending applications in the U.S., Australia, Canada, European Patent Office, Japan, and Taiwan that claim certain methods of use with respect to INF-a INDUKINE molecules and WTX-613. This family also claims certain methods of use of with respect to IL-12 INDUKINE molecules and our WTX-330 product candidate, and IL-2 INDUKINE molecules and our WTX-124 product candidate. The 20-year term for patents in this family will run through to 2042, excluding any extension of patent term that may be available. Our fifth patent family currently consists of a pending PCT application directed to certain methods of use with respect to WTX-613. The 20-year term for patents in this family will run through 2045, excluding any extension of patent term that may be available. We plan to file an international patent application under the PCT based on this provisional application before the applicable deadlines.

WTX-712

We own a patent family directed to our IL-21 INDUKINE molecules and our WTX-712 product candidate. This patent family includes a pending PCT application that claims certain compositions of matter and method of use with respect to WTX-712. We intend to file national applications in other jurisdictions based on the pending PCT application before the applicable deadline. The 20-year term for patents in this family runs through 2044, excluding any extension of patent term that may be available.

WTX-518

We have an exclusive option under our November 2022 collaboration agreement with Adimab LLC to acquire ownership of a patent family directed to our IL-18 INDUKINE molecules and our WTX-518 product candidate. This patent family includes a pending PCT application that claims certain compositions of matter and method of use with respect to IL-18 INDUKINE molecules and WTX-518. We intend to exercise the option and acquire ownership of this patent family before applicable deadlines and to file national applications in other jurisdictions based in the pending PCT application before applicable deadlines. The 20-year term for patents in this family runs through 2044.

WTX-921

We own two patent families directed to our IL-10 INDUKINE molecules and our WTX-921 product candidate. We own a first patent family that includes a pending PCT application that claims certain compositions of matter and method of use with respect to IL-10 INDUKINE molecules and WTX-921. We intend to file national applications in other jurisdictions based in the pending PCT application before applicable deadlines. The 20-year term for patents in this family runs through 2044. Our second patent family includes a pending U.S. provisional application directed to certain compositions of matter and method of use with respect to IL-10 INDUKINE molecules and WTX-921. The 20-year term for patents in this family will run through 2045, excluding any extension of patent term that may be available. We plan to file an international patent application under the PCT based on this provisional application before the applicable deadlines.

In-Licensed Patents

We have licensed from Harpoon certain patents that are directed to single immunoglobulin variable domains that bind human serum albumin. We use the licensed technology in our current product candidates and may use the technology in additional development candidates we discover in the future. The licensed patent family includes granted U.S. patents and pending applications, and pending applications in Brazil, India, Canada, Japan, Mexico, Singapore, Australia, Eurasian Patent Organization, Republic of Korea, European Patent Office, China, and Israel. The 20-year term for the licensed patents runs through 2037, excluding any extension of patent term that may be available. See the discussion under “License Agreement with Harpoon Therapeutics, Inc.” for more information regarding our license agreement with Harpoon.

Patent Term and Patent Term Extensions

The term of individual patents depends upon the legal term for patents in the countries in which they are obtained. In most countries, including the United States, the patent term is 20 years from the earliest filing date of a non-provisional patent application. In addition, in certain instances, the term of a U.S. patent can be extended to compensate a patentee for administrative delays by the USPTO in examining and granting a patent. The term of a patent that covers a drug, biological product or medical device approved pursuant to a pre-market approval may also be eligible for patent term extension when FDA approval is granted, provided statutory and regulatory requirements are met. The length of the patent term extension is related to the length of time the drug is under regulatory review while the patent is in force. The Drug Price Competition and Patent Term Restoration Act of 1984, or the Hatch-Waxman Amendments, permits a patent term extension of up to five years beyond the expiration date set for the patent. Patent extension cannot extend the remaining term of a patent beyond a total of 14 years from the date of product approval, only one patent applicable to each regulatory review period may be granted an

extension and only those claims reading on the approved drug are extended. Similar provisions are available in Europe and other foreign jurisdictions to extend the term of a patent that covers an approved drug. We will, in general, pursue available patent term extensions in the United States and in foreign jurisdictions that provide for patent term extensions, however, there is no guarantee that the applicable authorities, including the FDA in the United States, will agree with our assessment of whether such extensions should be granted, and if granted, the length of such extensions.

Trademarks, Trade Secrets and Know-How

In connection with the ongoing development and advancement of our product candidates in the United States and various international jurisdictions, we seek to create protection for our marks and enhance their value by pursuing trademarks where available and when appropriate. In addition to patent and trademark protection, we rely upon trade secrets and know-how and continuing technological innovation to develop and maintain our competitive position. We seek to protect our proprietary information, in part, using confidentiality agreements with our commercial partners, collaborators, employees and consultants and invention assignment agreements with our employees and selected consultants. We also seek to preserve the integrity and confidentiality of our data and trade secrets by maintaining physical security of our premises and physical and electronic security of our information technology systems. While we have confidence in these individuals, organizations and systems, agreements or security measures may be breached and our trade secrets and other proprietary information may be disclosed. We may not have adequate remedies for any breach and could lose our trade secrets and other proprietary information through such a breach. In addition, our trade secrets may otherwise become known or be independently discovered by competitors. To the extent that our consultants, contractors or collaborators use intellectual property owned by others in their work for us, disputes may arise as to the rights in related or resulting trade secrets, know-how and inventions.

Our commercial success will also depend in part on not infringing the proprietary rights of third parties. In addition, we have licensed rights under proprietary technologies of third parties to develop, manufacture and commercialize specific aspects of our future products and services. It is uncertain whether the issuance of any third-party patent would require us to alter our development or commercial strategies, alter our processes, obtain licenses or cease certain activities. The expiration of patents or patent applications licensed from third parties or our breach of any license agreements or failure to obtain a license to proprietary rights that we may require to develop or commercialize our future technology may have a material adverse impact on us. If third parties prepare and file patent applications in the United States that also claim technology to which we have rights, we may have to participate in interference proceedings in the USPTO to determine priority of invention.

For more information regarding the risks related to our intellectual property, please see “Risks Related to Our Intellectual Property” under Part I, Item 1A. Risk Factors in this Annual Report.

License and Royalty Agreements

License Agreement with Harpoon Therapeutics, Inc.

In March 2018, we entered into an assignment and license agreement, or the Harpoon Agreement, with Harpoon, pursuant to which we assigned to Harpoon certain patents related to adoptive cell therapies and binding moieties for conditional activation of immunoglobulin and non-immunoglobulin molecules, and Harpoon assigned to us certain patents related to certain inducible polypeptides and a binding moiety for conditional activation of certain polypeptides. Harpoon also granted to us a worldwide, non-exclusive, royalty-bearing, sublicensable license under certain other patents owned by Harpoon and related to certain proteins to make, have made, use, sell, offer for sale and import products that are covered by such patents in the field of molecules comprising a certain polypeptide. Under the Harpoon Agreement, we agreed to pay to Harpoon an upfront fee of $0.5 million and, if we commercialize any products covered by these licensed patents, a low single digit percentage royalty on net sales of such products by us or any of our affiliates or licensees, subject to an obligation to make a minimum annual royalty payment at an amount in the low hundreds of thousands of dollars beginning with the first commercial sale of any such product by us.

In October 2018, we and Harpoon amended the Harpoon Agreement by entering into a First Amended and Restated Assignment and License Agreement, which amended certain terms of the original agreement, but did not change the terms of the license to us, patent assignments between the parties or payments due to Harpoon.

In December 2019, we and Harpoon amended the Harpoon Agreement by entering into a Second Amended and Restated Assignment and License Agreement, or the Second Amended Harpoon Agreement, which granted to us an additional worldwide, exclusive, irrevocable, royalty-bearing, transferable, assignable, sublicensable license under certain patents owned by Harpoon and related to certain proteins, to make, have made, use, sell, offer for sale and import products that are covered by such patents in the field of molecules comprising a certain protein. Under the Second Amended Harpoon Agreement, we agreed to pay to Harpoon a low single digit percentage royalty on net sales by us or any of our affiliates or licensees of any products that we commercialize covered by these additional licensed patents. In addition, we also agreed to grant to Harpoon, and Harpoon agreed to grant to us, a perpetual, non-exclusive, irrevocable, royalty-free license under certain other patents directed

to a certain binding domain of a certain protein, to make, have made, use, sell, offer for sale and import products that are covered by such patents in a field defined by a certain type of molecule with respect to each party.

Unless earlier terminated, our obligations to pay any royalties under the Second Amended Harpoon Agreement will expire on a country-by-country basis upon expiration of the last to expire valid claim of the relevant patents covering the manufacture, use or sale of such covered products in the applicable country. Harpoon may terminate the Second Amended Harpoon Agreement in the event of a material breach by us and our failure to cure such breach within a specified period and may terminate certain licenses if we become insolvent or bankrupt. We may terminate the Second Amended Harpoon Agreement voluntarily with prior written notice to Harpoon.

Amended and Restated Royalty Transfer Agreement

In December 2017, in connection with our sale of convertible promissory notes, we entered into a royalty transfer agreement with MPM Oncology Impact Fund Charitable Foundation, Inc., or MPM Charitable Foundation, and UBS Optimus Foundation, or the Royalty Transfer Agreement. Under the Royalty Transfer Agreement, we agreed to pay a royalty of 0.5% of net sales of our products to each of MPM Charitable Foundation and UBS Optimus Foundation. In August 2019, we amended the Royalty Transfer Agreement by entering into an amended and restated royalty transfer agreement, or the Amended Royalty Transfer Agreement, which provided that only products in our product pipeline at the time of our initial public offering or a change in control would be subject to the royalty on net sales. Under the Amended Royalty Transfer Agreement, our obligation to pay a royalty expires on a product-by-product and country-by-country basis upon the later of the 12th anniversary of the first commercial sale of such product in such country and expiration of the last valid claim in such country covering such product. The royalty rate is subject to a specified reduction for lack of any valid claim covering such product in a country. The obligation to pay royalties under the Amended Royalty Transfer Agreement shall not apply to any product that would only infringe our intellectual property rights that are discovered or developed after our initial public offering or to any product of an acquirer, assignee of the agreement or merger partner of us so long as such product does not incorporate any of our pre-acquisition intellectual property.

Government Regulation and Product Approval

Government authorities in the United States, at the federal, state and local level, and in other countries and jurisdictions, including the European Union, or EU, extensively regulate, among other things, the research, development, testing, manufacture, quality control, approval, packaging, storage, recordkeeping, labeling, advertising, promotion, distribution, marketing, sales, pricing, reimbursement, post-approval monitoring and reporting, and import and export of pharmaceutical products. The processes for obtaining regulatory approvals in the United States and in foreign countries and jurisdictions, along with subsequent compliance with applicable statutes and regulations and other regulatory authorities, require the expenditure of substantial time and financial resources. The regulatory requirements applicable to product development, approval and marketing are subject to change, and regulations and administrative guidance often are revised or reinterpreted by the agencies in ways that may have a significant impact on our business.

Review and Approval of Drugs and Biologics in the United States

In the United States, the FDA approves and regulates drugs under the Federal Food, Drug, and Cosmetic Act, or FDCA, and related regulations. Biological products, or biologics, are licensed for marketing under the Public Health Service Act, or PHSA, and subject to regulation under the FDCA and related regulations. A company, institution, or organization which takes responsibility for the initiation and management of a clinical development program for such products, and for their regulatory approval, is typically referred to as a sponsor. A sponsor seeking approval to market and distribute a new drug or biological product in the United States must typically secure the following:

- completion of preclinical laboratory tests in compliance with the FDA's good laboratory practice, or GLP, standards and applicable regulations;
- design of a clinical protocol and submission to the FDA of an IND, which must take effect before human clinical trials may begin;
- approval by an independent institutional review board, or IRB, representing each clinical site before each clinical trial may be initiated;
- performance of adequate and well-controlled human clinical trials in accordance with good clinical practices, or GCPs, to establish the safety and efficacy of the proposed drug product for each proposed indication and the safety, potency and purity of the proposed biological product for each proposed indication;
- submission to the FDA of a new drug application, or NDA, for a drug candidate product and a biological license application, or BLA, for a biological product requesting marketing for one or more proposed indications;
- review of the request for approval by an FDA advisory committee, where appropriate or if applicable;

- completion of one or more FDA inspections of the manufacturing facility or facilities at which the product, or components thereof, are produced to assess compliance with current good manufacturing practice, or cGMP, requirements to assure the product's identity, strength, quality and purity;
- completion of FDA audits of clinical trial sites to assure compliance with GCPs and the integrity of the clinical data;
- payment of user application and program fees pursuant to the Prescription Drug User Fee Act, or PDUFA;
- securing FDA approval of the NDA or BLA authorizing marketing of the product in the United States or particular indications; and
- compliance with any post-approval requirements, including the potential requirement to implement a Risk Evaluation and Mitigation Strategy, or REMS, and the potential requirement to conduct post-approval studies.

Preclinical Studies

Before a sponsor begins testing a compound with potential therapeutic value in humans, the product candidate enters the preclinical testing stage. Preclinical studies include laboratory evaluation of the purity and stability of the manufactured substance or active pharmaceutical ingredient and the formulated product, as well as *in vitro* and animal studies to assess the safety and activity of the product candidate for initial testing in humans and to establish a rationale for therapeutic use. These studies are generally referred to as IND-enabling studies. The conduct of preclinical studies is subject to federal regulations and requirements, including GLP standards and regulations and the United States Department of Agriculture's Animal Welfare Act, if applicable. Some long-term preclinical testing, such as animal tests of reproductive adverse events and carcinogenicity, and long-term toxicity studies, may continue after the IND is submitted.

The IND and IRB Processes

An IND is a request for FDA authorization to administer an investigational product candidate to humans. Such authorization must be secured prior to interstate shipment and administration of any new drug or biologic that is not the subject of an approved NDA or BLA. In support of a request for an IND, sponsors must submit a protocol for each clinical trial and any subsequent protocol amendments must be submitted to the FDA as part of the IND. In addition, the results of the preclinical tests, together with manufacturing information, analytical data, any available clinical data or literature and plans for clinical trials, among other things, are submitted to the FDA as part of an IND. The FDA requires a 30-day waiting period after the filing of each IND before clinical trials may begin. This waiting period is designed to allow the FDA to review the IND to determine whether human research subjects and patients will be exposed to unreasonable health risks and to address any other issues, including chemistry, manufacturing and controls, or CMC, for the proposed product. At any time during this 30-day period, the FDA may raise concerns or questions about the conduct of the trials as outlined in the IND and impose a clinical hold or partial clinical hold. In this case, the IND sponsor and the FDA must resolve any outstanding concerns before clinical trials can begin. The FDA's primary objectives in reviewing an IND are to assure the safety and rights of patients and to help assure that the quality of the investigation will be adequate to permit an evaluation of the drug's effectiveness and safety and of the biological product's safety, purity and potency.

Following commencement of a clinical trial under an IND, the FDA may also place a clinical hold or partial clinical hold on that trial. Clinical holds imposed by the FDA may be a result of new data, findings, or developments in clinical, nonclinical, and CMC. A clinical hold is an order issued by the FDA to the sponsor to delay a proposed clinical investigation or to suspend an ongoing investigation. A partial clinical hold is a delay or suspension of only part of the clinical work requested under the IND. For example, a specific protocol or part of a protocol is not allowed to proceed, while other protocols may do so. No more than 30 days after imposition of a clinical hold or partial clinical hold, the FDA will provide the sponsor a written explanation of the basis for the hold. Following issuance of a clinical hold or partial clinical hold, an investigation may only resume after the FDA has notified the sponsor that the investigation may proceed. The FDA will base that determination on information provided by the sponsor correcting the deficiencies previously cited or otherwise satisfying the FDA that the investigation can proceed.

In addition to the foregoing IND requirements, an IRB representing each institution participating in the clinical trial must review and approve the plan for any clinical trial before it commences at that institution, and the IRB must conduct continuing review and reapprove the trial at least annually. The IRB must review and approve, among other things, the trial protocol and informed consent information to be provided to trial subjects. An IRB must operate in compliance with FDA regulations. An IRB can suspend or terminate approval of a clinical trial at its institution, or an institution it represents, if the clinical trial is not being conducted in accordance with the IRB's requirements or if the product candidate has been associated with unexpected serious harm to patients.

Additionally, some trials are overseen by an independent group of qualified experts organized by the trial sponsor, known as a data monitoring committee, or DMC. This group provides authorization for whether a trial may move forward at designated check points based on access that only the group maintains to available data from the trial. Suspension or termination of

development during any phase of clinical trials can occur if it is determined that the participants or patients are being exposed to an unacceptable health risk or for other reasons.

Human Clinical Studies in Support of an NDA or BLA

Clinical trials involve the administration of the investigational product to human subjects under the supervision of qualified investigators in accordance with GCP requirements, which include, among other things, the requirement that all research subjects provide their informed consent in writing before their participation in any clinical trial. Clinical trials are conducted under written trial protocols detailing, among other things, the inclusion and exclusion criteria, the objectives of the trial, the parameters to be used in monitoring safety and the effectiveness criteria to be evaluated.

The clinical investigation of an investigational drug or biological product is generally divided into four phases. Although the phases are usually conducted sequentially, they may overlap or be combined. The four phases of an investigation are as follows:

- Phase 1. Phase 1 studies include the initial introduction of an investigational new drug or biological product into humans. These studies are designed to evaluate the safety, dosage tolerance, metabolism and pharmacologic actions of the investigational drug or biological product in humans, the side effects associated with increasing doses, and if possible, to gain early evidence on effectiveness.
- Phase 2. Phase 2 includes the controlled clinical trials conducted to preliminarily or further evaluate the effectiveness of the investigational drug or biological product for a particular indication(s) in patients with the disease or condition under trial, to determine dosage tolerance and optimal dosage, and to identify possible adverse side effects and safety risks associated with the drug or biological product. Phase 2 clinical trials are typically well-controlled, closely monitored, and conducted in a limited patient population.
- Phase 3. Phase 3 clinical trials are generally controlled clinical trials conducted in an expanded patient population generally at geographically dispersed clinical trial sites. They are performed after preliminary evidence suggesting effectiveness of the drug or biological product has been obtained, and are intended to further evaluate dosage, clinical effectiveness and safety, to establish the overall benefit-risk relationship of the investigational drug or biological product, and to provide an adequate basis for product approval.
- Phase 4. Post-approval studies may be conducted after initial marketing approval. These studies are used to gain additional experience from the treatment of patients in the intended therapeutic indication.

A clinical trial may combine the elements of more than one phase and the FDA often requires more than one Phase 3 trial to support marketing approval of a product candidate. A company's designation of a clinical trial as being of a particular phase is not necessarily indicative that the study will be sufficient to satisfy the FDA requirements of that phase because this determination cannot be made until the protocol and data have been submitted to and reviewed by the FDA. Generally, pivotal trials are Phase 3 trials, but they may be Phase 2 trials if the design provides a well-controlled and reliable assessment of clinical benefit, particularly in an area of unmet medical need.

In March 2022, the FDA released final guidance entitled "Expansion Cohorts: Use in First-In-Human Clinical Trials to Expedite Development of Oncology Drugs and Biologics," which outlines how developers can utilize an adaptive trial design commonly referred to as a seamless trial design in early stages of oncology biological product development (i.e., the first-in-human clinical trial) to compress the traditional three phases of trials into one continuous trial called an expansion cohort trial. Information to support the design of individual expansion cohorts are included in IND applications and assessed by the FDA. Expansion cohort trials can potentially bring efficiency to biological product development and reduce developmental costs and time.

In December 2022, with the passage of Food and Drug Omnibus Reform Act, or FDORA, Congress required sponsors to develop and submit a diversity action plan, or DAP, for each Phase 3 clinical trial or any other "pivotal study" of a new drug or biological product. These plans are meant to encourage the enrollment of more diverse patient populations in late-stage clinical trials of FDA-regulated products. Specifically, action plans must include the sponsor's goals for enrollment, the underlying rationale for those goals, and an explanation of how the sponsor intends to meet them. In addition to these requirements, the legislation directs the FDA to issue new guidance on diversity action plans. In June 2024, as mandated by FDORA, the FDA issued draft guidance outlining the general requirements for DAPs. Unlike most guidance documents issued by the FDA, the DAP guidance when finalized will have the force of law because FDORA specifically dictates that the form and manner for submission of DAPs are specified in FDA guidance.

In June 2023, the FDA issued draft guidance with updated recommendations for GCPs aimed at modernizing the design and conduct of clinical trials. The updates are intended to help pave the way for more efficient clinical trials to facilitate the development of medical products. The draft guidance is adopted from the International Council for Harmonisation's recently updated E6(R3) draft guideline that was developed to enable the incorporation of rapidly developing technological and methodological innovations into the clinical trial enterprise. In addition, the FDA issued draft guidance outlining recommendations for the implementation of decentralized clinical trials.

Finally, sponsors of clinical trials are required to register and disclose certain clinical trial information on a public registry (clinicaltrials.gov) maintained by the U.S. National Institutes of Health, or NIH. In particular, information related to the product, patient population, phase of investigation, study sites and investigators and other aspects of the clinical trial is made public as part of the registration of the clinical trial. Although the FDA has historically not enforced these reporting requirements due to the long delay by the Department of Health and Human Services, or HHS, in issuing final implementing regulations, those regulations have now been issued. As of December 19, 2024, the FDA has issued six notices of non-compliance, thereby signaling the government's willingness to begin enforcing these requirements against non-compliant clinical trial sponsors. While these notices of non-compliance did not result in civil monetary penalties, the failure to submit clinical trial information to clinicaltrials.gov is a prohibited act under the FDCA with violations subject to potential civil monetary penalties of up to $10,000 for each day the violation continues. Violations may also result in injunctions and/or criminal prosecution or disqualification from federal grants.

Concurrent with clinical trials, companies often complete additional animal studies and must also develop additional information about the chemistry and physical characteristics of the candidate product as well as 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 drug candidate and, among other things, must develop methods for testing the identity, strength, quality, purity, and potency of the final drug. Additionally, appropriate packaging must be selected and tested and stability studies must be conducted to demonstrate that the drug candidate does not undergo unacceptable deterioration over its shelf life.

Interactions with FDA During the Clinical Development Program

Following the clearance of an IND and the commencement of clinical trials, the sponsor will continue to have interactions with the FDA. Progress reports detailing the results of clinical trials must be submitted annually within 60 days of the anniversary dates that the IND went into effect and more frequently if serious adverse events occur. These reports must include a development safety update report, or DSUR, which is submitted on an annual basis to the FDA. In addition, IND safety reports must be submitted to the FDA for any of the following: serious and unexpected suspected adverse reactions; findings from other trials or animal or *in vitro* testing that suggest a significant risk in humans exposed to the product; and any clinically important increase in the occurrence of a serious suspected adverse reaction over that listed in the protocol or investigator brochure. Phase 1, Phase 2 and Phase 3 clinical trials may not be completed successfully within any specified period, or at all. The FDA will typically inspect one or more clinical sites to assure compliance with GCP and the integrity of the clinical data submitted.

In addition, sponsors are given opportunities to meet with the FDA at certain points in the clinical development program. Specifically, sponsors may meet with the FDA prior to the submission of an IND (pre-IND meeting), at the end of Phase 2 clinical trial (EOP2 meeting) and before a BLA is submitted (pre-BLA meeting). Meetings at other times may also be requested. There are five types of meetings that occur between sponsors and the FDA. Type A meetings are those that are necessary for an otherwise stalled product development program to proceed or to address an important safety issue. Type B meetings include pre-IND and pre-BLA meetings, as well as end of phase meetings such as EOP2 meetings. A Type C meeting is any meeting other than a Type A or Type B meeting regarding the development and review of a product, including for example meetings to facilitate early consultations on the use of a biomarker as a new surrogate endpoint that has never been previously used as the primary basis for product approval in the proposed context of use. A Type D meeting is focused on a narrow set of issues, which should be limited to no more than two focused topics, and should not require input from more than three disciplines or divisions. Finally, INTERACT meetings are intended for novel products and development programs that present unique challenges in the early development of an investigational product.

The FDA has indicated that its responses, as conveyed in meeting minutes and advice letters, only constitute mere recommendations and/or advice made to a sponsor and, as such, sponsors are not bound by such recommendations and/or advice. Nonetheless, from a practical perspective, a sponsor's failure to follow the FDA's recommendations for design of a clinical program may put the program at significant risk of failure.

Clinical Studies Outside the United States in Support of FDA Approval

In connection with our clinical development program, we may conduct trials at sites outside the United States. When a foreign clinical study is conducted under an IND, all IND requirements must be met unless waived. When a foreign clinical study is not conducted under an IND, the sponsor must ensure that the study complies with certain regulatory requirements of the FDA in order to use the study as support for an IND or application for marketing approval. Specifically, the studies must be conducted in accordance with GCP, including undergoing review and receiving approval by an independent ethics committee, or IEC, and seeking and receiving informed consent from subjects. GCP requirements encompass both ethical and data integrity standards for clinical studies. The FDA's regulations are intended to help ensure the protection of human subjects enrolled in non-IND foreign clinical studies, as well as the quality and integrity of the resulting data. They further help ensure that non-IND foreign studies are conducted in a manner comparable to that required for IND studies.

The acceptance by the FDA of study data from clinical trials conducted outside the United States in support of U.S. approval 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, 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 are subject to the applicable local laws of the foreign jurisdictions where the trials are conducted.

Manufacturing and cGMP requirements

Concurrent with clinical trials, sponsors usually complete additional animal safety studies, develop additional information about the chemistry and physical characteristics of the product candidate and finalize a process for manufacturing commercial quantities of the product candidate in accordance with cGMP requirements. The manufacturing process must be capable of consistently producing quality batches of the product candidate and, among other criteria, the sponsor must develop methods for testing the identity, strength, quality, and purity of the finished product. Additionally, 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.

The FDA's regulations require that pharmaceutical products be manufactured in specific approved facilities and in accordance with cGMPs. The cGMP regulations include requirements relating to organization of personnel, buildings and facilities, equipment, control of components and product containers and closures, production and process controls, packaging and labeling controls, holding and distribution, laboratory controls, records and reports and returned or salvaged products. Manufacturers and other entities involved in the manufacture and distribution of approved pharmaceuticals are required to register their establishments with the FDA and some state agencies and they are subject to periodic unannounced inspections by the FDA for compliance with cGMPs and other requirements.

Inspections must follow a "risk-based schedule" that may result in certain establishments being inspected more frequently. Manufacturers may also have to provide, on request, electronic or physical records regarding their establishments. Delaying, denying, limiting, or refusing inspection by the FDA may lead to a product being deemed to be adulterated. Changes to the manufacturing process, specifications or container closure system for an approved product are strictly regulated and often require prior FDA approval before being implemented. The FDA's regulations also require, among other things, the investigation and correction of any deviations from cGMP and the imposition of reporting and documentation requirements upon the sponsor and any third-party manufacturers involved in producing the approved product. The PREVENT Pandemics Act, which was enacted in December 2022, clarifies that foreign drug manufacturing establishments are subject to registration and listing requirements even if a drug or biologic undergoes further manufacture, preparation, propagation, compounding, or processing at a separate establishment outside the United States prior to being imported or offered for import into the United States.

Pediatric Studies

Under the Pediatric Research Equity Act of 2003, or PREA, an application or supplement thereto must contain data that are adequate to assess the safety and effectiveness of the product for the claimed indications in all relevant pediatric subpopulations, and to support dosing and administration for each pediatric subpopulation for which the product is safe and effective. Sponsors must also submit an initial Pediatric Study Plan, or PSP, prior to the assessment data. The PSP must contain an outline of the proposed pediatric study or studies the sponsor plans to conduct, including study objectives and design, any deferral or waiver requests and other information required by regulation. The sponsor, the FDA, and the FDA's internal review committee must then review the information submitted, consult with each other and agree upon a final plan. The FDA or the sponsor may request an amendment to the plan at any time. In May 2023, the FDA issued new draft guidance that further describes the pediatric study requirements under PREA.

For investigational products intended to treat a serious or life-threatening disease or condition, the FDA must, upon the request of a sponsor, meet to discuss preparation of the initial pediatric study plan or to discuss deferral or waiver of pediatric assessments. In addition, the FDA will meet early in the development process to discuss pediatric study plans with sponsors, and the FDA must meet with sponsors by no later than the end-of-phase 1 meeting for serious or life-threatening diseases and by no later than ninety days after the FDA's receipt of the study plan.

The FDA may, on its own initiative or at the request of the sponsor, grant deferrals for submission of some or all pediatric data until after approval of the product for use in adults, or full or partial waivers from the pediatric data requirements. A deferral may be granted for several reasons, including a finding that the product or therapeutic candidate is ready for approval for use in adults before pediatric trials are complete or that additional safety or effectiveness data needs to be collected before the pediatric trials begin. The FDA is required to send a PREA Non-Compliance letter to sponsors who have failed to submit their pediatric assessments required under PREA, have failed to seek or obtain a deferral or deferral extension or have failed to request approval for a required pediatric formulation. Unless otherwise required by regulation, the pediatric data requirements do not apply to products with orphan designation, although the FDA has taken steps to limit what it considers abuse of this statutory exemption. Further, Section 505B of the FDCA, as amended by the FDA Reauthorization Act of 2017, or FDARA, requires that any original NDA or BLA submitted on or after August 18, 2020, for a new active ingredient, must contain reports on the molecularly targeted pediatric cancer investigation, unless the requirement is waived or deferred, if the drug that is the subject of the application is: (1) intended for the treatment of an adult cancer, and (2) directed at a molecular target that the Secretary determines to be substantially relevant to the growth or progression of a pediatric cancer in accordance with FDA guidance. The FDA also maintains a list of diseases that are exempt from PREA requirements due to low prevalence of disease in the pediatric population.

Submission and Review of an NDA or BLA by the FDA

In order to obtain approval to market a drug or biological product in the United States, a marketing application must be submitted to the FDA that provides data establishing the safety and effectiveness of the proposed drug product for the proposed indication, and the safety, purity and potency of the biological product for its intended indication. The application includes all relevant data available from pertinent preclinical and clinical trials, including negative or ambiguous results as well as positive findings, together with detailed information relating to the product's chemistry, manufacturing, controls and proposed labeling, among other things. Data can come from company-sponsored clinical trials intended to test the safety and effectiveness of a use of a product, or from a number of alternative sources, including studies initiated by investigators.

The application is the vehicle through which sponsors formally propose that the FDA approve a new product for marketing and sale in the United States for one or more indications. Every new product candidate must be the subject of an approved NDA or BLA before it may be commercialized in the United States. Under federal law, the fee required for the submission and review of an application under the Prescription Drug User Fee Act, or the PDUFA, is substantial (for example, for federal fiscal year 2025 this application fee is approximately $4.3 million), and the sponsor of an approved application is also subject to an annual program fee, currently more than $403,889 per eligible prescription product for federal fiscal year 2025. Certain exceptions and waivers are available for some of these fees, such as an exception from the application fee for products with orphan designation and a waiver for certain small businesses. If an application is withdrawn prior to the FDA acceptance for filing, 75% of these fees may be refunded to the sponsor. If an application is withdrawn after filing, a lower portion of these fees may be refunded in certain circumstances.

Following submission of an NDA or BLA, the FDA conducts a preliminary review of the application within 60 calendar days of its receipt and must inform the sponsor by that time or before whether the application is sufficiently complete to permit substantive review. In the event that the FDA determines that an application does not satisfy this standard, it will issue a Refuse to File, or RTF, determination to the sponsor. The FDA may request additional information and studies and the application must be resubmitted with the additional information. The resubmitted application is also 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 has agreed to specified performance goals in the review process of NDAs and BLAs. Under that agreement, 90% of applications seeking approval of New Molecular Entities, or NMEs, are meant to be reviewed within ten months from the date on which the FDA accepts the NDA for filing, and 90% of applications for NMEs that have been designated for "priority review" are meant to be reviewed within six months of the filing date. The review process and the PDUFA goal date may be extended by the FDA for three additional months to consider new information or clarification provided by the sponsor to address an outstanding deficiency identified by the FDA following the original submission.

The FDA seeks to meet these timelines for review of an application but its ability to do so may be affected by a variety of factors, including government budget and funding levels, the ability to hire and retain key personnel and statutory, regulatory and policy changes. Average review times at the agency have fluctuated in recent years as a result. For example, during the past decade, the U.S. government has shut down several times and certain regulatory agencies, including the FDA, have had to furlough critical employees and stop critical activities, including the review of both NDAs and BLAs.

In connection with its review of an application, the FDA typically will inspect the facility or facilities where the product is or will be manufactured. These pre-approval inspections may cover all facilities associated with an NDA or BLA submission, including drug component manufacturing (e.g., active pharmaceutical ingredients), finished drug product manufacturing, and control testing laboratories. The FDA will not approve an application unless it determines that the manufacturing processes and

facilities are in compliance with cGMP requirements and adequate to assure consistent production of the product within required specifications.

Moreover, the FDA will review a sponsor's financial relationship with the principal investigators who conducted the clinical trials in support of the BLA or NDA. Depending on the level of that compensation and any other financial interest a principal investigator may have in a sponsor, the sponsor may be required to report these relationships to the FDA. The FDA will then evaluate that financial relationship and determine whether it creates a conflict of interest or otherwise affects the interpretation of the trial or the integrity of the data generated at the principal investigator's clinical trial site. If so, the FDA may exclude data from the clinical trial site in connection with its determination of the approvability of the application for the investigational product.

Additionally, before approving an NDA or BLA, the FDA will typically inspect one or more clinical sites to assure compliance with GCP standards and the integrity of the clinical data supporting the application. With the passage of FDORA, Congress clarified the FDA's authority to conduct inspections by expressly permitting inspection of facilities involved in the preparation, conduct, or analysis of clinical and non-clinical studies submitted to the FDA as well as other persons holding study records or involved in the study process.

The FDA may also refer an application for a novel product to an advisory committee or explain why such referral was not made. Typically, an advisory committee is a panel of independent experts, including clinicians and other scientific experts, that reviews, evaluates and provides a recommendation as to whether the application should be approved and under what conditions. The FDA is not bound by the recommendations of an advisory committee, but it considers such recommendations carefully when making decisions.

The FDA's Decision on an NDA or BLA

After evaluating the application and all related information, including the advisory committee recommendations, if any, and inspection reports of manufacturing facilities and clinical trial sites, the FDA will issue either a Complete Response Letter, or CRL, or an approval letter. To reach this determination, the FDA must determine that the expected benefits of the proposed product outweigh its potential risks to patients. This "benefit-risk" assessment is informed by the extensive body of evidence about the product in the NDA or BLA.

If the FDA decides not to license or approve the application, it will issue a CRL. A CRL will describe all of the deficiencies that the FDA has identified in the application, except that where the FDA determines that the data supporting the application are inadequate to support approval, the FDA may issue the CRL without first conducting required inspections, testing submitted product lots, and/or reviewing proposed labeling. In issuing the CRL, the FDA may recommend actions that the applicant might take to place the application in condition for approval, including requests for additional information or clarification. The FDA may delay or refuse approval of an application if applicable regulatory criteria are not satisfied, require additional testing or information and/or require post-marketing testing and surveillance to monitor safety or efficacy of a product. If a CRL is issued, the applicant will have one year to respond to the deficiencies identified by the FDA, at which time the FDA can deem the application withdrawn or, in its discretion, grant the applicant an additional six month extension to respond. For those seeking to challenge the FDA's CRL decision, the FDA has indicated that sponsors may request a formal hearing on the CRL or they may file a request for reconsideration or a request for a formal dispute resolution.

An approval letter, on the other hand, authorizes commercial marketing of the product with specific prescribing information for specific indications. If the FDA approves a product, it may limit the approved indications for use for the product, require that contraindications, warnings or precautions be included in the product labeling, require that post-approval studies, including phase 4 clinical trials, be conducted to further assess the drug's safety after approval, require testing and surveillance programs to monitor the product after commercialization, or impose other conditions, including distribution restrictions or other risk management mechanisms, including REMS, which can materially affect the potential market and profitability of the product. The FDA may prevent or limit further marketing of a product based on the results of post-market studies or surveillance programs. After approval, many types of changes to the approved product, such as adding new indications, manufacturing changes and additional labeling claims, are subject to further testing requirements and FDA review and approval.

Fast Track, Breakthrough Therapy and Priority Review Designations

The FDA is authorized to designate certain products for expedited review if they are intended to address an unmet medical need in the treatment of a serious or life-threatening disease or condition. These programs include fast track designation, breakthrough therapy designation and priority review designation. None of these expedited programs changes the standards for approval but each may help expedite the development or approval process governing product candidates.

Specifically, the FDA may designate a product for Fast Track review if it is intended, whether alone or in combination with one or more other products, for the treatment of a serious or life-threatening disease or condition, and it demonstrates the potential to address unmet medical needs for such a disease or condition. For Fast Track products, sponsors may have greater interactions

with the FDA and the FDA may initiate review of sections of a Fast Track product's application before the application is complete. This rolling review may be available if the FDA determines, after preliminary evaluation of clinical data submitted by the sponsor, that a Fast Track product may be effective. The sponsor must also provide, and the FDA must approve, a schedule for the submission of the remaining information and the sponsor must pay applicable user fees. However, the FDA's time period goal for reviewing a Fast Track application does not begin until the last section of the application is submitted. In addition, the Fast Track designation may be withdrawn by the FDA if the FDA believes that the designation is no longer supported by data emerging in the clinical trial process.

Second, a product may be designated as a Breakthrough Therapy if it is intended, either alone or in combination with one or more other products, to treat a serious or life-threatening disease or condition and preliminary clinical evidence indicates that the product 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 FDA may take certain actions with respect to Breakthrough Therapies, including holding meetings with the sponsor throughout the development process; providing timely advice to the product sponsor regarding development and approval; involving more senior staff in the review process; assigning a cross-disciplinary project lead for the review team; and taking other steps to help the sponsor design the clinical trials in an efficient manner.

Third, the FDA may designate a product for priority review if it is a product that treats a serious condition and, if approved, would provide a significant improvement in safety or effectiveness. The FDA determines, on a case-by-case basis, whether the proposed product represents a significant improvement when compared with other available therapies. Significant improvement may be illustrated by evidence of increased effectiveness in the treatment of a condition, elimination or substantial reduction of a treatment-limiting product reaction, documented enhancement of patient compliance that may lead to improvement in serious outcomes, and evidence of safety and effectiveness in a new subpopulation. A priority designation is intended to direct overall attention and resources to the evaluation of such applications, and to shorten the FDA's goal for taking action on a marketing application from ten months to six months.

Accelerated Approval Pathway

The FDA may grant accelerated approval to a product for a serious or life-threatening condition that provides meaningful therapeutic advantage to patients over existing treatments based upon a determination that the product has an effect on a surrogate endpoint that is reasonably likely to predict clinical benefit. The FDA may also grant accelerated approval for such a condition when the product has an effect on an intermediate clinical endpoint that can be measured earlier than an effect on irreversible morbidity or mortality, or IMM, and 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. Products granted accelerated approval must meet the same statutory standards for safety and effectiveness as those granted traditional approval.

For the purposes of accelerated approval, a surrogate endpoint is a marker, such as a laboratory measurement, radiographic image, physical sign or other measure that is thought to predict clinical benefit, but is not itself a measure of clinical benefit. Surrogate endpoints can often be measured more easily or more rapidly than clinical endpoints. An intermediate clinical endpoint is a measurement of a therapeutic effect that is considered reasonably likely to predict the clinical benefit of a drug, such as an effect on IMM. The FDA has limited experience with accelerated approvals based on intermediate clinical endpoints, but has indicated that such endpoints generally may support accelerated approval where the therapeutic effect measured by the endpoint is not itself a clinical benefit and basis for traditional approval, if there is a basis for concluding that the therapeutic effect is reasonably likely to predict the ultimate clinical benefit of a product.

The accelerated approval pathway is most often used in settings in which the course of a disease is long and an extended period of time is required to measure the intended clinical benefit of a product, even if the effect on the surrogate or intermediate clinical endpoint occurs rapidly. Thus, accelerated approval has been used extensively in the development and approval of products for treatment of a variety of cancers in which the goal of therapy is generally to improve survival or decrease morbidity and the duration of the typical disease course requires lengthy and sometimes large trials to demonstrate a clinical or survival benefit. Thus, the benefit of accelerated approval derives from the potential to receive approval based on surrogate endpoints sooner than possible for trials with clinical or survival endpoints, rather than deriving from any explicit shortening of the FDA approval timeline, as is the case with priority review.

The accelerated approval pathway is usually contingent on a sponsor's agreement to conduct, in a diligent manner, additional post-approval confirmatory studies to verify and describe the product's clinical benefit. As a result, a product candidate approved on this basis is subject to rigorous post-marketing compliance requirements, including the completion of Phase 4 or post-approval clinical trials to confirm the effect on the clinical endpoint. Failure to conduct required post-approval studies, or confirm a clinical benefit during post-marketing studies, would allow the FDA to initiate expedited proceedings to withdraw approval of the product. All promotional materials for product candidates approved under accelerated regulations are subject to prior review by the FDA.

With the passage of FDORA, Congress modified certain provisions governing accelerated approval of drug and biologic products. Specifically, the new legislation authorized the FDA to require a sponsor to have its confirmatory clinical trial underway before accelerated approval is awarded and to submit progress reports on its post-approval studies to the FDA every six months until the study is completed. Moreover, FDORA established expedited procedures authorizing the FDA to withdraw an accelerated approval if certain conditions are met, including where a required confirmatory study fails to verify and describe the predicted clinical benefit or where evidence demonstrates the product is not shown to be safe or effective under the conditions of use. The FDA may also use such procedures to withdraw an accelerated approval if a sponsor fails to conduct any required post-approval study of the product with due diligence, including with respect to "conditions specified by the Secretary." The new procedures include the provision of due notice and an explanation for a proposed withdrawal, and opportunities for a meeting with the Commissioner or the Commissioner's designee and a written appeal, among other things.

In March 2023, the FDA issued draft guidance that outlines its current thinking and approach to accelerated approval. The agency indicated that the accelerated approval pathway is commonly used for approval of oncology drugs due to the serious and life-threatening nature of cancer. Although single-arm trials have been commonly used to support accelerated approval, a randomized controlled trial is the preferred approach as it provides a more robust efficacy and safety assessment and allows for direct comparisons to an available therapy. To that end, the FDA outlined considerations for designing, conducting, and analyzing data for trials intended to support accelerated approvals of oncology therapeutics. Subsequently, in December 2024 and January 2025, the FDA issued additional draft guidances relating to accelerated approval. These guidances describe FDA's views on what it means to conduct a confirmatory trial with due diligence and how the agency plans to interpret whether such a study needs to be underway at the time of approval. While these guidances are currently only in draft form and will ultimately not be legally binding even when finalized, sponsors typically observe the FDA's guidance closely to ensure that their investigational products qualify for accelerated approval.

Post-Approval Regulation

Drugs and biologics manufactured or distributed pursuant to FDA approvals are subject to pervasive and continuing regulation by the FDA, including, among other things, requirements relating to recordkeeping, periodic reporting, product sampling and distribution, advertising and promotion and reporting of adverse experiences with the product. After approval, most changes to the approved product, such as adding new indications or other labeling claims, are subject to prior FDA review and approval. There also are continuing, annual user fee requirements for any marketed products and the establishments at which such products are manufactured, as well as new application fees for supplemental applications with clinical data.

In addition, changes to the manufacturing process are strictly regulated and often require prior FDA approval before being implemented. FDA regulations also require investigation and correction of any deviations from cGMP and impose reporting and documentation requirements upon the sponsor and any third-party manufacturers that the sponsor may decide to use. Accordingly, manufacturers must continue to expend time, money, and effort in the area of production and quality control to maintain cGMP compliance.

Once an approval is granted, the FDA may withdraw the approval if compliance with regulatory requirements and standards is not maintained or if problems occur after the product reaches the market. Later discovery of previously unknown problems with a product, including adverse events of unanticipated severity or frequency, or with manufacturing processes, or failure to comply with regulatory requirements, may result in revisions to the approved labeling to add new safety information; imposition of post-market studies or clinical trials to assess new safety risks; or imposition of distribution or other restrictions under a REMS program. Other potential consequences include, among other things:

- restrictions on the marketing or manufacturing of the product, suspension of the approval, or complete withdrawal of the product from the market or product recalls;
- fines, warning letters or holds on post-approval clinical trials;
- refusal of the FDA to approve pending NDAs or supplements to approved NDAs, or suspension or revocation of product license approvals;
- product seizure or detention, or refusal to permit the import or export of products; or
- injunctions or the imposition of civil or criminal penalties.

In addition, the distribution of prescription pharmaceutical products is subject to a variety of federal and state laws. The Prescription Drug Marketing Act, or the PDMA, was the first federal law to set minimum standards for the registration and regulation of drug distributors by the states and to regulate the distribution of drug samples. Both the PDMA and state laws limit the distribution of prescription pharmaceutical product samples and impose requirements to ensure accountability in distribution. In November 2013, the federal Drug Supply Chain Security Act became effective in the United States, mandating an industry-wide, electronic, interoperable system to trace prescription drugs through the pharmaceutical distribution supply chain with a ten-year phase-in process. Manufacturers were required by November 2023 to have such systems and processes in place but in August 2023, the FDA set a one-year period in which it would exercise its enforcement discretion with respect to

these requirements. So as not to disrupt supply chains, the FDA has granted certain exemptions from enhanced drug distribution security requirements for eligible trading partners for particular periods of time.

Finally, the FDA strictly regulates marketing, labeling, advertising and promotion of products that are placed on the market. Products may be promoted only for the approved indications and in accordance with the provisions of the approved label. 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 liability. In September 2021, the FDA published final regulations which describe the types of evidence that it will consider in determining the intended use of a drug or biologic.

If a company is found to have promoted off-label uses, it may become subject to adverse public relations and administrative and judicial enforcement by the FDA, the Department of Justice, or the Office of the Inspector General of the Department of Health and Human Services, as well as state authorities. This could subject a company to a range of penalties that could have a significant commercial impact, including civil and criminal fines and agreements that materially restrict the manner in which a company promotes or distributes drug products.

It may be permissible, under very specific, narrow conditions, for a manufacturer to engage in nonpromotional, non-misleading communication regarding off-label information, such as distributing scientific or medical journal information. Moreover, with passage of the Pre-Approval Information Exchange Act in December 2022, sponsors of products that have not been approved may proactively communicate to payors certain information about products in development to help expedite patient access upon product approval. Previously, such communications were permitted under FDA guidance, but the new legislation explicitly provides protection to sponsors who convey certain information about products in development to payors, including unapproved uses of approved products.

In addition, in January 2025, the FDA published final guidance outlining its policies governing the distribution of scientific information to healthcare providers about unapproved uses of approved products. The final guidance calls for such communications to be truthful, non-misleading and scientifically sound and to include all information necessary for healthcare providers to interpret the strengths and weaknesses and validity and utility of the information about the unapproved use of the approved product. If a company engages in such communications consistent with the guidance's recommendations, the FDA indicated that it will not treat such communications as evidence of unlawful promotion of a new intended use for the approved product.

Section 505(b)(2) NDAs

NDAs for most new drug products are based on two full clinical studies which must contain substantial evidence of the safety and efficacy of the proposed new product. These applications are submitted under Section 505(b)(1) of the FDCA. The FDA is, however, authorized to approve an alternative type of NDA under Section 505(b)(2) of the FDCA. This type of application allows the sponsor to rely, in part, on the FDA's previous findings of safety and effectiveness for a similar product or published literature. Specifically, Section 505(b)(2) applies to NDAs for a drug for which the investigations made to show whether or not the drug is safe for use and effective in use and relied upon by the sponsor for approval of the application "were not conducted by or for the sponsor and for which the sponsor has not obtained a right of reference or use from the person by or for whom the investigations were conducted."

Section 505(b)(2) authorizes the FDA to approve an NDA based on safety and efficacy data that were not developed by the sponsor. NDAs filed under Section 505(b)(2) may provide an alternate and potentially more expeditious pathway to FDA approval for new or improved formulations or new uses of previously approved products. If the Section 505(b)(2) sponsor can establish that reliance on the FDA's previous approval is scientifically appropriate, the sponsor may eliminate the need to conduct certain preclinical or clinical studies of the new product. The FDA may also require companies to perform additional studies or measurements to support the change from the approved product. The FDA may then approve the new drug candidate for all or some of the label indications for which the referenced product has been approved, as well as for any new indication sought by the Section 505(b)(2) sponsor.

Generic Drugs and Regulatory Exclusivity

In 1984, with passage of the Hatch-Waxman Amendments to the FDCA, Congress established an abbreviated regulatory scheme authorizing the FDA to approve generic drugs that are shown to contain the same active ingredients as, and to be bioequivalent to, drugs previously approved by the FDA pursuant to NDAs. To obtain approval of a generic drug, a sponsor must submit an abbreviated new drug application, or ANDA, to the FDA. An ANDA is a comprehensive submission that contains, among other things, data and information pertaining to the active pharmaceutical ingredient, bioequivalence, drug product formulation, specifications and stability of the generic drug, as well as analytical methods, manufacturing process validation data and quality control procedures. ANDAs are "abbreviated" because they generally do not include preclinical and clinical data to demonstrate safety and effectiveness. Instead, in support of such applications, a generic manufacturer may rely

on the preclinical and clinical testing previously conducted for a drug product previously approved under an NDA, known as the reference-listed drug, or RLD.

Under the Hatch-Waxman Amendments, the FDA may not approve an ANDA or 505(b)(2) application until any applicable period of non-patent exclusivity for the RLD has expired. The FDCA provides a period of five years of regulatory exclusivity for a new drug containing a new chemical entity, or NCE. For the purposes of this provision, an NCE is a drug that contains no active moiety that has previously been approved by the FDA in any other NDA. This interpretation of the FDCA by the FDA was confirmed with enactment of the Ensuring Innovation Act in April 2021. An active moiety is the molecule or ion responsible for the physiological or pharmacological action of the drug substance. In cases where such NCE exclusivity has been granted, an ANDA may not be filed with the FDA until the expiration of five years unless the submission is accompanied by a Paragraph IV certification, in which case the sponsor may submit its application four years following the original product approval. The FDCA also provides for a period of three years of exclusivity if the NDA includes reports of one or more new clinical investigations, other than bioavailability or bioequivalence studies, that were conducted by or for the sponsor and are essential to the approval of the application.

Biosimilars and Regulatory Exclusivity

The 2010 Patient Protection and Affordable Care Act, or ACA, which was signed into law on March 23, 2010, included a subtitle called the Biologics Price Competition and Innovation Act of 2009, or BPCIA. The BPCIA established a regulatory scheme authorizing the FDA to approve biosimilars and interchangeable biosimilars. To date, the FDA has approved a number of biosimilars and several interchangeable biosimilar products.

Under the BPCIA, a manufacturer may submit an application for licensure of a biologic product that is "biosimilar to" or "interchangeable with" a previously approved biological product or "reference product." In order for the FDA to license a biosimilar product, it must find that there are no clinically meaningful differences between the reference product and proposed biosimilar product in terms of safety, purity, and potency. For the FDA to license a biosimilar product as interchangeable with a reference product, the FDA must find that the biosimilar product can be expected to produce the same clinical results as the reference product, and (for products administered multiple times) that the biologic and the reference biologic may be switched after one has been previously administered without increasing safety risks or risks of diminished efficacy relative to exclusive use of the reference biologic. In December 2022, Congress clarified through FDORA that the FDA may license multiple first interchangeable biosimilar biological products so long as the products are all licensed on the first day on which such a product is approved as interchangeable with the reference product.

Under the BPCIA, an application for a biosimilar product may not be submitted to the FDA until four years following the date of approval of the reference product. The FDA may not license a biosimilar product until 12 years from the date on which the reference product was licensed. Even if a product is considered to be a reference product eligible for exclusivity, another company could market a competing version of that product if the FDA approves a full BLA for such 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 licensed as interchangeable products. There have been recent government proposals to reduce the 12-year reference product exclusivity period, but none has been enacted to date. At the same time, since passage of the BPCIA, many states have passed laws or amendments to laws, which address pharmacy practices involving biosimilar products.

Orphan Drug Designation and Exclusivity

Under the Orphan Drug Act, the FDA may designate a drug product as an "orphan drug" if it is intended to treat a rare disease or condition, generally meaning that it affects fewer than 200,000 individuals in the United States, or more in cases in which there is no reasonable expectation that the cost of developing and making a drug product available in the United States for treatment of the disease or condition will be recovered from sales of the product. A company must request orphan drug designation before submitting an NDA or BLA for the candidate product. If the request is granted, the FDA will disclose the identity of the therapeutic agent and its potential use. Orphan drug designation does not shorten the PDUFA goal dates for the regulatory review and approval process, although it does convey certain advantages such as tax benefits and exemption from the PDUFA application fee.

If a product with orphan drug designation receives the first FDA approval for the disease or condition for which it has such designation or for a select indication or use within the rare disease or condition for which it was designated, the product generally will receive orphan drug exclusivity. Orphan drug exclusivity means that the FDA may not approve another sponsor's marketing application for the same drug for the same indication for seven years, except in certain limited circumstances. Orphan drug exclusivity does not block the approval of a different product for the same rare disease or condition, nor does it block the approval of the same product for different indications. If a drug or biologic designated as an orphan drug ultimately receives marketing approval for an indication broader than what was designated in its orphan drug application, it may not be entitled to exclusivity.

Orphan drug exclusivity will not bar approval of another product under certain circumstances, including if a company with orphan drug exclusivity is not able to meet market demand and in cases where a subsequent product with the same drug or biologic for the same indication is shown to be clinically superior to the approved product on the basis of greater efficacy or safety, or providing a major contribution to patient care. Under Omnibus legislation signed by President Trump on December 27, 2020, the requirement for a subsequent product to show clinical superiority in order to break the previous product's orphan drug exclusivity applies to drugs and biologics that received orphan drug designation before enactment of FDARA in 2017 but have not yet been approved or licensed by FDA.

In September 2021, the Court of Appeals for the 11th Circuit held that, for the purpose of determining the scope of market exclusivity, the term "same disease or condition" in the statute means the designated "rare disease or condition" and could not be interpreted by the FDA to mean the "indication or use." Thus, the court concluded, orphan drug exclusivity applies to the entire designated disease or condition rather than the "indication or use." Although there have been legislative proposals to overrule this decision, they have not been enacted into law. On January 23, 2023, the FDA announced that, in matters beyond the scope of that court order, the FDA will continue to apply its existing regulations tying orphan drug exclusivity to the uses or indications for which the orphan drug was approved.

Pediatric Exclusivity

Pediatric exclusivity is another type of non-patent marketing exclusivity in the United States and, if granted, provides for the attachment of an additional six months of regulatory exclusivity. For drug products, the six-month period of exclusivity may be attached to the term of any existing patent or regulatory exclusivity. For biologic products, the six-month period may only be attached to any existing regulatory exclusivities but not to any patent terms. This six-month exclusivity may be granted if an NDA or BLA sponsor submits pediatric data that fairly respond to a written request from the FDA for such data. The data do not need to show the product to be effective in the pediatric population studied; rather, if the clinical trial is deemed to fairly respond to the FDA's request, the additional protection is granted. If reports of requested pediatric studies are submitted to and accepted by the FDA within the statutory time limits, whatever statutory or regulatory periods of non-patent exclusivity for drugs and biologics, or patent protection that covers a drug product, are extended by six months. This is not a patent term extension, but it effectively extends the regulatory period during which the FDA cannot approve another application.

Patent Term Restoration and Extension

A patent claiming a new drug product may be eligible for a limited patent term extension under the Hatch-Waxman Amendments, which permits a patent restoration of up to five years for patent term lost during product development and the FDA regulatory review. The restoration period granted on a patent covering a product is typically one-half the time between the effective date of the IND approval and the submission date of an application, plus the time between the submission date of an application and the ultimate approval date. Patent term restoration cannot be used to extend the remaining term of a patent past a total of 14 years from the product's approval date. Only one patent applicable to an approved product is eligible for the extension, and the application for the extension must be submitted prior to the expiration of the patent in question. A patent that covers multiple products for which approval is sought can only be extended in connection with one of the approvals. The USPTO reviews and approves the application for any patent term extension or restoration in consultation with the FDA.

Pharmaceutical Coverage, Pricing and Reimbursement

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. Significant uncertainty exists as to the coverage and reimbursement status of products approved by the FDA and other government authorities. Thus, even if a product candidate is approved, sales of the product will depend, in part, on the extent to which third-party payors, including government health programs in the United States such as Medicare and Medicaid, commercial health insurers and managed care organizations, provide coverage, and establish adequate reimbursement levels for, the product. The process for determining whether a payor will provide coverage for a product may be separate from the process for setting the price or reimbursement rate that the payor will pay for the product once coverage is approved. Third-party payors are increasingly challenging the prices charged, examining the medical necessity, and reviewing the cost-effectiveness of medical products and services and imposing controls to manage costs. 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 approved products for a particular indication.

In order to secure coverage and reimbursement for any product that might be approved for sale, a company may need to conduct expensive pharmacoeconomic studies in order to demonstrate the medical necessity and cost-effectiveness of the product, in addition to the costs required to obtain FDA or other comparable marketing approvals. Nonetheless, product candidates may not be considered medically necessary or cost effective. A decision by a third-party payor not to cover a product candidate could reduce physician utilization once the product is approved and have a material adverse effect on sales, results of operations and financial condition. Additionally, a payor's decision to provide coverage for a product does not imply that an

adequate reimbursement rate will be approved. Further, one payor's determination to provide coverage for a drug product does not assure that other payors will also provide coverage and reimbursement for the product, and the level of coverage and reimbursement can differ significantly from payor to payor.

Healthcare Law and Regulation

Health care providers and third-party payors play a primary role in the recommendation and prescription of drug products that are granted marketing approval. Arrangements with providers, consultants, third-party payors and customers are subject to broadly applicable fraud and abuse, anti-kickback, false claims laws, patient privacy laws and regulations and other health care laws and regulations that may constrain business and/or financial arrangements.

Restrictions under applicable federal and state healthcare laws and regulations, including certain laws and regulations applicable only if we have marketed products, include the following:

- federal false claims, false statements and civil monetary penalties laws prohibiting, among other things, any person from knowingly presenting, or causing to be presented, a false claim for payment of government funds or knowingly making, or causing to be made, a false statement to get a false claim paid;
- federal healthcare program anti-kickback law, which prohibits, among other things, persons from offering, soliciting, receiving or providing remuneration, directly or indirectly, to induce either the referral of an individual for, or the purchasing or ordering of, a good or service for which payment may be made under federal healthcare programs such as Medicare and Medicaid; the federal Health Insurance Portability and Accountability Act of 1996, or HIPAA, which, in addition to privacy protections applicable to healthcare providers and other entities, prohibits executing a scheme to defraud any healthcare benefit program or making false statements relating to healthcare matters;
- federal laws that require pharmaceutical manufacturers to report certain calculated product prices to the government or provide certain discounts or rebates to government authorities or private entities, often as a condition of reimbursement under government healthcare programs;
- federal Open Payments (or federal "sunshine" law), which requires pharmaceutical and medical device companies to monitor and report certain financial interactions with certain healthcare providers to the Center for Medicare & Medicaid Services, or the CMS, within the HHS for re-disclosure to the public, as well as ownership and investment interests held by physicians and their immediate family members;
- federal consumer protection and unfair competition laws, which broadly regulate marketplace activities and activities that potentially harm consumers;
- analogous state laws and regulations, including: state anti-kickback and false claims laws; state laws requiring pharmaceutical companies to comply with specific compliance standards, restrict financial interactions between pharmaceutical companies and healthcare providers or require pharmaceutical companies to report information related to payments to health care providers or marketing expenditures; and state laws governing privacy, security and breaches of health information in certain circumstances, many of which differ from each other in significant ways and often are not preempted by HIPAA, thus complicating compliance efforts; and
- laws and regulations prohibiting bribery and corruption such as the Foreign Corrupt Practices Act, which, among other things, prohibits U.S. companies and their employees and agents from authorizing, promising, offering, or providing, directly or indirectly, corrupt or improper payments or anything else of value to foreign government officials, employees of public international organizations or foreign government-owned or affiliated entities, candidates for foreign public office, and foreign political parties or officials thereof.

Similar healthcare laws and regulations exist in the EU and other jurisdictions, including reporting requirements detailing interactions with and payments to healthcare providers and laws governing the privacy and security of personal information.

Further, some state laws require pharmaceutical companies to comply with the pharmaceutical industry's voluntary compliance guidelines and the relevant compliance guidance promulgated by the federal government in addition to requiring manufacturers to report information related to payments to physicians and other health care providers or marketing expenditures. Additionally, some state and local laws require the registration of pharmaceutical sales representatives in the jurisdiction.

State and foreign laws also govern the privacy and security of health information in some circumstances, many of which differ from each other in significant ways and often are not preempted by HIPAA, thus complicating compliance efforts. In particular, numerous federal and state laws and regulations, including state data breach notification laws, state health information privacy laws, and federal and state consumer protection laws, govern the collection, use, disclosure, and protection of health-related and other personal information.

Violation of the laws described above or any other governmental laws and regulations may result in significant penalties, including civil, criminal, and administrative penalties, damages, fines, the curtailment or restructuring of operations, the exclusion from participation in federal and state healthcare programs, disgorgement, contractual damages, reputational harm, diminished profits and future earnings, imprisonment, and additional reporting requirements and oversight if a manufacturer becomes subject to a corporate integrity agreement or similar agreement to resolve allegations of non-compliance with these laws. Furthermore, efforts to ensure that business activities and business arrangements comply with applicable healthcare laws and regulations can be costly.

Healthcare Reform

The containment of health care costs also has become a priority of federal, state and foreign governments and the prices of products have been a focus in this effort. Governments have shown significant interest in implementing cost-containment programs, including price controls, restrictions on reimbursement and requirements for substitution of generic products. Adoption of price controls and cost-containment measures, and adoption of more restrictive policies in jurisdictions with existing controls and measures, could further limit a company's revenue generated from the sale of any approved products. Coverage policies and third-party reimbursement rates may change at any time. Even if favorable coverage and reimbursement status is attained for one or more products for which a company or its collaborators receive marketing approval, less favorable coverage policies and reimbursement rates may be implemented in the future.

There have been a number of federal and state proposals during the last few years regarding the pricing of pharmaceutical and biopharmaceutical products, limiting coverage and reimbursement for drugs and biologics and other medical products, government control and other changes to the health care system in the United States. In March 2010, President Obama signed into law the ACA. In addition, other legislative changes have been proposed and adopted since the ACA was enacted. In August 2011, the Budget Control Act of 2011, among other things, created measures for spending reductions by Congress including aggregate reductions to Medicare payments to providers of up to 2% per fiscal year, which went into effect in April 2013 and will remain in effect through 2031.

The American Taxpayer Relief Act of 2012, among other things, reduced Medicare payments to several providers and increased the statute of limitations period for the government to recover overpayments to providers from three to five years. These laws may result in additional reductions in Medicare and other healthcare funding and otherwise affect the prices we may obtain for any of our product candidates for which we may obtain regulatory approval or the frequency with which any such product candidate is prescribed or used. The Consolidated Appropriations Act, which was signed into law by President Biden in December 2022, made several changes to sequestration of the Medicare program. Section 1001 of the Consolidated Appropriations Act delays the 4% Statutory Pay-As-You-Go Act of 2010 sequester for two years, through the end of calendar year 2024. Triggered by enactment of the American Rescue Plan Act of 2021, the 4% cut to the Medicare program would have taken effect in January 2023. The Consolidated Appropriations Act's health care offset title includes Section 4163, which extends the 2% Budget Control Act of 2011 Medicare sequester for six months into fiscal year 2032 and lowers the payment reduction percentages in fiscal years 2030 and 2031.

Since enactment of the ACA, there have been, and continue to be, numerous legal challenges and Congressional actions to repeal and replace provisions of the law. For example, with enactment of the Tax Cuts and Jobs Act of 2017, or the TCJA, which was signed by President Trump on December 22, 2017, Congress repealed the "individual mandate." The repeal of this provision, which requires most Americans to carry a minimal level of health insurance, became effective in 2019. On June 17, 2021, the U.S. Supreme Court dismissed a judicial challenge to the ACA brought by several states without specifically ruling on the constitutionality of the ACA. Thus, the ACA will remain in effect in its current form. The nature and scope of health care reform in the second Trump administration remains uncertain but early actions suggest that efforts to undermine the ACA will be renewed and litigation and legislation over the ACA are likely to continue, with unpredictable and uncertain results.

Pharmaceutical Price Reform

The prices of prescription pharmaceuticals have also been the subject of considerable discussion in the United States. There have been several recent U.S. congressional inquiries, as well as proposed and enacted state and federal legislation designed to, among other things, bring more transparency to pharmaceutical pricing, review the relationship between pricing and manufacturer patient programs, and reduce the costs of pharmaceuticals under Medicare and Medicaid.

In addition, in October 2020, HHS and the FDA published a final rule allowing states and other entities to develop a Section 804 Importation Program to import certain prescription drugs from Canada into the United States. That regulation was challenged in a lawsuit by the Pharmaceutical Research and Manufacturers of America, or PhRMA, but the case was dismissed by a federal district court in February 2023 after the court found that PhRMA did not have standing to sue HHS. Seven states (Colorado, Florida, Maine, New Hampshire, New Mexico, Texas and Vermont) have passed laws allowing for the importation of products from Canada. North Dakota and Virginia have passed legislation establishing workgroups to examine the impact of a state importation program. As of May 2024, five states (Colorado, Florida, Maine, New Hampshire and New Mexico) had

submitted Section 804 Importation Program proposals to the FDA. On January 5, 2023, the FDA approved Florida's plan for Canadian product importation. That state now has authority to import certain products from Canada for a period of two years once certain conditions are met. Florida will first need to submit a pre-import request for each product selected for importation, which must be approved by the FDA. The state will also need to relabel the products and perform quality testing of the products to meet FDA standards.

Further, on November 20, 2020, HHS finalized a regulation removing safe harbor protection for price reductions from pharmaceutical manufacturers to plan sponsors under Part D, either directly or through pharmacy benefit managers, unless the price reduction is required by law. The rule also creates a new safe harbor for price reductions reflected at the point-of-sale, as well as a safe harbor for certain fixed fee arrangements between pharmacy benefit managers and manufacturers. Pursuant to court order, the removal and addition of the aforementioned safe harbors were delayed and recent legislation imposed a moratorium on implementation of the rule until January 1, 2026. The Inflation Reduction Act of 2022, or IRA, further delayed implementation of this rule to January 1, 2032.

On August 16, 2022, the IRA was signed into law by President Biden. The new legislation has implications for Medicare Part D, which is a program available to individuals who are entitled to Medicare Part A or enrolled in Medicare Part B to give them the option of paying a monthly premium for outpatient prescription drug coverage. 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 (beginning in 2025). The IRA permits the Secretary of HHS to implement many of these provisions through guidance, as opposed to regulation, for the initial years.

Specifically, with respect to price negotiations, Congress authorized Medicare to negotiate lower prices for certain costly single-source drug and biologic products that do not have competing generics or biosimilars and are reimbursed under Medicare Part B and Medicare Part D. CMS may negotiate prices for ten high-cost drugs paid for by Medicare Part D starting in 2026, followed by 15 Medicare Part D drugs in 2027, 15 Medicare Part B or Medicare Part D drugs in 2028, and 20 Medicare Part B or Medicare Part D drugs in 2029 and beyond. This provision applies to drug products that have been approved for at least nine years and biologics that have been licensed for 13 years, but it does not apply to drugs and biologics that have been approved for a single rare disease or condition.

The first cycle of negotiations for the Medicare Drug Price Negotiation Program commenced in the summer of 2023. On August 15, 2024, the HHS published the results of the first Medicare drug price negotiations for ten selected drugs that treat a range of conditions, including diabetes, chronic kidney disease, and rheumatoid arthritis. The prices of these ten drugs will become effective January 1, 2026. On January 17, 2025, CMS announced its selection of 15 additional drugs covered by Part D for the second cycle of negotiations. CMS issued a public statement on January 29, 2025, declaring that lowering the cost of prescription drugs is a top priority of the new administration and CMS is committed to considering opportunities to bring greater transparency in the negotiation program. The second cycle of negotiations with participating drug companies will occur during 2025, and any negotiated prices for this second set of drugs will be effective starting January 1, 2027.

Further, the legislation subjects drug manufacturers to civil monetary penalties and a potential excise tax for failing to comply with the legislation by offering a price that is not equal to or less than the negotiated "maximum fair price" under the law or for taking price increases that exceed inflation. In addition to the drug price negotiation program, the IRA established inflation rebate programs under Medicare Part B and Part D. These programs require manufacturers to pay rebates to Medicare if they raise their prices for certain Part B and Part D drugs faster than the rate of inflation. On December 9, 2024, with issuance of its 2025 Physician Fee Schedule final regulation, CMS finalized its rules governing the IRA inflation rebate programs. The new law also caps Medicare out-of-pocket drug costs at an estimated $4,000 a year in 2024 and, thereafter beginning in 2025, at $2,000 a year.

On June 6, 2023, Merck & Co. filed a lawsuit against the HHS and CMS asserting that, among other things, the IRA's Drug Price Negotiation Program for Medicare constitutes an uncompensated taking in violation of the Fifth Amendment of the Constitution. Subsequently, a number of other parties, including the U.S. Chamber of Commerce, Bristol Myers Squibb Company, the PhRMA, Astellas, Novo Nordisk, Janssen Pharmaceuticals, Novartis, AstraZeneca and Boehringer Ingelheim, also filed lawsuits in various courts with similar constitutional claims against the HHS and CMS. HHS has generally won the substantive disputes in these cases, and various federal district court judges have expressed skepticism regarding the merits of the legal arguments being pursued by the pharmaceutical industry. Certain of these cases are now on appeal and, on October 30, 2024, the Court of Appeals for the Third Circuit heard oral argument in three of these cases. We expect that litigation involving these and other provisions of the IRA will continue, with unpredictable and uncertain results.

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

importation from other countries and bulk purchasing. A number of states, for example, require drug manufacturers and other entities in the drug supply chain, including health carriers, pharmacy benefit managers, wholesale distributors, to disclose information about pricing of pharmaceuticals. In addition, regional health care authorities and individual hospitals are increasingly using bidding procedures to determine what pharmaceutical products and which suppliers will be included in their prescription drug and other health care programs. These measures could reduce the ultimate demand for our products, once approved, or put pressure on our product pricing. We expect that additional state and federal healthcare reform measures will be adopted in the future, any of which could limit the amounts that federal and state governments will pay for healthcare products and services, which could result in reduced demand for our product candidates or additional pricing pressures. This is increasingly true with respect to products approved pursuant to the accelerated approval pathway. State Medicaid programs and other payers are developing strategies and implementing significant coverage barriers, or refusing to cover these products outright, arguing that accelerated approval drugs have insufficient or limited evidence despite meeting the FDA's standards for accelerated approval.

Federal and State Data Privacy Laws

There are multiple privacy and data security laws that may impact our business activities, in the United States and in other countries where we conduct trials or where we may do business in the future. These laws are evolving and may increase both our obligations and our regulatory risks in the future. In the health care industry generally, under HIPAA, the HHS has issued regulations to protect the privacy and security of protected health information used or disclosed by covered entities including certain healthcare providers, health plans and healthcare clearinghouses. HIPAA also imposes certain obligations on the business associates of covered entities that obtain protected health information in providing services to or on behalf of covered entities. HIPAA may apply to us in certain circumstances and may also apply to our business partners in ways that may impact our relationships with them.

Our clinical trials are regulated by the Common Rule, which also includes specific privacy-related provisions. In addition to federal privacy regulations, there are a number of state laws governing confidentiality and security of health information that may be applicable to our business. In addition to possible federal civil and criminal penalties for HIPAA violations, state attorneys general are authorized to file civil actions for damages or injunctions in federal courts to enforce HIPAA and seek attorney's fees and costs associated with pursuing federal civil actions. In addition, state attorneys general (along with private plaintiffs) have brought civil actions seeking injunctions and damages resulting from alleged violations of HIPAA's privacy and security rules. State attorneys general also have authority to enforce state privacy and security laws. New laws and regulations governing privacy and security may be adopted in the future as well.

At the state level, California has enacted the California Consumer Privacy Act, or CCPA, which creates new individual privacy rights for consumers (as that word is broadly defined in the law) and places increased privacy and security obligations on entities handling personal data of consumers or households. The CCPA went into effect on January 1, 2020 and requires covered companies to provide new disclosures to California consumers, provide such consumers new ways to opt-out of certain sales of personal information, and allow for a new cause of action for data breaches. Additionally, effective starting on January 1, 2023, the California Privacy Rights Act, or CPRA, significantly modified the CCPA, including by expanding consumers' rights with respect to certain sensitive personal information. The CPRA also creates a new state agency that will be vested with authority to implement and enforce the CCPA and the CPRA. The CCPA and CPRA could impact our business activities depending on how it is interpreted and exemplifies the vulnerability of our business to not only cyber threats but also the evolving regulatory environment related to personal data and individually identifiable health information. These provisions may apply to some of our business activities.

In addition to California, at least eighteen other states have passed comprehensive privacy laws similar to the CCPA and CPRA. These laws are either in effect or will go into effect sometime before the end of 2026. Like the CCPA and CPRA, these laws create obligations related to the processing of personal information, as well as special obligations for the processing of "sensitive" data, which includes health data in some cases. Some of the provisions of these laws may apply to our business activities. There are also states that are strongly considering or have already passed comprehensive privacy laws during the 2024 legislative sessions that will go into effect in 2025 and beyond. Other states will be considering similar laws in the future, and Congress has also been debating passing a federal privacy law. There are also states that are specifically regulating health information that may affect our business. For example, the State of Washington passed the My Health My Data Act in 2023 which specifically regulated health information that is not otherwise regulated by the HIPAA rules, and the law also has a private right of action, which further increases the relevant compliance risk. Connecticut and Nevada have also passed similar laws regulating consumer health data, and more states are considering such legislation in 2024. These laws may impact our business activities, including our identification of research subjects, relationships with business partners and ultimately the marketing and distribution of our products.

Plaintiffs' lawyers are also increasingly using privacy-related statutes at both the state and federal level to bring lawsuits against companies for their data-related practices. In particular, there have been a significant number of cases filed against companies

for their use of pixels and other web trackers. These cases often allege violations of the California Invasion of Privacy Act and other state laws regulating wiretapping, as well as the federal Video Privacy Protection Act.

Review and Approval of Biologics and Drugs Outside the United States

In addition to regulations in the United States, we are subject to a variety of foreign regulations governing clinical trials and commercial sales and distribution of our products outside of the United States. Whether or not we obtain FDA approval for a product candidate, we must obtain approval by the comparable regulatory authorities of foreign countries or economic areas, such as the 27-member EU, or EU, before we may commence clinical trials or market products in those countries or areas. In the EU, our product candidates also may be subject to extensive regulatory requirements. As in the United States, medicinal products can be marketed only if a marketing authorization from the competent regulatory agencies has been obtained. Similar to the United States, the various phases of preclinical and clinical research in the EU are subject to significant regulatory controls.

With the exception of the EU and European Economic Area, or EEA, applying the harmonized regulatory rules for medicinal products, the approval process and requirements governing the conduct of clinical trials, product licensing, pricing and reimbursement vary greatly between countries and jurisdictions and can involve additional testing and additional administrative review periods. The time required to obtain approval in other countries and jurisdictions might differ from and be longer than that required to obtain FDA approval. Regulatory approval in one country or jurisdiction does not ensure regulatory approval in another, but a failure or delay in obtaining regulatory approval in one country or jurisdiction may negatively impact the regulatory process in others.

Human Capital

As of December 31, 2024, we had 46 full-time employees, including a total of 18 employees with M.D. or Ph.D. degrees. Of these full-time employees, 33 employees are engaged in research and development. None of our employees are represented by labor unions or covered by collective bargaining agreements. We consider our relationship with our employees to be good.

Our human capital resources objectives include, as applicable, identifying, recruiting, retaining, incentivizing and integrating our existing and additional employees. We conduct annual performance and development reviews for each of our employees to discuss the individual's strengths and development opportunities, career development goals and performance goals. In addition, each regular full-time employee is encouraged to attend appropriate job-related trainings and other professional development courses, seminars, meetings, and similar sessions. The principal purposes of our equity incentive plans are to attract, retain and motivate selected employees, consultants and directors through the granting of stock-based compensation awards. We value our employees and regularly benchmark total rewards we provide, such as short and long term compensation, 401(k) contributions, health, welfare and quality of life benefits, paid time off and personal leave, against our industry peers to ensure we remain competitive and attractive to potential new hires.

Corporate Information

Our principal offices are located at 200 Talcott Ave, 2nd Floor, Watertown, Massachusetts, 02472, and our telephone number is (617) 952-0555.

Our website address is www.werewolftx.com. Our website and the information contained on, or that can be accessed through, the website will not be deemed to be incorporated by reference in, and are not considered part of, this Annual Report or any other report or document we file with the Securities and Exchange Commission, or the SEC, and any reference to our website address is intended to be an inactive textual reference only. Through our website, we make available, free of charge, our annual reports on Form 10-K, quarterly reports on Form 10-Q, current reports on Form 8-K, any amendments to those reports, proxy and registration statements, and all of our insider Section 16 reports, as soon as reasonably practicable after such material is electronically filed with, or furnished to, the SEC. These SEC reports can be accessed through the "Investors" section of our website. You should not rely on any such information in making your decision whether to purchase our common stock.

Item 1A. Risk Factors.

Our business is subject to numerous risks. You should carefully consider the risks described below, as well as the other information in this Annual Report, including our consolidated financial statements and the related notes and Item 7. Management's Discussion and Analysis of Financial Condition and Results of Operations. The occurrence of any of the events or developments described below could materially and adversely affect our business, financial condition, results of operations and future growth prospects. Additional risks and uncertainties not presently known to us or that we currently deem immaterial also may impair our business operations. This Annual Report also contains forward-looking statements that involve risks and uncertainties. Our actual results could differ materially from those anticipated in the forward-looking statements as a result of a number of factors, including the risks described below.

Risks Related to Our Limited Operating History, Financial Position and Capital Requirements

We have a limited operating history, have incurred significant operating losses since our inception and expect to incur significant losses for the foreseeable future.

We are an early-stage biopharmaceutical company with a limited operating history upon which our business and prospects can be evaluated. We commenced operations in 2017. To date, we have focused primarily on organizing and staffing our company; business planning; raising capital; developing and optimizing our platform technology; identifying potential product candidates; enhancing our intellectual property portfolio; undertaking research, preclinical studies, and clinical trials; and enabling manufacturing for our development programs. Our approach to the discovery and development of product candidates based on our PREDATOR platform is unproven, and we do not know whether we will be able to develop any approved products of commercial value. In addition, we currently only have two product candidates that we are developing independently, WTX-124 and WTX-330, and all of our other development programs are in discovery or preclinical stages. We have not yet demonstrated an ability to successfully complete any Phase 1, Phase 2 or pivotal clinical trials, obtain regulatory approvals, manufacture a commercial-scale product, or arrange for a third party to do so on our behalf, or conduct the sales and marketing activities necessary for successful product commercialization. Consequently, any predictions made about our future success or viability may not be as accurate as they could be if we had a history of successfully developing and commercializing biopharmaceutical products.

We have incurred significant operating losses since our inception and have not yet generated any product revenue. If our product candidates are not successfully developed and approved, we may never generate any product revenue. Our net loss was $70.5 million for the fiscal year ended December 31, 2024. As of December 31, 2024, we had an accumulated deficit of $414.6 million. We expect to continue to incur losses for the foreseeable future, and we anticipate these losses will increase substantially as WTX-124 and WTX-330 advance through development, and any future product candidates advance through preclinical studies and into and through clinical trials, and as we expand our clinical, regulatory, quality and manufacturing capabilities and incur additional costs associated with operating as a public company. If we obtain marketing approval for any of our product candidates, we will incur significant commercialization expenses for marketing, sales, manufacturing and distribution. We may encounter unforeseen expenses, difficulties, complications, delays and other known or unknown factors in achieving our business objectives. We will need to develop commercial capabilities, and we may not be successful in doing so. The net losses we incur may fluctuate significantly from quarter to quarter and year to year.

We have no products approved for commercial sale and have not generated any revenue from product sales. We may never generate any revenue or become profitable or, if we achieve profitability, we may not be able to sustain it.

To date, we have not generated any revenue from our product candidates or product sales, we do not expect to generate any revenue from the sale of products for a number of years and we may never generate revenue from the sale of products. Our ability to generate product revenue depends on a number of factors, including, but not limited to, our ability to:

- successfully complete our ongoing and planned preclinical studies;
- successfully submit investigational new drug, or IND, submissions to the U.S. Food and Drug Administration, or FDA, for any future product candidates;
- successfully complete clinical trials for WTX-124 and WTX-330;
- successfully enroll subjects in and complete future clinical trials;
- initiate and successfully complete all safety and efficacy studies to obtain U.S. and foreign regulatory approval for our product candidates;
- establish clinical and commercial manufacturing capabilities or make arrangements with third party manufacturers for clinical supply and commercial manufacturing;
- obtain and maintain patent and trade secret protection or regulatory exclusivity for our product candidates;
- launch commercial sales of our products, if and when approved, whether alone or in collaboration with others;
- obtain and maintain acceptance of the products, if and when approved, by patients, the medical community and third-party payors;
- effectively compete with other therapies;
- obtain and maintain healthcare coverage and adequate reimbursement;
- enforce and defend intellectual property rights and claims; and
- maintain a continued acceptable safety profile of our products following approval.

Because of the numerous risks and uncertainties associated with biopharmaceutical product development, we are unable to accurately predict the timing or amount of expenses we may incur in connection with these activities prior to generating product revenue. In addition, we may never succeed in these activities and, even if we do, may never generate revenues that are significant enough to achieve profitability. Even if we do achieve profitability, we may not be able to sustain or increase profitability on a quarterly or annual basis. Our failure to become and remain profitable would depress the value of our company and could impair our ability to raise capital, expand our business, maintain our research and development efforts, diversify our product candidates or even continue our operations. A decline in the value of our company could also cause our stockholders to lose all or part of their investment.

We will need to obtain substantial additional funding to finance our operations and complete the development and any commercialization of WTX-124, WTX-330 and any future product candidates. If we are unable to raise this capital when needed, we may be forced to delay, reduce or eliminate one or more of our research and development programs or other operations.

Identifying potential product candidates and conducting preclinical testing and clinical trials is a time-consuming, expensive and uncertain process that takes years to complete, and we may never generate the necessary data or results required to obtain regulatory approval and achieve product sales. We expect to incur increasing expenses and operating losses over the next several years as we pursue clinical development of our product candidates and implement the additional infrastructure necessary to support our operations as a public reporting company. Our revenue, if any, will be derived from sales of products that we do not expect to be commercially available for a number of years, if at all. If we obtain marketing approval for WTX-124, WTX-330 or any other product candidates that we develop, we expect to incur significant commercialization expenses related to product sales, marketing, distribution and manufacturing. Some of these expenses may be incurred in advance of marketing approval and could be substantial.

As of December 31, 2024, we had cash and cash equivalents of $111.0 million. We expect that our cash and cash equivalents as of December 31, 2024, will allow us to complete the development of WTX-124 through dose escalation and expansion as a monotherapy or in combination with pembrolizumab and the development of WTX-330 through dose escalation and expansion as a monotherapy.

Our cash and cash equivalents will not be sufficient to complete development of WTX-124, WTX-330 or any other product candidate. Accordingly, we will be required to obtain further funding through public or private equity offerings, debt financings, collaborations and licensing arrangements or other sources. Adequate additional financing may not be available to us on acceptable terms, or at all. Our failure to raise capital as and when needed, on attractive terms or at all, would have a negative effect on our financial condition and our ability to develop and commercialize our current and any future product candidates, and otherwise pursue our business strategy and we may be forced to delay, reduce or eliminate our research and development programs or future commercialization efforts.

In addition, our cash forecasts are based on assumptions that may prove to be wrong, and we could use our available capital resources earlier than we currently expect. Changing circumstances could cause us to consume capital significantly faster than we currently anticipate, and we may need to seek additional financing sooner than planned. In addition, we may seek additional capital due to favorable market conditions or strategic considerations even if we believe we have sufficient funds for our current or future operating plans.

Our future capital requirements, both short-term and long-term, will depend on many factors, including:

- the scope, progress, timing, costs and results of researching and developing our current product candidates, including with respect to WTX-124 and WTX-330, or any future product candidates;
- the costs associated with attracting, hiring and retaining skilled personnel and consultants as our preclinical and clinical activities increase;
- the cost of manufacturing our lead product candidates, WTX-124 and WTX-330, and any future product candidates for clinical trials and, if we are able to obtain marketing approval, for commercial sale;
- the costs of any third-party products used in our combination clinical trials that are not covered by such third parties or other sources;
- the timing of, and the cost involved in, obtaining marketing approval for WTX-124, WTX-330 or any future product candidates, and our ability to obtain marketing approval and generate revenue from any potential commercial sales of such product candidates;
- the cost of building a sales force in anticipation of product commercialization and the cost of commercialization activities for WTX-124, WTX-330 or any future product candidates if we receive marketing approval, including marketing, sales and distribution costs;

- the potential emergence of competing therapies and other adverse market developments;
- the amount and timing of any payments we may be required to make pursuant to our license agreement with Harpoon Therapeutics, Inc., or Harpoon, or other future license agreements or collaboration agreements;
- our ability to establish future collaborations, licensing or other arrangements and the financial terms of any such agreements, including the timing and amount of any future milestone, royalty or other payments due under any such agreement;
- the costs involved in preparing, filing, prosecuting, maintaining, expanding, defending and enforcing patent claims, including litigation costs and the outcome of such litigation;
- any product liability or other lawsuits related to our product candidates;
- the extent to which we in-license or acquire other products and technologies; and
- the costs of operating as a public company.

We do not have any committed external source of funds, and adequate additional financing may not be available to us on acceptable terms, or at all. In addition, our ability to raise additional capital may be adversely impacted by potential worsening global economic conditions both inside and outside the U.S. Our failure to raise capital as and when needed or on acceptable terms would have a negative impact on our financial condition and our ability to pursue our business strategy, and we may have to delay, reduce the scope of, suspend or eliminate one or more of our research-stage programs, clinical trials or future commercialization efforts or other operations.

Raising additional capital may cause dilution to our stockholders, restrict our operations or require us to relinquish rights to our platform technology or product candidates.

Unless and until we can generate a substantial amount of product revenue, we expect to seek additional capital through a combination of public or private equity offerings, debt financings, collaborations and licensing arrangements or other sources. Our issuance of additional securities, whether equity or debt, or the possibility of such issuance, may cause the market price of our common stock to decline, and our stockholders may not agree with our financing plans or the terms of such financings. For example, pursuant to the terms of our loan and security agreement, or the K2HV Loan Agreement, with K2 HealthVentures LLC, or K2HV, the lenders have the right to convert any portion of the outstanding principal amount of the first tranche part A term loan then outstanding into shares of our common stock, which right, if exercised, could have a dilutive impact on our stockholders' ownership interests. To the extent that we raise additional capital through the sale of equity or convertible debt securities, our stockholders' ownership interests will be diluted and the terms of these securities may include liquidation or other preferences that adversely affect our stockholders' rights. The incurrence of indebtedness would result in payment obligations and could require us to comply with certain restrictive covenants, such as limitations on our ability to incur additional debt, limitations on our ability to declare dividends, limitations on our ability to acquire or license intellectual property rights and other operating restrictions that could adversely impact our ability to conduct our business. Further, our ability to obtain additional debt financing may be limited by covenants we have made under the K2HV Loan Agreement, including our pledge of substantially all of our assets, other than our intellectual property, as collateral. If we raise additional funds through collaborations and licensing arrangements with third parties, we may have to relinquish valuable rights to our platform technology or product candidates or grant licenses on terms unfavorable to us. In addition, securing additional financing would require a substantial amount of time and attention from our management and may divert a disproportionate amount of their attention away from day-to-day activities, which may adversely affect our management's ability to oversee the development of our product candidates.

We have a term loan facility that requires us to comply with certain operating covenants and places restrictions on our operating and financial flexibility.

All outstanding obligations under the K2HV Loan Agreement are secured by our personal property (exclusive of any intellectual property) and are subject to acceleration upon an event of default. Under the K2HV Loan Agreement, we are required to comply with certain negative covenants, which among other things, restrict us from incurring future debt or granting liens, effectuating a merger or consolidation with or into any other business organization, paying dividends or making certain other distributions or repurchasing our equity, disposing of our assets, and making investments in any entities or instruments, subject, in each case, to certain exceptions specified in the K2HV Loan Agreement. The K2HV Loan Agreement also contains standard affirmative covenants, including with respect to the issuance of audited consolidated financial statements, insurance, and maintenance of good standing and government compliance in our state of formation. Our failure to comply with any of the foregoing covenants would result in an event of default under the K2HV Loan Agreement.

Our financial obligations and contractual commitments under the K2HV Loan Agreement could have significant adverse consequences, including:

- requiring us to dedicate a portion of our cash resources to the payment of interest and principal, reducing money available to fund working capital, capital expenditures, product development and other general corporate purposes;
- increasing our vulnerability to adverse changes in general economic, industry and market conditions;
- subjecting us to restrictive covenants that may reduce our ability to take certain corporate actions or obtain further debt or equity financing;
- limiting our flexibility in planning for, or reacting to, changes in our business and the industry in which we compete; and
- placing us at a competitive disadvantage compared to our competitors that have less debt or better debt servicing options.

Under the K2HV Loan Agreement, the occurrence of an event or circumstance that could be expected to have a material adverse effect on our business, operations, properties, assets or condition is an event of default. If an event of default occurs and the lenders accelerate the amounts due, we may not be able to make accelerated payments, and the lenders could seek to enforce security interests in the collateral securing such indebtedness, which includes substantially all of our assets other than our intellectual property. In addition, the covenants under the K2HV Loan Agreement, the pledge of our assets as collateral and the negative pledge with respect to our intellectual property could limit our ability to obtain additional debt financing.

Changes in tax laws or in their implementation or interpretation could adversely affect our business and financial condition.

Changes in tax laws or in their implementation or interpretation may adversely affect our business or financial condition. The TCJA, as amended by the Coronavirus Aid, Relief, and Economic Security Act, or CARES Act, significantly revised the Internal Revenue Code of 1986, as amended, or the Code. The TCJA, among other things, contains significant changes to corporate taxation, including the reduction of the corporate tax rate from a top marginal rate of 35% to a flat rate of 21% and, for taxable years beginning after December 31, 2020, the limitation of the deduction for net operating losses to 80% of current year taxable income for losses arising in taxable years beginning after December 31, 2017 (though any such net operating losses may be carried forward indefinitely but no longer carried back). In addition, beginning in 2022, the TCJA eliminated the option to deduct research and development expenditures currently and generally requires corporations to capitalize and amortize them over five years or 15 years (for expenditures attributable to foreign research).

In addition to the CARES Act, as part of Congress's response to the COVID-19 pandemic, economic relief legislation was enacted in 2020 and 2021 containing tax provisions. The Inflation Reduction Act, or the IRA, which was signed into law in August 2022, also introduced new tax provisions, including a one percent excise tax imposed on certain stock repurchases by publicly traded companies, which generally applies to any acquisition of stock by the publicly traded company (or certain of its affiliates) from a stockholder of the company in exchange for money or other property (other than stock of the company itself), subject to a de minimis exception. Thus, the excise tax could apply to certain transactions that are not traditional stock repurchases. Regulatory guidance under the TCJA and such additional legislation is and continues to be forthcoming, and such guidance could ultimately increase or lessen their impact on our business and financial condition. Congress may also enact additional legislation, some of which could have an impact on us. In addition, it is uncertain if and to what extent various states will conform to the TCJA and additional tax legislation.

Our ability to utilize our net operating loss carryforwards and certain other tax attributes may be limited.

We have incurred substantial losses during our history. We do not anticipate generating revenue from sales of products for the foreseeable future, if ever, and we may never achieve profitability. As of December 31, 2024, we had federal and state net operating loss carryforwards of $126.8 million and $76.8 million, respectively. Under Section 382 of the Code, if a corporation undergoes an "ownership change" (generally defined as a greater than 50 percentage point change (by value) in the ownership of its equity by certain stockholders over a three-year period), the corporation's ability to use its pre-change net operating loss carryforwards and other pre-change tax attributes to offset its post-change income may be limited. As a result of our prior private placement financings or other transactions, we have experienced ownership changes on June 10, 2019, August 2, 2019 and August 31, 2022, and we may in the future experience ownership changes as a result of subsequent changes in our stock ownership for purposes of Section 382. As a result, if we earn net taxable income, our ability to use our pre-change net operating loss carryforwards and other pre-change tax attributes to offset U.S. federal taxable income are subject to limitations, which could result in increased future tax liability to us and could have an adverse effect on our future results of operations. There is also a risk that due to regulatory changes, such as suspension of the use of net operating losses, or for other unforeseen reasons, our existing net operating losses and other tax attributes could expire or otherwise become unavailable to offset future income tax liabilities. As described above in "Changes in tax laws or in their implementation or interpretation could adversely affect our business and financial condition," the TCJA, as amended by the CARES Act, includes changes to U.S. federal tax rates and rules governing net operating loss carryforwards that may significantly impact our ability to utilize net operating

losses to offset taxable income in the future. In addition, state net operating losses generated in one state cannot be used to offset income generated in another state. For these reasons, we may be unable to use a material portion of our net operating losses and other tax attributes.

Risks Related to the Discovery, Development, Regulatory Approval and Commercialization of Our Product Candidates

We are early in our development efforts and our current product candidates will require successful completion of preclinical and clinical development before we can seek regulatory approval for any product candidates.

We are early in our development efforts and have invested substantially all of our efforts and financial resources in building our PREDATOR platform and developing our initial INDUKINE molecules by leveraging our PREDATOR platform. Our lead product candidates are in the early stages of clinical trial development. Additionally, we have a portfolio of programs that are in even earlier stages of preclinical development and may never advance to clinical-stage development. Our ability to generate product revenue, which we do not expect will occur for many years, if ever, will depend heavily on the successful development and eventual commercialization of our product candidates, which may never occur. We currently generate no revenue from sales of any product, and we may never be able to develop or commercialize a marketable product.

Our business is highly dependent on the success of our initial INDUKINE molecules, which are in the early stages of development and will require significant additional preclinical and clinical development before we can seek regulatory approval for and launch a product commercially.

Our business and future success is highly dependent on our ability to obtain regulatory approval of and then successfully launch and commercialize our initial INDUKINE molecules, including our most advanced product candidates, WTX-124 and WTX-330.

Commencing clinical trials in the United States is subject to acceptance by the FDA of an IND and finalizing the trial design based on discussions with the FDA and other regulatory authorities. In the event that the FDA requires us to complete additional preclinical studies or we are required to satisfy other FDA requests prior to commencing clinical trials, the start of a clinical trial may be delayed. Even after we receive and incorporate guidance from these regulatory authorities, the FDA or other regulatory authorities could disagree that we have satisfied their requirements to commence any clinical trial or change their position on the acceptability of our trial design or the clinical endpoints selected, which may require us to complete additional preclinical studies or clinical trials or impose stricter approval conditions than we currently expect. There are equivalent processes and risks applicable to clinical trial applications in other countries, including countries in the European Union.

We may experience issues surrounding preliminary trial execution, such as delays in FDA acceptance of our INDs, revisions in trial design and finalization of trial protocols, difficulties with patient recruitment and enrollment, quality and provision of clinical supplies, or early safety signals.

We are not permitted to market any biological product or drug product in the United States until we receive approval of a Biologics License Application, or BLA, or a new drug application, or NDA, from the FDA. We have not previously submitted a BLA or an NDA to the FDA, or similar marketing application to comparable foreign regulatory authorities. A BLA or an NDA must include extensive preclinical and clinical data and supporting information to establish that the product candidate is safe, pure and potent for each desired indication. A BLA or an NDA must also include significant information regarding the chemistry, manufacturing and controls for the product, and the manufacturing facilities must complete a successful pre-license inspection.

FDA approval of a BLA or an NDA is not guaranteed, and the review and approval process is expensive and uncertain and may take several years. The FDA also has substantial discretion in the approval process. The number and types of preclinical studies and clinical trials that will be required for BLA or NDA approval varies depending on the product candidate, the disease or the condition that the product candidate is designed to treat and the regulations applicable to any particular product candidate. Despite the time and expense associated with preclinical studies and clinical trials, failure can occur at any stage.

The FDA may also require a panel of experts, referred to as an Advisory Committee, to deliberate on the adequacy of the safety and efficacy data to support approval. The opinion of the Advisory Committee, although not binding, may have a significant impact on our ability to obtain approval of any product candidate that we develop based on the completed clinical trials.

Our ability to generate product revenues, which we do not expect will occur for many years, if ever, will depend heavily on our ability to successfully develop and commercialize WTX-124, WTX-330 and any future product candidates. The success of our product candidates will depend on several factors, including the following:

- completion of preclinical studies and clinical trials with favorable results;
- acceptance of INDs by the FDA or similar regulatory filing by comparable foreign regulatory authorities for the conduct of clinical trials of our product candidates and our proposed design of future clinical trials;

- receipt of marketing approvals from applicable regulatory authorities, including BLAs or NDAs from the FDA and maintaining such approvals;
- making arrangements with our third-party manufacturers for, or establishing, commercial manufacturing capabilities;
- maintaining an acceptable safety profile of our products following approval; and
- maintaining and growing an organization of scientists and business people who can develop our products and technology.

Generally, public concern regarding the safety of biopharmaceutical products could delay or limit our ability to obtain regulatory approval, result in the inclusion of unfavorable information in our labeling or require us to undertake other activities that may entail additional costs. We have not obtained FDA approval for any product. This lack of experience may impede our ability to obtain FDA approval in a timely manner, if at all, for WTX-124, WTX-330 or any future product candidates.

The success of our business, including our ability to finance our company and generate any revenue in the future, will primarily depend on the successful development, regulatory approval and commercialization of WTX-124, WTX-330 and any future product candidates, which may never occur. Given our early stage of development, it will be years before we are able to demonstrate the safety and efficacy of a treatment sufficient to warrant approval for commercialization, and we may never be able to do so. If we are unable to develop, or obtain regulatory approval for, or, if approved, successfully commercialize our current or any future product candidates, we may not be able to generate sufficient revenue to continue our business.

Our approach to the discovery and development of product candidates based on our PREDATOR platform is unproven, and we do not know whether we will be able to develop any products of commercial value.

The success of our business depends primarily upon our ability to discover, develop and commercialize products based on our novel PREDATOR platform. While we have had favorable preclinical study results related to WTX-124 and WTX-330, both of which we are developing by leveraging our PREDATOR platform, and have announced favorable early-stage clinical trial results related to WTX-124 and WTX-330, we have not yet succeeded and may not succeed in demonstrating efficacy and safety for any product candidates in clinical trials or in obtaining marketing approval thereafter. We have no assurance that our PREDATOR platform will be able to produce product candidates that will successfully progress from preclinical studies into clinical development and ultimately marketing approval. We have invested substantially all of our efforts and financial resources in building our PREDATOR platform and developing our initial INDUKINE molecules by leveraging our PREDATOR platform, and our future success is highly dependent on the continued successful development of our platform and product candidates that we develop by leveraging our platform. Because all of our product candidates are based upon our PREDATOR platform, any development problems we may experience in the future related to any of our product candidates has the potential to impact the development of our other product candidates and any such development problems have the potential to cause significant delays or unanticipated costs and may ultimately not be able to be solved.

In addition, the clinical trial requirements of the FDA and other regulatory agencies and the criteria these regulators use to determine the safety and efficacy of a product candidate may vary according to the type, complexity, novelty and intended use and market of the potential products. The regulatory approval process for novel product candidates can be more expensive and take longer than for other, better known or extensively studied pharmaceutical or other product candidates. As a result, we may face a greater regulatory burden to initiate clinical trials or to obtain regulatory approval of our product candidates as compared to product candidates based on more established technology. In addition, any product candidates for which we may be able to obtain marketing approval may be subject to extensive post-approval regulatory requirements, including requirements pertaining to manufacturing, distribution and promotion. We may need to devote significant time and resources to compliance with these requirements.

Manufacturing INDUKINE molecules is subject to risk since they are a novel class of multi-domain biologics that include protease cleavable linkers, and they have never been produced on a commercial scale. We may be unable to manufacture INDUKINE molecules at the scale needed for late-stage clinical development and commercial production on a timely basis or at all, which would adversely affect our ability to conduct clinical trials and seek regulatory approvals or commercialize our programs, which would have an adverse effect on our business.

The manufacturing cell line currently in use, and any future cell line that may be used, to manufacture multi-domain proteins that include our protease cleavable linkers presents a risk that unintended proteolysis may occur during the manufacture of INDUKINE molecules and that undesired fragments may not be able to be sufficiently removed by the purification process. The novel multi-domain composition of INDUKINE molecules may present a risk due to its complexity and challenges inherent to the manufacture of biologics. As a result, the risk of delays or failure in the manufacture of our INDUKINE molecules is high. Additionally, each INDUKINE molecule that we may develop is unique, from a manufacturing perspective, so any learnings from the manufacture of other INDUKINE molecules may not apply to the manufacture of new INDUKINE

molecules. Before commencing clinical trials for new product candidates, the manufactured INDUKINE molecules must complete extensive analytical testing and be qualified for use in human studies. We cannot be certain of the timely completion or outcome of our analytical testing and suitability for human studies and cannot predict if the FDA or other regulatory authorities will accept our proposed clinical material or if the outcome of our analytical testing will ultimately support the further development of future programs or clinical trials. As a result, we cannot be sure that we will be able to submit INDs or similar applications for any future clinical programs on the timelines we expect, if at all, and we cannot be sure that the submission of INDs or similar applications will result in the FDA or other regulatory authorities allowing future clinical trials to begin. In addition, we cannot be certain that we will be able to produce product candidates at the scale required for our clinical trials and, for any approved products, commercial production on a timely basis or at all, which could also have an adverse effect on our business.

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

We have chosen to initially develop our lead product candidates, WTX-124 and WTX-330, for the treatment of advanced solid tumors and the treatment of relapsed or refractory advanced or metastatic tumors or lymphoma, respectively. Nevertheless, our development efforts will be limited to a small number of cancer types and we may forego or delay pursuit of opportunities in other cancer types that may prove to have greater potential. Likewise, we may forego or delay the pursuit of opportunities with other potential product candidates that may 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 similar arrangements in cases in which it would have been more advantageous for us to retain sole development and commercialization rights to the product candidate.

Preclinical development is uncertain. Our preclinical programs may experience delays or may never advance to clinical trials, which would adversely affect our ability to obtain regulatory approvals or commercialize these programs on a timely basis or at all, which would have an adverse effect on our business.

Risk of failure for preclinical product candidates is high. Before we can commence clinical trials for our preclinical product candidates, we must complete extensive preclinical testing and studies that support INDs in the United States, or similar applications in other jurisdictions. We cannot be certain of the timely completion or outcome of our preclinical testing and studies and cannot predict if the FDA or other regulatory authorities will accept our proposed clinical programs or if the outcome of our preclinical testing and studies will ultimately support the further development of our programs. As a result, we cannot be sure that we will be able to successfully submit INDs or similar applications for our preclinical programs on the timelines we expect, if at all, and we cannot be sure that submission of INDs or similar applications will result in the FDA or other regulatory authorities allowing clinical trials to begin.

Preclinical studies and clinical trials are expensive, time-consuming and difficult to design and implement, and involve uncertain outcomes. Furthermore, results of earlier preclinical studies and clinical trials may not be predictive of results of future preclinical studies or clinical trials.

The risk of failure for our current and any future product candidates is high. It is impossible to predict when or if any of our future product candidates will successfully complete preclinical studies, or if any of our current or future product candidates will complete clinical trials evaluating their safety and effectiveness in humans or will ultimately receive regulatory approval. To obtain the requisite regulatory approvals to market and sell any of our product candidates, we must demonstrate through extensive preclinical studies and clinical trials that our product candidates are safe and effective in humans for use in each target indication. Preclinical and clinical testing is expensive and can take many years to complete, and the outcome is inherently uncertain. Failure can occur at any time during the preclinical or clinical trial process. The outcome of preclinical testing and early clinical trials may not be predictive of the results of later clinical trials, and interim results of a clinical trial do not necessarily predict final results. In particular, while we have conducted certain preclinical studies of WTX-124 and WTX-330 and have entered early clinical stage development, we do not know whether either of these product candidates will perform in our clinical trials as it has performed in these prior preclinical studies. Similarly, there can be no assurance that interim or preliminary clinical data or results, including, without limitation, the Phase 1/1b clinical data reported for WTX-124 and Phase 1 clinical data reported for WTX-330, will be predictive of future clinical data or results, and there can be no assurance that success in early clinical trials will lead to success in later clinical trials. Many companies in the biopharmaceutical and biotechnology industries have suffered significant setbacks in late-stage clinical trials after achieving positive results in early-stage development and we cannot be certain that we will not face similar setbacks. These setbacks have been caused by, among other things, preclinical findings made while clinical trials were underway, or safety or efficacy observations made in preclinical studies and clinical trials, including previously unreported adverse events. Moreover, preclinical and clinical data are

often susceptible to varying interpretations and analyses, and many companies that have believed their product candidates performed satisfactorily in preclinical studies and clinical trials have nonetheless failed to obtain marketing approval of their products.

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

We may encounter substantial delays in the commencement or completion, or termination or suspension, of our clinical trials, which could result in increased costs to us, delay or limit our ability to generate revenue and adversely affect our commercial prospects.

Before obtaining marketing approval from regulatory authorities for the sale of our product candidates, we must conduct extensive clinical trials to demonstrate the safety and efficacy of the product candidate for its intended indications. We cannot guarantee that any clinical trials will be conducted as planned or completed on schedule, if at all. We may experience numerous unforeseen events during or as a result of clinical trials that could delay or prevent our ability to receive marketing approval or commercialize our current or future product candidates, including:

- we may be unable to generate sufficient preclinical, toxicology, or other *in vivo* or *in vitro* data to obtain regulatory authorizations to commence a clinical trial;
- we may experience issues in reaching a consensus with regulatory authorities on trial design;
- regulators or institutional review boards, or IRBs, or ethics committees may not authorize us or our investigators to commence a clinical trial or conduct a clinical trial at a prospective trial site;
- we may experience delays in reaching, or fail to reach, agreement on acceptable terms with prospective trial sites and prospective contract research organizations, or CROs, the terms of which can be subject to extensive negotiation and may vary significantly among different CROs and trial sites;
- clinical trial sites may deviate from a trial protocol or drop out of a trial or fail to conduct the trial in accordance with regulatory requirements;
- the number of subjects required for clinical trials of our product candidates may be larger than we anticipate or subjects may fail to enroll or remain in clinical trials at the rate we expect;
- subjects that enroll in our studies may misrepresent their eligibility or may otherwise not comply with the clinical trial protocol, resulting in the need to drop the subject from the trial, increase the needed enrollment size for the clinical trial or extend its duration;
- subjects may choose an alternative treatment for the indication for which we are developing our product candidates, or participate in competing clinical trials;
- subjects may experience severe or unexpected drug-related adverse effects;
- clinical trials of our product candidates may produce unfavorable, inconclusive, or clinically insignificant results;
- we may decide to, or regulators or IRBs or ethics committees may require us to, make changes to a clinical trial protocol or conduct additional preclinical studies or clinical trials, or we may decide to abandon product development programs;
- we may need to add new or additional clinical trial sites;
- our third-party contractors, including those manufacturing our product candidates or conducting clinical trials on our behalf, may fail to comply with regulatory requirements or meet their contractual obligations to us in a timely manner, or at all;
- we may experience manufacturing delays, and any changes to manufacturing processes or third party contractors that may be necessary or desired could result in other delays;
- we or our third party contractors may experience delays due to complications associated with public health crises such as the COVID-19 pandemic;
- the cost of preclinical testing and studies and clinical trials of any product candidates may be greater than we anticipate or greater than our available financial resources;

- the supply or quality of our product candidates or other materials necessary to conduct clinical trials of our product candidates may be insufficient or inadequate or we may not be able to obtain sufficient quantities of combination therapies for use in clinical trials;
- reports may arise from preclinical or clinical testing of other cancer therapies that raise safety or efficacy concerns about our product candidates; and
- regulators may revise the requirements for approving our product candidates, or such requirements may not be as we anticipate.

If we are required to conduct additional clinical trials or other testing of our product candidates beyond the clinical trials and testing that we contemplate, if we are unable to successfully complete clinical trials or other testing of our product candidates, if the results of these clinical trials or tests are unfavorable or are only modestly favorable or if there are safety concerns associated with any of product candidates, we may:

- incur additional unplanned costs;
- be required to suspend or terminate ongoing clinical trials;
- be delayed in obtaining marketing approval, if at all;
- obtain approval for indications or patient populations that are not as broad as intended or desired;
- obtain approval with labeling that includes significant use or distribution restrictions or safety warnings;
- be subject to additional post-marketing testing or other requirements;
- be required to perform additional clinical trials to support approval;
- have regulatory authorities withdraw, or suspend, their approval of the drug or impose restrictions on its distribution in the form of a modified risk evaluation and mitigation strategy, or REMS;
- be subject to the addition of labeling statements, such as warnings or contraindications;
- have the product removed from the market after obtaining marketing approval;
- be subject to lawsuits; or
- experience damage to our reputation.

Conducting clinical trials in foreign countries, as we may do for our product candidates, presents additional risks that may delay completion of our clinical trials. These risks include the failure of enrolled patients in foreign countries to adhere to clinical protocols as a result of differences in healthcare services or cultural customs, managing additional administrative burdens associated with foreign regulatory schemes, as well as political and economic risks relevant to such foreign countries.

Moreover, principal investigators for our clinical trials may serve as scientific advisors or consultants to us from time to time and receive compensation in connection with such services. Under certain circumstances, we may be required to report some of these relationships to the FDA or comparable foreign regulatory authorities. The FDA or comparable foreign regulatory authority may conclude that a financial relationship between us and a principal investigator has created a conflict of interest or otherwise affected interpretation of the trial. The FDA or comparable foreign regulatory authority may therefore question the integrity of the data generated at the applicable clinical trial site and the utility of the clinical trial itself may be jeopardized. This could result in a delay in approval, or rejection, of our marketing applications by the FDA or comparable foreign regulatory authorities, as the case may be, and may ultimately lead to the denial of marketing approval of one or more of our product candidates.

In addition, the FDA's and other regulatory authorities' policies with respect to clinical trials may change and additional government regulations may be enacted. 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 be impacted. For example, in December 2022 with the passage of the Food and Drug Omnibus Reform Act of 2022, Congress required sponsors to develop and submit a diversity action plan, or DAP, for each Phase 3 clinical trial or any other "pivotal study" of a new drug or biological product. These plans are meant to encourage the enrollment of more diverse patient populations in late-stage clinical trials of FDA-regulated products. Specifically, actions plans must include the sponsor's goals for enrollment, the underlying rationale for those goals, and an explanation of how the sponsor intends to meet them In June 2024, as mandated by FDORA, the FDA issued draft guidance outlining the general requirements for DAPs. Unlike most guidance documents issued by the FDA, the DAP guidance when finalized will have the force of law because FDORA specifically dictates that the form and manner for submission of DAPs are specified in FDA guidance.

Similarly, the regulatory landscape related to clinical trials in the European Union, or EU, recently evolved. The EU Clinical Trials Regulation, or CTR, which was adopted in April 2014 and repeals the EU Clinical Trials Directive, became applicable on January 31, 2022. While the Clinical Trials Directive required a separate clinical trial application, or CTA, to be submitted in each member state, 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 to all member states concerned. 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. If we are not able to adapt to these and other changes in existing requirements or the adoption of new requirements or policies governing clinical trials, our development plans may be impacted.

In addition to the factors above, we may make formulation or manufacturing changes to our product candidates, in which case we may need to conduct additional preclinical studies to bridge our modified product candidates to earlier versions, which may be costly, time consuming and may not be successful at all.

Our failure to successfully initiate and complete clinical trials of our product candidates and to demonstrate the efficacy and safety necessary to obtain regulatory approval to market any of our product candidates would significantly harm our business. We cannot provide assurances that our clinical trials will begin as planned or be completed on schedule, if at all, or that we will not need to restructure our clinical trials. Significant preclinical study or clinical trial delays could also shorten any periods during which we may have the exclusive right to commercialize our product candidates or allow our competitors to bring products to market before we do and impair our ability to successfully commercialize our product candidates, which may harm our business and results of operations. In addition, many of the factors that cause, or lead to, delays of clinical trials may ultimately lead to the denial of regulatory approval of our product candidates.

If we experience delays or difficulties in the enrollment of patients in clinical trials, our clinical development activities could be delayed or otherwise adversely affected.

We may experience difficulties in patient enrollment in our clinical trials for a variety of reasons. The timely completion of clinical trials in accordance with their protocols depends, among other things, on our ability to enroll a sufficient number of patients who remain in the study until its conclusion. We may experience difficulties in patient enrollment in our clinical trials for a variety of reasons. The enrollment of patients depends on many factors, including:

- the severity of the disease under investigation;
- the patient eligibility and the inclusion and exclusion criteria defined in the protocol;
- the size and health of the patient population required for analysis of the trial's primary endpoints;
- the proximity of patients to trial sites;
- the design of the trial;
- our ability to recruit clinical trial investigators with the appropriate competencies and experience;
- clinicians' and patients' perceptions as to the potential advantages of the drug candidate being studied in relation to other available therapies, including any new drugs that may be approved for the indications we are investigating;
- our ability to obtain and maintain patient consents;
- our ability to monitor patients adequately during and after treatment;
- the risk that patients enrolled in clinical trials will drop out of the trials before completion; and
- factors we may not be able to control, including the impacts of public health crises such as the COVID-19 pandemic, which may limit the availability of patients, principal investigators or staff or clinical sites.

In addition, our clinical trials will compete with other clinical trials for product candidates that are in the same therapeutic areas as our product candidates, and this competition will reduce the number and types of patients available to us, because some patients who might have opted to enroll in our trials may instead opt to enroll in a trial being conducted by one of our competitors. Since the number of qualified clinical investigators is limited, we expect to conduct some of our clinical trials at the same clinical trial sites that some of our competitors use, which will reduce the number of patients who are available for our clinical trials at such clinical trial sites.

Our inability to enroll a sufficient number of patients for our clinical trials would result in significant delays or might require us to abandon one or more clinical trials altogether. Enrollment delays in our clinical trials may result in increased development costs for our product candidates, slow down or halt our product candidate development and approval process and jeopardize our ability to seek and obtain the marketing approval required to commence product sales and generate revenue, which would cause the value of our company to decline and limit our ability to obtain additional financing, if needed.

Our product candidates may cause undesirable or unexpectedly severe side effects that could delay or prevent their regulatory approval, limit the commercial profile of an approved label, or result in significant negative consequences following marketing approval, if any.

Undesirable or unexpectedly severe side effects caused by our product candidates could cause us to interrupt, delay or halt preclinical studies or could cause us or regulatory authorities to interrupt, delay or halt clinical trials and could result in a more restrictive label or the delay or denial of regulatory approval by the FDA or comparable foreign regulatory authorities. It is likely that, as is the case with many treatments for cancer, there may be side effects associated with the use of our product candidates. Results of our trials 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. Treatment-related side effects could also 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.

Further, by design, clinical trials rely on a sample of the potential patient population. With a limited number of patients and limited duration of exposure, rare and severe side effects of our product candidates may only be uncovered when a significantly larger number of patients is exposed to the product candidate. If our product candidates receive marketing approval and we or others identify undesirable side effects caused by such product candidates after such approval, a number of potentially significant negative consequences could result, including:

- regulatory authorities may require the addition of labeling statements, such as a “black box” warning or a contraindication;
- we may be required to create a medication guide outlining the risks of such side effects for distribution to patients;
- regulatory authorities may require a REMS plan to mitigate risks, which 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;
- we may be required to change the way such product candidates are distributed or administered, conduct additional clinical trials or change the labeling of the product candidates;
- we may be subject to regulatory investigations and government enforcement actions;
- regulatory authorities may withdraw or limit their approval of such product candidates;
- we may decide to remove such product candidates from the marketplace;
- we could be sued and held liable for injury caused to individuals exposed to or taking our product candidates; and
- we may suffer reputational harm.

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.

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 publish interim top-line or preliminary data from our 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. Preliminary or “top-line” data also remain subject to audit and verification procedures that may result in the final data being materially different from the preliminary data previously published. As a result, interim and preliminary data should be viewed with caution until the final data are available. Adverse differences between preliminary or interim data and final data could significantly harm our business prospects.

We are developing WTX-124, and could potentially develop WTX-330 and future product candidates, in combination with third-party drugs, some of which may still be in development, and we will have limited or no control over the safety, supply, regulatory status or regulatory approval of such drugs.

We are developing WTX-124, and could potentially develop WTX-330 and other future product candidates, in combination with third-party cancer drugs, which may be either approved or unapproved. For example, we are conducting a clinical trial of WTX-124 both as monotherapy and in combination with pembrolizumab. Our ability to develop and ultimately commercialize our current product candidates, and any future product candidates, used in combination with third-party drugs will depend on our ability to access such drugs on commercially reasonable terms for clinical trials and their availability for use with our commercialized product, if approved. We cannot be certain that current or potential future commercial relationships will provide us with a steady supply of such drugs on commercially reasonable terms or at all. Any failure to maintain or enter into new successful commercial relationships, or the expense of purchasing such third-party drugs in the market, may delay our development timelines, increase our costs and jeopardize our ability to develop our current product candidates and any future product candidates as commercially viable therapies. If any of these occur, our business, financial condition, operating results, or prospects may be materially harmed.

Moreover, the development of product candidates for use in combination with another product or product candidate may present challenges that are not faced for single agent product candidates. For example, our clinical trial for WTX-124 in combination with pembrolizumab may result in adverse events based on the combination therapy that may negatively impact the reported safety profile of the monotherapy in such clinical trials. Checkpoint inhibitors have been shown to have adverse events, including immune-related adverse events involving the lung, liver and other organ systems, which may limit the maximum dose in our clinical trials or otherwise negatively impact our combination clinical trials. In addition, the FDA or comparable foreign regulatory authorities may require us to use more complex clinical trial designs in order to evaluate the contribution of each product and product candidate to any observed effects. It is possible that the results of such trials could show that any positive previous trial results are attributable to the third-party drug and not our product candidate. Developments related to the third-party drug may also impact our clinical trials for the combination as well as our commercial prospects should we receive regulatory approval. Such developments may include changes to the third-party drug's safety or efficacy profile, changes to the availability of the third-party drug, quality, and manufacturing and supply issues with respect to the third-party drug.

If we are able to obtain marketing approval, the FDA or comparable foreign regulatory authorities may require that products used in conjunction with each other be cross labeled for combined use. To the extent that we do not have rights to the third-party drug, this may require us to work with such third party to satisfy such a requirement. We would also continue to be subject to the risks that the FDA or comparable foreign regulatory authorities could revoke approval of the third-party drug used in combination with our product candidate or that safety, efficacy, manufacturing or supply issues could arise with such drug. Similarly, if the third-party drugs we use in combination with our product candidates are replaced as the standard of care for the indications we choose for any of our product candidates, the FDA or comparable foreign regulatory authorities may require us to conduct additional clinical trials. The occurrence of any of these risks could result in our own products, if approved, being removed from the market or being less successful commercially.

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

Although we intend to explore other therapeutic opportunities in addition to the product candidates that we are currently developing, we may fail to identify or discover viable new product candidates for clinical development for a number of reasons. If we fail to identify additional potential product candidates, our business could be materially harmed.

Research programs to pursue the development of our existing and planned product candidates for additional indications and to identify new product candidates and disease targets require substantial technical, financial and human resources whether or not they are ultimately successful. Our research programs may initially show promise in identifying potential indications and/or product candidates, yet fail to yield results for clinical development for a number of reasons, including:

- the research methodology used may not be successful in identifying potential indications and/or product candidates;
- potential product candidates may, after further study, be shown to have harmful adverse effects or other characteristics that indicate they are unlikely to be effective drugs; or
- it may take greater human and financial resources than we will possess to identify additional therapeutic opportunities for our product candidates or to develop suitable potential product candidates through internal research programs, thereby limiting our ability to develop, diversify and expand our product portfolio.

Accordingly, there can be no assurance that we will ever be able to identify additional therapeutic opportunities for our current product candidates or to develop suitable additional product candidates through internal research programs, which could materially adversely affect our future growth and prospects.

We may become exposed to costly and damaging liability claims, either when testing our product candidates in the clinic or following commercial sale, and any product liability insurance we may obtain may not cover all damages from such claims.

We are exposed to potential product liability risks that are inherent in the research, development, manufacturing, marketing and use of biopharmaceutical products. The use of product candidates by us in clinical trials, and any sale of approved products in the future, may expose us to liability claims. For example, we may be sued if our product candidates cause or are perceived to cause injury or are found to be otherwise unsuitable during clinical trials, 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, negligence, strict liability or a breach of warranties. Claims could also be asserted under state consumer protection acts.

Although the clinical trial process is designed to identify and assess potential side effects, it is always possible that a drug, even after regulatory approval, may exhibit unforeseen side effects. If any of our product candidates were to cause adverse side effects during clinical trials or after approval thereof, we may be exposed to substantial liabilities. Physicians and patients may not comply with any warnings that identify known potential adverse effects and patients who should not use our product candidates. If we cannot successfully defend ourselves against product liability claims, we may incur substantial liabilities or be required to limit or cease the development or commercialization of our product candidates or any products for which we may have received marketing approval. Even a successful defense would require significant financial and management resources. Regardless of the merits or eventual outcome, liability claims may result in:

- delay or termination of clinical trials;
- decreased demand for any product candidates or products that we may develop;
- injury to our reputation and significant negative media attention;
- withdrawal of clinical trial participants or difficulties in recruiting new trial participants;
- initiation of investigations by regulators;
- costs to defend or settle 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;
- significant negative financial impact; and
- the inability to commercialize any of our product candidates, if approved.

Although we will seek to procure and maintain product liability insurance coverage, such insurance may not be adequate to cover all liabilities that we may incur. We may need to increase our insurance coverage each time we commence a clinical trial and if we successfully commercialize any product candidate. As the expense of insurance coverage is increasing, we may not be able to maintain insurance coverage at a reasonable cost or in an amount adequate to satisfy any liability that may arise. If a successful product liability claim or series of claims is brought against us for uninsured liabilities or in excess of insured liabilities, our assets may not be sufficient to cover such claims and our business operations could be materially harmed.

We have never commercialized a product candidate and we may lack the necessary expertise, personnel and resources to successfully commercialize any products that receive regulatory approval, either on our own or together with collaborators.

We have never commercialized a product candidate. We currently have no sales force or marketing or distribution capabilities. To achieve commercial success of our product candidates, if any are approved, we will have to develop our own sales, marketing and supply capabilities or outsource these activities to one or more third parties.

Factors that may affect our ability to commercialize our product candidates on our own include our ability to recruit and retain adequate numbers of effective sales and marketing personnel and obtain access to or persuade adequate numbers of physicians to prescribe our product candidates, as well as any unforeseen costs we may incur in connection with creating an independent sales and marketing organization. Developing a sales and marketing organization requires significant investment, is time-consuming and could delay the launch of our product candidates. We may not be able to build an effective sales and marketing organization in the United States, the European Union or other key global markets. To the extent we need to rely upon one or more third parties, we may have little or no control over the marketing and sales efforts of those third parties and our revenue

from product sales may be lower than if we had commercialized our product candidates ourselves. We will also face competition in any search for third parties to assist us with sales and marketing efforts for our product candidates. If we are unable to build our own distribution and marketing capabilities or to find suitable partners for the commercialization of our product candidates, we may have difficulties generating revenue from them.

We face substantial competition, which may result in others discovering, developing or commercializing products before or more successfully than we do.

The development and commercialization of new drug products is highly competitive. We face competition with respect to our current product candidates and will face competition with respect to any product candidates that we may seek to develop or commercialize in the future, from major pharmaceutical, specialty pharmaceutical and biotechnology companies among others. We compete in the segments of the pharmaceutical, biotechnology and other related markets that develop immunotherapies for the treatment of cancer. There are other companies working to develop immunotherapies for the treatment of cancer including divisions of pharmaceutical and biotechnology companies of various sizes. Some of these competitive therapies are based on scientific approaches that are the same as or similar to our approach, and others are based on entirely different approaches. Potential competitors also include academic institutions, government agencies and other public and private research organizations that conduct research, seek patent protection and establish collaborative arrangements for research, development, manufacturing and commercialization.

We are developing our initial product candidates for the treatment of cancer and have not received marketing approval for any of our product candidates. There are already a variety of available therapies marketed for cancer and some of the currently approved therapies are branded and subject to patent protection, and others are available on a generic basis. Many of these approved therapies are well-established and widely accepted by physicians, patients and third-party payors. Insurers and other third-party payors may also encourage the use of generic products. We expect that if our product candidates are approved, they will be priced at a significant premium over competitive generic products. This may make it difficult for us to achieve our business strategy of using our product candidates in combination with existing therapies or replacing existing therapies with our product candidates. Competition may further increase with advances in the commercial applicability of technologies and greater availability of capital for investment in these industries.

We are aware of a number of companies that are developing cytokines as immunotherapies, as well as different modalities, including monoclonal antibodies, cell therapies, oncolytic viruses and vaccines.

Our lead product candidate, WTX-124, if approved, may face competition from other Interleukin-2, or IL-2, based cancer therapies. Proleukin (aldesleukin) has been approved and is marketed for the treatment of both metastatic renal cell carcinoma and metastatic melanoma. In addition, we are aware of numerous clinical and preclinical IL-2 molecules using different platforms being developed for oncology indications, including programs from Anaveon AG, Anwita Biosciences, Inc., Ascendis Pharma A/S, Asher Biotherapeutics, Inc., Aulos Bioscience, Inc., BioNTech SE, Cue Biopharma, Inc., DEKA Biosciences, Inc., Merck & Co., Inc., Medicenna Therapeutics Corp., Mural Oncology PLC, F. Hoffmann-La Roche AG, Synthekine, Inc., and Xilio Therapeutics, Inc.

There are no approved IL-12 therapies currently on the market for the treatment of cancer. However, if approved, WTX-330 may face competition from other IL-12 cytokine programs in clinical and preclinical development for oncology indications, including programs from Sanofi S.A. (Amunix), DEKA Biosciences, Inc., DragonFly Therapeutics, Inc., Juno Therapeutics, Inc. (Bristol-Myers Squibb Company), Mural Oncology, OncoSec Medical Incorporated, Philogen S.p.A., Sonnet BioTherapeutics, Inc., Turnstone Biologics Corp. (partnered with Takeda Pharmaceutical Company Limited), Xilio Therapeutics, Inc., and Zymeworks Inc.

Our competitors may succeed in developing, acquiring or licensing, on an exclusive basis, products that are safer, more effective, have fewer or less severe side effects, are more convenient or are less expensive than any products that we may develop. We also compete with these organizations in establishing clinical trial sites and patient registration for clinical trials, as well as in recruiting and retaining qualified scientific and management personnel, which could negatively affect our level of expertise and our ability to execute our business plan.

Many of our competitors, either alone or with their collaborators, have significantly greater financial resources and expertise in research and development, manufacturing, preclinical and clinical testing, obtaining regulatory approvals and reimbursement and marketing approved products than we do. Established pharmaceutical companies may invest heavily to accelerate discovery and development of novel product candidates or to in-license novel product candidates that could make our product candidates less competitive or obsolete. Smaller or early-stage companies may also prove to be significant competitors, including through collaborative arrangements with large and established companies. In addition, any new product that competes with an approved product must demonstrate compelling advantages in efficacy, convenience, tolerability and safety in order to overcome price competition and to be commercially successful. The availability of competing products could limit the demand and the price we

are able to charge for product candidates we commercialize, if any. The inability to compete with existing or subsequently introduced drugs would harm our business, financial condition and results of operations.

The sizes of the potential markets for our product candidates are difficult to estimate and, if any of our assumptions are inaccurate, the actual markets for our product candidates may be smaller than our estimates.

The potential market opportunities for our product candidates are difficult to estimate and, if our product candidates are approved, will ultimately depend on, among other things, the indications for which our product candidates are approved for sale, any drugs with which our product candidates are co-administered, the success of competing therapies and therapeutic approaches, acceptance by the medical community, patient access, product pricing and reimbursement. Our estimates of the potential market opportunities for our product candidates are predicated on many assumptions, which may include industry knowledge and publications, third-party research reports and other surveys. Although we believe that our internal assumptions are reasonable, these assumptions involve the exercise of significant judgment on the part of our management, are inherently uncertain, and their reasonableness has not been assessed by an independent source. If any of the assumptions proves to be inaccurate, the actual markets for our product candidates could be smaller than our estimates of the potential market opportunities.

The successful commercialization of our product candidates will depend in part on the extent to which we obtain and maintain favorable coverage, adequate reimbursement levels and pricing policies with third party payors.

The availability and adequacy of coverage and reimbursement by third-party payors, including governmental healthcare programs such as Medicare and Medicaid, managed care organizations, and private health insurers, are essential for most patients to be able to afford prescription medications such as our product candidates, if approved. Our ability to achieve acceptable levels of coverage and reimbursement for products by third-party payors will have an effect on our ability to successfully commercialize our product candidates. We cannot be sure that coverage and reimbursement in the United States, the European Union or elsewhere will be available for our product candidates, if approved, or any product that we may develop, and any reimbursement that may become available may be decreased or eliminated in the future.

Third-party payors increasingly are challenging prices charged for pharmaceutical products and services, and many third-party payors may refuse to provide coverage and reimbursement for particular drugs or biologics when an equivalent generic drug, biosimilar or a less expensive therapy is available. It is possible that a third-party payor may consider our product candidates as substitutable and only offer to reimburse patients for the less expensive product. Even if we show improved efficacy or improved convenience of administration with our product candidates, pricing of existing third-party therapeutics may limit the amount we will be able to charge for our product candidates. These payors may deny or revoke the reimbursement status of a given product or establish prices for new or existing marketed products at levels that are too low to enable us to realize an appropriate return on our investment in our product candidates, if approved. Even if our product candidates are approved and we obtain coverage for our product candidates by a third-party payor, the resulting reimbursement payment rates may not be adequate or may require co-payments that patients find unacceptably high. Interim reimbursement levels for new medicines, if applicable, may also not be sufficient to cover our costs and may not be made permanent. Net prices for medicines may be reduced by mandatory discounts or rebates required by government healthcare programs or private payors and by any future relaxation of laws that presently restrict imports of medicines from countries where they may be sold at lower prices than in the United States. If reimbursement is not available or is available only at limited levels, we may not be able to successfully commercialize our product candidates, if approved, and may not be able to obtain a satisfactory financial return on our product candidates.

There is significant uncertainty related to the insurance coverage and reimbursement of newly approved products. The regulations that govern marketing approvals, pricing and reimbursement for new medicines vary widely from country to country. In the United States, third-party payors play an important role in determining the extent to which new drugs and biologics will be covered. The Medicare and Medicaid programs increasingly are used as models in the United States for how third-party payors develop their coverage and reimbursement policies for drugs and biologics. Some third-party payors may require pre-approval of coverage for new or innovative devices or drug therapies before they will reimburse healthcare providers who use such therapies. We cannot predict at this time what third-party payors will decide with respect to the coverage and reimbursement for our product candidates, if approved.

No uniform policy for coverage and reimbursement for products exists among third-party payors in the United States. Therefore, coverage and reimbursement for products can differ significantly from payor to payor and coverage and reimbursement by one payor does not guarantee coverage and reimbursement by another payor. As a result, the coverage determination process is often a time-consuming and costly process that will require us to provide scientific and clinical support for the use of our product candidates to each payor separately, with no assurance that coverage and adequate reimbursement will be applied consistently or obtained in the first instance. Furthermore, rules and regulations regarding reimbursement change frequently, in some cases on short notice, and we believe that changes in these rules and regulations are likely.

Even if a product candidate we develop receives marketing approval, it may fail to achieve the degree of market acceptance by physicians, patients, hospitals, cancer treatment centers, third-party payors and others in the medical community necessary for commercial success.

If any product candidate we develop receives marketing approval, whether as a single agent or in combination with other therapies, it may nonetheless fail to gain sufficient market acceptance by physicians, patients, hospitals, cancer treatment centers, third-party payors, and others in the medical community. For example, cancer treatments like chemotherapy, radiation therapy and certain existing immunotherapies are well established in the medical community, and doctors may continue to rely on these therapies. If the product candidates we develop do not achieve an adequate level of acceptance, we may not generate significant product revenues and we may not become profitable.

The degree of market acceptance of any product, if approved for commercial sale, will depend on a number of factors, including:

- its efficacy, safety and potential advantages compared to alternative treatments;
- the prevalence and severity of any side effects;
- the product's convenience and ease of administration compared to alternative treatments;
- the clinical indications for which the product is approved;
- the willingness of the target patient population to try a novel treatment and of physicians to prescribe such treatments;
- the recommendations with respect to the product in guidelines published by scientific organizations;
- the ability to obtain sufficient third-party insurance coverage and adequate reimbursement, including, if applicable, with respect to the use of the product as a combination therapy;
- the strength of marketing, sales and distribution support;
- the effectiveness of our sales and marketing efforts;
- the approval of other new products for the same indications; and
- our ability to offer the product for sale at competitive prices.

If we obtain marketing approval for a product but such product does not achieve an adequate level of market acceptance, we may not generate or derive significant revenue from that product and our business, financial condition and results of operations may be adversely affected.

We expect that WTX-124 and WTX-330, and other product candidates we develop, will be regulated as biological products, or biologics, and therefore they may be subject to competition sooner than anticipated.

The Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act of 2010, or collectively the ACA, includes a subtitle called the Biologics Price Competition and Innovation Act of 2009, or BPCIA, which created an abbreviated approval pathway for biologic products that are biosimilar to or interchangeable with an FDA-licensed reference biologic product. Under the BPCIA, a reference biological product is granted 12 years of non-patent exclusivity from the time of first licensure of the product, and the FDA will not accept an application for a biosimilar or interchangeable product based on the reference biological product until four years after the date of first licensure of the reference product. In addition, the approval of a biosimilar product may not be made effective by the FDA until 12 years from the date on which the reference product was first licensed. During this 12-year period of exclusivity, another company may still market a competing version of the reference product if the FDA approves a 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 the other company's product.

We believe that any of our product candidates approved as a biologic product under a BLA should qualify for the 12-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 investigational medicines to be reference products for competing products, potentially creating the opportunity for biosimilar competition sooner than anticipated. Moreover, the extent to which a biosimilar, once licensed, will be substituted for any one of our reference products in a way that is similar to traditional generic substitution for non-biologic products is not yet clear, and will depend on a number of marketplace and regulatory factors that are still developing.

If competitors are able to obtain regulatory approval for biosimilars referencing our product candidates, our product candidates may become subject to competition from such biosimilars, with the attendant competitive pressure and consequences.

Risks Related to Our Dependence on Third Parties

We rely, and expect to continue to rely, on third parties to conduct our preclinical studies and clinical trials. If these third parties do not successfully carry out their contractual duties or meet expected deadlines or comply with regulatory requirements, we may not be able to obtain regulatory approval of or commercialize any product candidates.

We depend, and expect to continue to depend, upon third parties, including independent investigators and contract research organizations, or CROs, to conduct preclinical studies and clinical trials. We expect to have to negotiate budgets and contracts with CROs and trial sites, and any of these third parties may terminate their engagements with us at any time, any of which may result in delays to our development timelines and increased costs.

Our reliance on these third parties for research and development activities will reduce our control over these activities but will not relieve us of our responsibility to ensure that each of our trials is conducted in accordance with the applicable protocol, legal and regulatory requirements and scientific standards, and our reliance on third parties does not relieve us of our regulatory responsibilities. We and these third parties are required to comply with current Good Clinical Practices, or cGCP, requirements for clinical trials, which are regulations and guidelines enforced by the FDA and comparable foreign regulatory authorities for product candidates in clinical development. Regulatory authorities enforce these cGCP requirements through periodic inspections of trial sponsors, clinical investigators and trial sites. If we or any of these third parties fail to comply with applicable cGCP requirements, the clinical data generated in our clinical trials may be deemed unreliable and the FDA or comparable foreign regulatory authorities may require us to suspend or terminate these trials or perform additional preclinical studies or clinical trials before approving our marketing applications. We cannot be certain that, upon inspection, such regulatory authorities will determine that any of our clinical trials comply with the cGCP requirements. In addition, our clinical trials must be conducted with biologic product produced under current Good Manufacturing Practice, or cGMP, requirements.

Our failure or any failure by these third parties to comply with the applicable regulations may require us to repeat clinical trials, which would delay the regulatory approval process. Moreover, our business may be implicated if any of these third parties violates federal or state fraud and abuse or false claims laws and regulations or healthcare privacy and security laws.

Any third parties conducting our clinical trials will not be our employees and, except for remedies that may be available to us under our agreements with such third parties, we cannot control whether or not they devote sufficient time and resources to our clinical trials. These third parties may also have relationships with other commercial entities, including our competitors, for whom they may also be conducting clinical trials or other product development activities, which could affect their performance on our behalf. If these third parties do not successfully carry out their contractual duties or obligations or meet expected deadlines, if they need to be replaced or if the quality or accuracy of the clinical data they obtain is compromised due to the failure to adhere to our clinical protocols or regulatory requirements or for other reasons, our clinical trials may be extended, delayed or terminated and we may not be able to complete development of, obtain regulatory approval of or successfully commercialize our product candidates. As a result, our financial results and the commercial prospects for our product candidates would be harmed, our costs could increase and our ability to generate revenue could be delayed.

If any of our relationships with these third-party CROs or others terminate, we may not be able to enter into arrangements with alternative CROs or other third parties or to do so on commercially reasonable terms. Switching or adding additional CROs involves additional cost and requires management time and focus. In addition, there is a natural transition period when a new CRO begins work. As a result, delays may occur, which could materially impact our ability to meet our desired clinical development timelines. Though we plan to carefully manage our relationships with CROs, there can be no assurance that we will not encounter challenges or delays in the future or that these delays or challenges will not have a material adverse impact on our business, financial condition and prospects.

The manufacturing of biologics is complex and we do not have our own clinical manufacturing capabilities. We will rely on third parties to produce preclinical, clinical and commercial supplies of all current and any future product candidates.

To date, we have produced limited quantities of our product candidates at our own facilities for preclinical evaluation. However, going forward we will rely on third-party contract manufacturers to manufacture some of our preclinical supply and all of our clinical trial supply. We do not own manufacturing facilities capable of producing drug products at clinical scale. We have in the past experienced delays in receiving preclinical product supplies from third-party manufacturers and there can be no assurance that our preclinical and clinical development product supplies from third parties will not in the future be limited or interrupted, or be of satisfactory quality or continue to be available at acceptable prices. Additionally, the process of manufacturing biologics is complex, highly regulated, and subject to multiple risks. Manufacturing biologics is highly susceptible to product loss due to contamination, equipment failure, improper installation or operation of equipment, vendor or operator error, inconsistency in yields, variability in product characteristics and difficulties in scaling the production process. Even minor deviations from normal manufacturing processes could result in reduced production yields, product defects, other supply disruptions and higher costs. If microbial, viral or other contaminations are discovered at the facilities of our contract manufacturing organizations, or CMOs, such facilities may need to be closed for an extended period of time to investigate and

remedy the contamination, which could delay clinical trials, result in higher costs of drug product and adversely affect our business.

We have engaged CMOs to provide certain services to support our clinical and preclinical development. Pursuant to the terms of separate contract manufacturing services agreements, we have engaged one CMO to provide drug substance manufacturing process development and to manufacture WTX-124 and WTX-330 drug substance to cGMP specifications for use in the further manufacture of clinical supply and a second CMO to provide drug product manufacturing process development and to manufacture clinical supply of WTX-124 and WTX-330 vialled drug product to cGMP specifications. To support the manufacture of drug substance and drug product, our CMOs will conduct substantial analytical testing of drug substance and vialled drug product. If our CMOs are unable to supply us with sufficient clinical grade quantities of WTX-124 or WTX-330, and we are unable to timely establish an alternate supply from one or more third-party contract manufacturers, we will experience delays in our development efforts as we seek to locate and qualify new manufacturers. In particular, any replacement of our CMOs could require significant effort and expertise because there may be a limited number of qualified replacements or capacity could be limited at each of the qualified replacements. Additionally, contract manufacturers may rely on single source suppliers for certain of the raw materials for our preclinical and clinical product supplies. If current or future suppliers are delayed or unable to supply sufficient raw materials to manufacture product for our preclinical studies and clinical trials, we may experience delays in our development efforts as materials are obtained or we locate and qualify new raw material manufacturers. Further, for our combination clinical trial of WTX-124 with pembrolizumab, an immune checkpoint inhibitor, we will need to procure supply of pembrolizumab for use in the clinical trials. If we are unable to procure sufficient supply from third-party manufacturers or other sources, we may be required to purchase our supply of checkpoint inhibitors on the open market, which may result in significant additional expense.

The manufacturing process for a clinical candidate is subject to FDA and foreign regulatory authority review. Suppliers and manufacturers must meet applicable manufacturing requirements and undergo rigorous facility and process validation tests required by regulatory authorities in order to comply with their standards, such as cGMPs. In the event that any of our CMOs fail to comply with such requirements or to perform their obligations to us in relation to quality, timing or otherwise, or if our supply of components or other materials becomes limited or interrupted for other reasons, we may be forced to manufacture the materials ourselves, for which we currently do not have the capabilities or resources, or enter into an agreement with another third-party, which we may not be able to do on reasonable terms, if at all. The transfer of the manufacturing of biologic products to a new CMO and any additional process development that may be necessary can be lengthy and involve significant additional costs. If we are required to change CMOs for any reason, we will be required to verify that the new CMO maintains facilities and procedures that comply with quality standards and with all applicable regulations and guidelines. The delays associated with the verification of a new CMO would negatively affect our ability to develop product candidates in a timely manner or within budget.

Further, our reliance on third-party manufacturers exposes us to risks beyond our control, including the:

- inability to meet our drug specifications and quality requirements consistently;
- inability to initiate or continue preclinical studies or clinical trials of product candidates under development;
- delay or inability to procure or expand sufficient manufacturing capacity;
- manufacturing and drug quality issues, including related to scale-up of manufacturing;
- failure to comply with cGMP and similar foreign standards;
- reliance on a limited number of sources, and in some cases, single sources for drug components and raw materials, such that if we are unable to secure a sufficient supply of these drug components and raw materials, we will be unable to manufacture and sell our future product candidate in a timely fashion, in sufficient quantities or under acceptable terms;
- lack of qualified backup suppliers for those components and raw materials that are purchased from a sole or single source supplier;
- inability to negotiate manufacturing agreements with third parties under commercially reasonable terms;
- termination or nonrenewal of manufacturing agreements with third parties in a manner or at a time that is costly or damaging to us;
- disruption of operations by conditions unrelated to our business or operations, including the bankruptcy of the manufacturer or supplier or the issuance of an FDA Form 483 notice or warning letter, or as a result of the effects of the COVID-19 pandemic on third-party manufacturers;
- carrier disruptions or increased costs that are beyond our control;

- failure to deliver our drugs under specified storage conditions and in a timely manner; and
- the possible misappropriation of our proprietary information, including our trade secrets and know-how.

Some of these events could be the basis for FDA action, including injunction, recall, seizure or total or partial suspension of production, any of which could result in a failure to begin our clinical trials or having to stop ongoing clinical trials. In addition, our CMOs and suppliers are subject to FDA inspection from time to time. Failure by our CMOs and suppliers to pass such inspections and otherwise satisfactorily complete the FDA approval regimen with respect to our product candidate may result in regulatory actions such as the issuance of FDA Form 483 notices of observations, warning letters or injunctions or the loss of operating licenses. In addition, our CMOs and suppliers are subject to numerous environmental, health and safety laws and regulations, including those governing the handling, use, storage, treatment and disposal of waste products, and failure to comply with such laws and regulations could result in significant costs associated with civil or criminal fines and penalties for such third parties. Based on the severity of the regulatory action, our clinical or commercial supply of drug and packaging and other services could be interrupted or limited, which could harm our business.

In addition, our CMOs are or may be engaged with other companies to supply and manufacture materials or products for such companies, which also exposes our suppliers and CMOs to regulatory risks for the production of such materials and products. As a result, failure to meet the regulatory requirements for the production of those materials and products may also affect the regulatory clearance of a contract supplier's or CMO's facility, which could impact the contract supplier's or CMO's ability to manufacture drug product for us.

We have entered into, and may in the future seek to enter into, collaborations or other similar arrangements for our product candidates. If we are unable to enter into such collaborations, or if these collaborations are not successful, our business could be adversely affected.

A part of our strategy is to strategically evaluate and, as deemed appropriate, enter into collaborations in the future on an asset-by-asset basis to maximize the value of each of our programs. For example, in April 2022, we entered into a Collaboration and License Agreement, or the Collaboration Agreement, with Jazz Pharmaceuticals Ireland Limited, or Jazz, pursuant to which we granted Jazz certain licenses to develop and commercialize products containing our Interferon alpha, or IFNα, INDUKINE molecule, JZP898, as well as products containing certain isolated recombinant polypeptides comprising IFNα that meet specified criteria. We may also enter into collaborations in connection with our platform technology in order to advance the development of programs beyond our initial focus in cytokines. Such collaborations may include the development and commercialization of any of our product candidates or the commercialization of any of our product candidates that are approved for marketing outside the United States. Our likely collaborators for any collaboration arrangements include large and mid-size pharmaceutical companies, regional and national pharmaceutical companies and biotechnology companies. We have limited capabilities for product development and do not yet have any capability for commercialization. Accordingly, we may enter into collaborations with other companies to provide us with important technologies and funding for our programs and platform technology. We will face significant competition in seeking appropriate collaborators. We may not be successful in our efforts to establish a strategic partnership or other alternative arrangements for any product candidates because they may be deemed to be at too early of a stage of development for collaborative effort and third parties may not view such product candidates as having the requisite potential to demonstrate safety and efficacy. We may also be restricted under future license agreements from entering into agreements on certain terms or at all with potential collaborators.

Existing and future collaborations involving our product candidates may pose significant risks to us, including the following:

- collaborators have significant discretion in determining the efforts and resources that they will apply to these collaborations;
- collaborators may not perform their obligations as expected;
- we could grant exclusive rights to our collaborators that would prevent us from collaborating with others;
- collaborators may not pursue development and commercialization of any product candidates that achieve regulatory approval or may elect not to continue or renew development or commercialization programs based on clinical trial results, changes in the collaborators' strategic focus or available funding, or external factors, such as an acquisition, that divert resources or create competing priorities;
- collaborators may delay clinical trials, provide insufficient funding for a clinical trial program, stop a clinical trial or abandon a product candidate, repeat or conduct new clinical trials or require a new formulation of a product candidate for clinical testing;
- collaborators could independently develop, or develop with third parties, products that compete directly or indirectly with our product candidates if the collaborators believe that competitive products are more likely to be successfully developed or can be commercialized under terms that are more economically attractive than ours;

- product candidates discovered in collaboration with us may be viewed by our collaborators as competitive with their own product candidates or drugs, which may cause collaborators to cease to devote resources to the commercialization of our product candidates;
- a collaborator with marketing and distribution rights to one or more of our product candidates that achieve regulatory approval may not commit sufficient resources to the marketing and distribution of such products;
- a collaborator's sales and marketing activities or other operations may not be in compliance with applicable laws resulting in civil or criminal proceedings;
- disagreements with collaborators, including disagreements over proprietary rights, contract interpretation or the preferred course of development, might cause delays in or termination of the research, development or commercialization of product candidates, might lead to additional responsibilities for us with respect to product candidates, or might result in litigation or arbitration, any of which would be time-consuming and expensive;
- collaborators may not properly maintain or defend our or their intellectual property rights or may use our or their proprietary information in such a way as to invite litigation that could jeopardize or invalidate such intellectual property or proprietary information or expose us to potential litigation;
- collaborators may infringe the intellectual property rights of third parties, which may expose us to litigation and potential liability;
- collaborators may not provide us with timely and accurate information regarding development, regulatory or commercialization status or results, which could adversely impact our ability to manage our own development efforts, accurately forecast financial results or provide timely information to our stockholders regarding our out-licensed product candidates;
- if a collaborator of ours were to be involved in a business combination, the continued pursuit and emphasis on our product development or commercialization program could be delayed, diminished or terminated; and
- collaborations may be terminated, including for the convenience of the collaborator, and, if terminated, we may find it more difficult to enter into future collaborations or be required to raise additional capital to pursue further development or commercialization of the applicable product candidates.

Any collaborations that we enter into may not be successful. The success of our collaboration arrangements will depend heavily on the efforts and activities of our collaborators. Collaboration agreements may not lead to development or commercialization of product candidates in the most efficient manner or at all. In addition, all of the risks relating to product development, regulatory approval and commercialization described in this Annual Report will apply to the activities of any of our collaborators.

Risks Related to Our Intellectual Property

If we are unable to obtain and maintain patent protection for any product candidates we develop or for our PREDATOR platform and other proprietary technologies we may develop, or if the scope of the patent protection obtained is not sufficiently broad, our competitors could develop and commercialize product candidates and technology similar or identical to our product candidates and technology, and our ability to successfully commercialize any product candidates we may develop, and our technology may be adversely affected.

Our success depends in large part on our ability to obtain and maintain patent protection in the United States and other countries with respect to our PREDATOR platform, our product candidates, their respective components, formulations, combination therapies, methods used to manufacture them and methods of treatment and development that are important to our business. If we do not adequately protect our intellectual property rights, competitors may be able to erode or negate any competitive advantage we may have, which could harm our business and ability to achieve profitability. To protect our proprietary position, we file patent applications in the United States and abroad related to our PREDATOR platform and our product candidates that are important to our business; we also license and may in the future license or purchase additional patents and patent applications filed by others. If we are unable to secure or maintain patent protection with respect to our PREDATOR platform, our product candidates and any proprietary products and technology we develop, our business, financial condition, results of operations and prospects could be materially harmed.

If the scope of the patent protection we or our potential licensors obtain is not sufficiently broad, we may not be able to prevent others from developing and commercializing technology and products similar or identical to ours. The degree of patent protection we require to successfully compete in the marketplace may be unavailable or severely limited in some cases and may not adequately protect our rights or permit us to gain or keep any competitive advantage. We cannot provide any assurances that any of our patents have, or that any of our pending patent applications that mature into issued patents will include, claims with a scope sufficient to protect our current and future product candidates or otherwise provide any competitive advantage. In

addition, to the extent that we license intellectual property in the future, we cannot provide assurances that those licenses will remain in force. In addition, the laws of foreign countries may not protect our rights to the same extent as the laws of the United States. Furthermore, patents have a limited lifespan. In the United States, the natural expiration of a patent is generally 20 years after it is filed. Various extensions may be available; however, the life of a patent, and the protection it affords, is limited. 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.

Our patents and pending patent applications, if issued, may not provide us with any meaningful protection or prevent competitors from designing around our patent claims to circumvent our patents by developing similar or alternative technologies or therapeutics in a non-infringing manner. For example, a third party may develop a competitive therapy that provides benefits similar to one or more of our product candidates but that uses a formulation and/or a device that falls outside the scope of our patent protection. If the patent protection provided by the patents and patent applications we hold or pursue with respect to our product candidates is not sufficiently broad to impede such competition, our ability to successfully commercialize our product candidates could be negatively affected, which would harm our business.

Patent positions of life sciences companies can be uncertain and involve complex factual and legal questions. No consistent policy governing the scope of claims allowable in the field of engineered therapeutic proteins has emerged in the United States. The scope of patent protection in jurisdictions outside of the United States is also uncertain. Changes in either the patent laws or their interpretation in any jurisdiction that we seek patent protection may diminish our ability to protect our inventions, maintain and enforce our intellectual property rights; and, more generally, may affect the value of our intellectual property, including the narrowing of the scope of our patents and any that we may license.

The patent prosecution process is complex, expensive, time-consuming and inconsistent across jurisdictions. We may not be able to file, prosecute, maintain, enforce, or license all necessary or desirable patent rights at a commercially reasonable cost or in a timely manner. In addition, we may not pursue or obtain patent protection in all relevant markets. It is possible that we will fail to identify important patentable aspects of our research and development efforts in time to obtain appropriate or any patent protection. While we enter into non-disclosure and confidentiality agreements with parties who have access to confidential or patentable aspects of our research and development efforts, including for example, our employees, external academic scientific collaborators, CROs, contract manufacturers, consultants, advisors and other third parties, any of these parties may breach the agreements and disclose our confidential or proprietary information before a patent application is filed, thereby endangering our ability to seek patent protection. In addition, publications of discoveries in the scientific and scholarly literature often lag behind the actual discoveries, and patent applications in the United States and other jurisdictions are typically not published until 18 months after filing, or in some cases not at all. Consequently, we cannot be certain that we were the first to file for patent protection on the inventions claimed in our patents or pending patent applications.

The issuance, scope, validity, enforceability and commercial value of our patent rights are highly uncertain. Pending patent applications cannot be enforced against third parties unless, and until, patents issue from such applications, and then only to the extent the issued claims cover the technology. There can be no assurance that our patent applications or any patent applications that we may license in the future will result in patents being issued. Further, the scope of the invention claimed in a patent application can be significantly reduced before the patent is issued, and this scope can be reinterpreted after issuance. Even if patent applications we currently own or that we may license in the future issue as patents, they may not issue in a form that will provide us with adequate protection to prevent competitors or other third parties from competing with us, or otherwise provide us with a competitive advantage. Any patents that eventually issue may be challenged, narrowed or invalidated by third parties. Consequently, we do not know whether our PREDATOR platform or any of our product candidates will be protectable or remain protected by valid and enforceable patent rights. Our competitors or other third parties may be able to evade our patent rights by developing new products that are similar to our product candidates, biosimilars of our product candidates, or alternative technologies or products in a non-infringing manner.

The issuance or grant of a patent is not irrefutable as to its inventorship, scope, validity or enforceability, and our patents may be challenged in the courts or patent offices in the United States and abroad. There may be prior art of which we are not aware that may affect the validity or enforceability of a patent claim. There also may be prior art of which we are aware, but which we do not believe affects the validity or enforceability of a claim, which may, nonetheless, ultimately be found to affect the validity or enforceability of a claim. We may in the future, become subject to a third-party pre-issuance submission of prior art or opposition, derivation, revocation, re-examination, post-grant and *inter partes* review, or interference proceeding and other similar proceedings challenging our patent rights or the patent rights of others in the U.S. Patent and Trademark Office, or USPTO, or other foreign patent office. An unfavorable determination in any such submission, proceeding or litigation could reduce the scope of, or invalidate, our patent rights, allow third parties to commercialize our technology or products and compete directly with us, without payment to us, or extinguish our ability to manufacture or commercialize products without infringing third-party patent rights.

In addition, 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. Moreover, some of our owned and in-licensed patents and patent applications may in the future be co-owned with third parties. If we are unable to obtain an exclusive license to any such third-party co-owners' interest in such patents or patent applications, such co-owners may be able to license their rights to other third parties, including our competitors, and our competitors could market competing products and technology. In addition, we or our licensors may need the cooperation of any such co-owners of our owned and in-licensed patents in order to enforce such patents against third parties, and such cooperation may not be provided to us or our licensors. Any of the foregoing could have a material adverse effect on our competitive position, business, financial conditions, results of operations and prospects.

We rely on the Harpoon Agreement for patent rights with respect to our product candidates and may in the future acquire additional third-party intellectual property rights on which we may similarly rely. We face risks with respect to such reliance, including the risk that we could lose these rights that are important to our business if we fail to comply with our obligations under these licenses.

We rely on our Second Amended and Restated Assignment and License Agreement, or the Harpoon Agreement, with Harpoon, pursuant to which we have non-exclusive and exclusive rights to technology that is incorporated into our PREDATOR platform, development programs and product candidates. The Harpoon Agreement gives us non-exclusive, sublicensable, worldwide rights to develop, manufacture, and commercialize products containing certain of Harpoon's patented technology and exclusive, irrevocable rights to certain other Harpoon inventions that may be made during a limited collaboration period. The Harpoon Agreement imposes disclosure, royalty payment and other obligations on us.

Moreover, the growth of our business may depend in part on our ability to acquire, in-license or use additional third-party intellectual property rights. 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. Licenses to additional third-party intellectual property, technology and materials that may be required for the development and commercialization of our product candidates or technology may not be available at all or on commercially reasonable terms. In that event, we may be required to expend significant time and resources to redesign our product candidates or to develop or license replacement technology, all of which may not be feasible on a technical or commercial basis. If we are unable to do so, we may be unable to develop or commercialize our future product candidates or technologies, which could materially harm our business, financial condition, results of operations and growth prospects.

Under the Harpoon Agreement, Harpoon is responsible for prosecution and maintenance of the licensed patents and any future third party from whom we may license patent rights may similarly be responsible for prosecution and maintenance of such patents. We have limited control over the activities that are the responsibility of Harpoon and would have limited control over the activities that are the responsibility of any future licensor, and it is possible that prosecution and maintenance of licensed patents by Harpoon or any future licensor may be less vigorous than had we conducted such activities ourselves. Furthermore, the Harpoon Agreement is subject to, and we expect our future license agreements may also be subject to, a reservation of rights by the licensor and/or one or more third parties. The resolution of any contract interpretation disagreement that may arise could narrow what we believe to be the scope of our rights to the relevant intellectual property or technology, or increase what we believe to be our financial or other obligations under the relevant agreement, either of which could have a material adverse effect on our business, financial condition, results of operations and growth prospects.

Disputes may arise regarding intellectual property subject to the Harpoon Agreement or any future license agreements of ours, including:

- the scope of rights granted under the license agreement and other interpretation-related issues;
- our or our licensor's ability to defend intellectual property and to enforce intellectual property rights against third parties;
- the extent to which our technology, product candidates and processes infringe, misappropriate or otherwise violate any intellectual property of the licensor that is not subject to the licensing agreement;
- the sublicensing of patent and other rights under the license agreement;
- our diligence obligations under the license agreement and what activities satisfy those diligence obligations;
- the inventorship and ownership of inventions and know-how resulting from the joint creation or use of intellectual property by our licensors and us and any partners of ours; and

- the priority of invention of patented technology.

If disputes over intellectual property that we have licensed prevent or impair our ability to maintain our licensing arrangements on acceptable terms, we may be unable to successfully develop and commercialize the affected product candidates. We are generally also subject to all of the same risks described in this Annual Report with respect to protection of intellectual property that we license as we are for intellectual property that we own. If we or our licensors fail to adequately protect this intellectual property, our ability to commercialize products could suffer.

Harpoon and any potential future licensors might conclude that we have materially breached our license agreements and might therefore terminate the relevant license agreements, thereby removing our ability to develop and commercialize products and technology covered by such license agreements. If any of our current or future inbound license agreements are terminated, or if the underlying patents fail to provide the intended exclusivity, competitors would have the freedom to seek regulatory approval of, and to market, products that are covered by such license agreements and underlying patents, which might be identical to our products or product candidates. This could have a material adverse effect on our competitive position, business, financial conditions, results of operations and growth prospects. Our business also would suffer if any current or future licensors fail to abide by the terms of the license or fail to enforce licensed patents against infringing third parties, if the licensed patents or other rights are found to be invalid or unenforceable, or if we are unable to enter into necessary licenses on acceptable terms. Moreover, our licensors may own or control intellectual property that has not been licensed to us and, as a result, we may be subject to claims, regardless of their merit, that we are infringing or otherwise violating the licensor's rights.

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

In addition, while we cannot currently determine the amount of the royalty obligations we would be required to pay on sales of future products, if any, the amounts may be significant. The amount of our future royalty obligations will depend on the technology and intellectual property we use in products that we successfully develop and commercialize, if any. Therefore, even if we successfully develop and commercialize products, we may be unable to achieve or maintain profitability.

If our efforts to protect the proprietary nature of the intellectual property related to our technologies and product candidates are not adequate, we may not be able to compete effectively in our market.

Biotechnology and pharmaceutical companies generally, and we in particular, compete in a crowded competitive space characterized by rapidly evolving technologies and aggressive defense of intellectual property. 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. Our or our licensor's failure to comply with all such provisions during the patent process could result in abandonment or lapse of a patent or patent application that we own or license, resulting in partial or complete loss of patent rights in the relevant jurisdiction. In such an event, competitors might be able to enter the market and compete with us earlier than would otherwise have been the case.

We rely upon a combination of patents, confidentiality agreements, trade secret protection and license agreements to protect the intellectual property related to our technologies and our product candidates. Any disclosure to or misappropriation by third parties of our confidential proprietary information could enable competitors to quickly duplicate or surpass our technological achievements and product candidates, thus eroding our competitive position in our market. We, or any future partners, collaborators, or licensees, may fail to identify patentable aspects of inventions made in the course of development and commercialization activities before it is too late to obtain patent protection on them. Therefore, we may miss potential opportunities to strengthen our patent position.

It is possible that defects of form in the preparation or filing of our patents or patent applications may exist, or may arise in the future, for example with respect to proper priority claims, inventorship, claim scope, or requests for patent term adjustments. If we or our partners, collaborators, licensees or licensors fail to establish, maintain or protect such patents and other intellectual property rights, such rights may be reduced or eliminated. If our partners, collaborators, licensees or licensors are not fully cooperative or disagree with us as to the prosecution, maintenance or enforcement of any patent rights, such patent rights could be compromised. If there are material defects in the form, preparation, prosecution, or enforcement of our patents or patent applications, such patents may be invalid and/or unenforceable, and such applications may never result in valid, enforceable patents. Any of these outcomes could impair our ability to prevent competition from third parties, which may have an adverse impact on our business.

We seek or plan to seek patent protection for our PREDATOR platform and product candidates by filing and prosecuting patent applications in the United States and other countries as appropriate. However, we cannot predict:

- if and when patents will issue;
- if patents will issue with claims that cover our product candidates;
- the degree and range of protection any issued patents will afford us against competitors including whether third parties will find ways to invalidate or otherwise circumvent our patents;
- whether any of our intellectual property will provide any competitive advantage;
- whether any of our patents that may be issued may be challenged, invalidated, modified, revoked, circumvented, found to be unenforceable or otherwise may not provide any competitive advantage;
- whether or not others will obtain patents claiming aspects similar to those covered by our patents and patent applications; or
- whether we will need to initiate or defend litigation or administrative proceedings which may be costly regardless of whether we win or lose.

Additionally, we cannot be certain that the claims in our pending patent applications covering our product candidates, PREDATOR platform and research programs will be considered patentable by the USPTO, or by patent offices in foreign countries, or that the claims in any of our issued patents will be considered valid by courts in the United States or foreign countries.

The strength of patents in the biotechnology and pharmaceutical field involves complex legal and scientific questions and can be uncertain. The patent applications that we own or in-license may fail to result in issued patents with claims that cover our product candidates or technology or uses thereof in the United States or in other foreign countries. Even if patents do successfully issue, third parties may challenge the validity, enforceability or scope thereof, which may result in such patents being narrowed, invalidated or held unenforceable. Furthermore, even if they are unchallenged, our patents and patent applications may not adequately protect our intellectual property or prevent others from designing around our claims. If the breadth or strength of protection provided by the patents and patent applications we hold with respect to our product candidates or technology is threatened, it could dissuade companies from collaborating with us to develop, and threaten our ability to commercialize, our product candidates. Further, if we encounter delays in our clinical trials, the period of time during which we could market our product candidates under patent protection would be reduced. Since patent applications in the United States and most other countries are confidential for a period of time after filing, we cannot be certain that we were the first to file any patent application related to our product candidates. Furthermore, for U.S. applications in which all claims are entitled to a priority date before March 16, 2013, an interference proceeding can be provoked by a third-party or instituted by the USPTO to determine who was the first to invent any of the subject matter covered by the patent claims of our applications. We cannot be certain that we are the first to invent the inventions covered by pending patent applications and, if we are not, we may be subject to priority disputes. We may be required to disclaim part or all of the term of certain patents or all of the term of certain patent applications. Various post-grant review proceedings, such as *inter partes* review, post-grant review and derivation proceedings, are available and may be pursued by any interested third party in the USPTO to challenge the patentability of claims issued in patents to us or our licensors. No assurance can be given as to the outcome of any such post-grant review proceedings. No assurance can be given that if challenged, our patents would be declared by a court to be valid or enforceable or that even if found valid and enforceable, a competitor's technology or product would be found by a court to infringe our patents. We may analyze patents or patent applications of our competitors that we believe are relevant to our activities, and consider that we are free to operate in relation to our product candidates, but our competitors may achieve issued claims, including in patents we consider to be unrelated, which block our efforts or may potentially result in our product candidates or our activities infringing such claims. The possibility exists that others will develop products which have the same effect as our products on an independent basis which do not infringe our patents or other intellectual property rights, or will design around the claims of patents that we have had issued that cover our products.

Recent or future 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. In March 2013, under the Leahy-Smith America Invents Act, or America Invents Act, the United States moved from a "first to invent" to a "first-to-file" system. Under a "first-to-file" system, assuming the other requirements for patentability are met, the first inventor to file a patent application generally will be entitled to a patent on the invention regardless of whether another inventor had made the invention earlier. The America Invents Act includes a number of other significant changes to U.S. patent law, including provisions that affect the way patent applications are prosecuted, redefine prior art and establish a USPTO-administered post-grant review system that has affected patent litigation. The America Invents Act and its implementation could increase the uncertainties and costs surrounding the

prosecution of our patent applications and the enforcement or defense of our issued patents, all of which could have a material adverse effect on our business and financial condition.

The degree of future protection for our proprietary rights is uncertain because legal means afford only limited protection and may not adequately protect our rights or permit us to gain or keep our competitive advantage. For example:

- others may be able to make or use polypeptides or nucleic acids that are similar to our product candidates or components of our product candidates but that are not covered by the claims of our patents;
- the active biological ingredients in our current product candidates will eventually become commercially available in biosimilar drug products, and no patent protection may be available with regard to formulation or method of use;
- we or our licensors, as the case may be, may fail to meet our obligations to the U.S. government in regards to any patents and patent applications funded by U.S. government grants, leading to the loss of patent rights;
- we or our licensors, as the case may be, might not have been the first to file patent applications for these inventions;
- others may independently develop similar or alternative technologies or duplicate any of our technologies;
- it is possible that our pending patent applications will not result in issued patents;
- it is possible that there are prior public disclosures that could invalidate our or our licensors' patents, as the case may be, or parts of our or their patents;
- it is possible that others may circumvent our owned or in-licensed patents;
- it is possible that there are unpublished applications or patent applications maintained in secrecy that may later issue with claims covering our products or technology similar to ours;
- the laws of foreign countries may not protect our or our licensors', as the case may be, proprietary rights to the same extent as the laws of the United States;
- the claims of our owned or in-licensed issued patents or patent applications, if and when issued, may not cover our product candidates or technology;
- our owned or in-licensed issued patents may not provide us with any competitive advantages, may be narrowed in scope, or be held invalid or unenforceable as a result of legal challenges by third parties;
- the inventors of our owned or in-licensed patents or patent applications may become involved with competitors, develop products or processes which design around our patents, or become hostile to us or the patents or patent applications on which they are named as inventors;
- it is possible that our owned or in-licensed patents or patent applications omit individual(s) that should be listed as inventor(s) or include individual(s) that should not be listed as inventor(s), which may cause these patents or patents issuing from these patent applications to be held invalid or unenforceable;
- we have engaged in scientific collaborations in the past and will continue to do so in the future, and such collaborators may develop adjacent or competing products to ours that are outside the scope of our patents;
- we may not develop additional proprietary technologies for which we can obtain patent protection;
- it is possible that product candidates or technology we develop may be covered by third parties' patents or other exclusive rights; or
- the patents of others may have an adverse effect on our business.

Our proprietary position in part depends upon patents that are manufacturing, formulation or method-of-use patents, which may not prevent a competitor or other third party from using the same product candidate for another use.

Composition of matter patents for biological and pharmaceutical products are generally considered to be the strongest form of intellectual property protection for those types of products, as such patents provide protection without regard to any method of making or method of use. We have issued patents with certain composition of matter claims with respect to WTX-124 and IL-12 INDUKINE molecules and also have pending patent applications with other composition of matter claims with respect to our product candidates. We cannot be certain, however, that the claims in our pending patent applications, including those claims covering the composition of matter of our product candidates, will be considered patentable by the USPTO or by patent offices in foreign countries, or that the claims in any of our patents that have issued or may issue will be considered valid and enforceable by courts in the United States or foreign countries. Furthermore, in some cases, we may not be able to obtain issued

claims covering compositions of matter relating to our product candidates, and instead may need to rely on filing patent applications with claims covering a method of use and/or method of manufacture. Method of use patents protect a specified method of using a product, such as a method of use for treating a particular medical indication. This type of patent does not prevent a competitor from making and marketing a product that is identical to our product for an indication that is outside the scope of the patented method. Moreover, even if competitors do not actively promote their products for our targeted indications, physicians may prescribe these products "off-label" for those uses that are covered by our method of use patents. Although off-label prescriptions may infringe or contribute to the infringement of method of use patents, the practice is common and such infringement is difficult to prevent by enforcing patent rights or otherwise. There can be no assurance that any such patent applications will issue as granted patents, and even if they do issue, such patent claims may be insufficient to prevent third parties, such as our competitors, from utilizing our technology. Any failure to obtain or maintain patent protection with respect to our product candidates could have a material adverse effect on our business, financial condition, results of operations, and prospects.

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

In addition to the protection afforded by patents, we seek to rely on trade secret protection, confidentiality agreements, and license and other agreements to protect proprietary know-how that is not patentable, processes for which patents are difficult to enforce and any other elements of our product discovery and development processes that involve proprietary know-how, information, or technology that is not covered by patents. We cannot be certain that our trade secrets and other confidential proprietary information will not be disclosed or that competitors will not otherwise gain access to our trade secrets or independently develop substantially equivalent information and techniques. Furthermore, the laws of some foreign countries do not protect proprietary rights to the same extent or in the same manner as the laws of the United States. As a result, we may encounter significant problems in protecting and defending our intellectual property both in the United States and abroad. If we are unable to prevent unauthorized material disclosure of our intellectual property to third parties, we will not be able to establish or maintain a competitive advantage in our market, which could materially adversely affect our business, operating results and financial condition.

Courts outside the United States are sometimes less willing to protect trade secrets. If we choose to go to court to stop a third party from using any of our trade secrets, we may incur substantial costs. These lawsuits may consume our time and other resources even if we are successful. For example, significant elements of our product candidates and PREDATOR platform, including aspects of sample preparation, methods of manufacturing, cell culturing conditions, computational-biological algorithms and related processes are based on unpatented trade secrets that are not publicly disclosed. Although we take steps to protect our proprietary information and trade secrets, including through contractual means with our employees and consultants, third parties may independently develop substantially equivalent proprietary information and techniques or otherwise gain access to our trade secrets or disclose our technology.

Thus, we may not be able to meaningfully protect our trade secrets. It is our policy to require our employees, consultants, outside scientific collaborators, sponsored researchers and other advisors to execute confidentiality agreements upon the commencement of employment or consulting relationships with us. These agreements provide that all confidential information concerning our business or financial affairs developed or made known to the individual or entity during the course of the party's relationship with us is to be kept confidential and not disclosed to third parties except in specific circumstances. In the case of employees, the agreements provide that all inventions conceived by the individual, and which are related to our current or planned business or research and development or made during normal working hours, on our premises or using our equipment or proprietary information, are our exclusive property. In addition, we take other appropriate precautions, such as physical and technological security measures, to guard against misappropriation of our proprietary technology by third parties. We have also adopted policies and conduct training that provides guidance on our expectations, and our advice for best practices, in protecting our trade secrets. However, we cannot provide assurance that these agreements and policies will not be breached by our employees, consultants, outside scientific collaborators, sponsored researchers and other advisors and that our trade secrets and other proprietary and confidential information will not be disclosed publicly or to competitors.

Third-party claims of intellectual property infringement may prevent or delay our product discovery and development efforts.

Our commercial success depends in part on our avoiding infringement of the patents and proprietary rights of third parties. There is a substantial amount of litigation involving patents and other intellectual property rights in the biotechnology and pharmaceutical industries, as well as administrative proceedings for challenging patents, including interference, reexamination, and post-grant review proceedings before the USPTO or oppositions and other comparable proceedings in foreign jurisdictions. We may be exposed to, or threatened with, future litigation by third parties having patent or other intellectual property rights alleging that our product candidates and/or proprietary technologies infringe their intellectual property rights. Numerous U.S. and foreign issued patents and pending patent applications, which are owned by third parties, exist in the fields in which we are developing our product candidates. As the biotechnology and pharmaceutical industries expand and more patents are issued, the

risk increases that our product candidates may give rise to claims of infringement of the patent rights of others. Moreover, it is not always clear to industry participants, including us, which patents cover various types of drugs, products or their methods of use or manufacture. Thus, because of the large number of patents issued and patent applications filed in our fields, there may be a risk that third parties may allege they have patent rights encompassing our product candidates, technologies or methods.

If a third party claims that we infringe its intellectual property rights, we may face a number of issues, including, but not limited to:

- infringement and other intellectual property claims which, regardless of merit, may be expensive and time-consuming to litigate and may divert our management's attention from our core business;
- substantial damages for infringement, which we may have to pay if a court decides that the product candidate or technology at issue infringes on or violates the third party's rights, and, if the court finds that the infringement was willful, we could be ordered to pay treble damages and the patent owner's attorneys' fees;
- a court prohibiting us from developing, manufacturing, marketing or selling our product candidates, or from using our proprietary technologies, unless the third party licenses its product rights to us, which it is not required to do;
- if a license is available from a third party, we may have to pay substantial royalties, upfront fees and other amounts, and/or grant cross-licenses to intellectual property rights for our products; and
- redesigning our product candidates or processes so they do not infringe third party intellectual property rights, which may not be possible or may require substantial monetary expenditures and time.

Some of our competitors may be able to sustain the costs of complex patent litigation more effectively than we can because they have substantially greater resources. In addition, any uncertainties resulting from the initiation and continuation of any litigation could have a material adverse effect on our ability to raise the funds necessary to continue our operations or could otherwise have a material adverse effect on our business, results of operations, financial condition and prospects.

Third parties may assert that we are employing their proprietary technology without authorization. Generally, conducting preclinical and clinical trials and other development activities in the United States is not considered an act of infringement. If WTX-124, WTX-330, JZP898, WTX-712, WTX-518, WTX-921 or another product candidate we develop in the future is approved by the FDA, a third party may then seek to enforce its patent by filing a patent infringement lawsuit against us. For example, we have received, and we may in the future receive, correspondence from third parties or their legal counsel disclosing that such third party owns patents that may encompass one or more of our product candidates. It is also possible that a third party may file a lawsuit against us alleging infringement of its patents. The outcome of any such proceeding is uncertain and would likely result in the expenditure of significant financial resources and the diversion of management's time and resources, which could harm our business. While we do not believe that any claims that could otherwise have a materially adverse effect on the commercialization of our product candidates are valid and enforceable, we may be incorrect in this belief, or we may not be able to prove it in litigation. In this regard, patents issued in the United States by law enjoy a presumption of validity that can be rebutted only with evidence that is "clear and convincing," a heightened standard of proof. There may be issued third-party patents of which we are currently unaware with claims to compositions, formulations, methods of manufacture or methods for treatment related to the use or manufacture of our product candidates. Patent applications can take many years to issue. There may be currently pending patent applications which may later result in issued patents that our product candidates may infringe. In addition, third parties may obtain patents in the future and claim that use of our technologies infringes upon these patents. Moreover, we may fail to identify relevant patents or incorrectly conclude that a patent is invalid, not enforceable, exhausted, or not infringed by our activities. If any third-party patents were held by a court of competent jurisdiction to cover the manufacturing process of our product candidates, constructs or molecules used in or formed during the manufacturing process, or any final product itself, the holders of any such patents may be able to block our ability to commercialize the product candidate unless we obtained a license under the applicable patents, or until such patents expire or they are finally determined to be held invalid or unenforceable. Similarly, if any third-party patent were held by a court of competent jurisdiction to cover aspects of our formulations, processes for manufacture or methods of use, including combination therapy or patient selection methods, the holders of any such patent may be able to block our ability to develop and commercialize the product candidate unless we obtained a license or until such patent expires or is finally determined to be held invalid or unenforceable. In either case, such a license may not be available on commercially reasonable terms or at all. If we are unable to obtain a necessary license to a third-party patent on commercially reasonable terms, or at all, our ability to commercialize our product candidates may be impaired or delayed, which could in turn significantly harm our business. Even if we obtain a license, it may be non-exclusive, thereby giving our competitors access to the same technologies licensed to us. In addition, if the breadth or strength of protection provided by our patents and patent applications is threatened, it could dissuade companies from collaborating with us to license, develop or commercialize current or future product candidates.

Parties making claims against us may seek and obtain injunctive or other equitable relief, which could effectively block our ability to further develop and commercialize our product candidates. Defense of these claims, regardless of their merit, could

involve substantial litigation expense and would be a substantial diversion of employee resources from our business. In the event of a successful claim of infringement against us, we may have to pay substantial damages, including treble damages and attorneys' fees for willful infringement, obtain one or more licenses from third parties, pay royalties or redesign our infringing products, which may be impossible or require substantial time and monetary expenditure. We cannot predict whether any such license would be available on commercially reasonable terms or at all. Furthermore, even in the absence of litigation, we may need or may choose to obtain licenses from third parties to advance our research or allow commercialization of our product candidates. We may fail to obtain any of these licenses at a reasonable cost or on reasonable terms, if at all. In that event, we would be unable to further develop and commercialize our product candidates, which could harm our business significantly.

We may not be successful in obtaining or maintaining necessary rights to product components and processes for our development pipeline through acquisitions and in-licenses.

Presently we have certain intellectual property rights, under patents and patent applications that we own or will own and under the Harpoon Agreement, related to WTX-124, WTX-330, JZP898, WTX-712, WTX-518, WTX-921 and other product candidates we may develop in the future. Our development of additional product candidates may require the use of proprietary rights held by third parties, the growth of our business will likely depend in part on our ability to acquire, in-license or use these proprietary rights. In addition, while we have patent rights directed to certain INDUKINE constructs we may not be able to obtain intellectual property to broad INDUKINE polypeptides or engineered INDUKINE constructs.

Our product candidates may also require specific formulations to work effectively and efficiently, and rights to such formulation technology may be held by others. Similarly, efficient production or delivery of our product candidates may also require specific compositions or methods, and the rights to these may be owned by third parties. 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 or important to our business operations. We may fail to obtain any of these licenses at a reasonable cost or on reasonable terms, if at all, which would harm our business. We may need to cease use of the compositions or methods covered by such third-party intellectual property rights and may need to seek to develop alternative approaches that do not infringe on such intellectual property rights which may entail additional costs and development delays, even if we were able to develop such alternatives, which may not be feasible. Even if we are able to obtain a license, it may be non-exclusive, thereby giving our competitors access to the same technologies licensed to us. In that event, we may be required to expend significant time and resources to develop or license replacement technology. Moreover, the specific components, such as linkers and antibody fragments, that will be used with our product candidates may be covered by the intellectual property rights of others.

Additionally, we may collaborate with or sponsor research at academic institutions to accelerate our preclinical research or development under written agreements with these institutions. In certain cases, 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 or sponsorship. 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 others, potentially blocking our ability to pursue our program. If we are unable to successfully obtain rights to required third-party intellectual property or to maintain the existing intellectual property rights we have, we may have to abandon development of such program and our business and financial condition could suffer.

The licensing and acquisition of third-party intellectual property rights is a competitive area, and companies, which may be more established, or have greater resources than we do, may also be pursuing strategies to license or acquire third-party intellectual property rights that we may consider necessary or attractive in order to commercialize our product candidates. More established companies may have a competitive advantage over us due to their size, cash resources and greater clinical development and commercialization capabilities.

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.

Competitors may infringe our patents or the patents of our licensors. To counter infringement or unauthorized use, we may be required to file lawsuits with infringement claims, which can be expensive and time-consuming. In addition, in an infringement proceeding, a court may decide that one or more of our patents is not valid or is unenforceable or may refuse to stop the other party from using the technology at issue on the grounds that our patents do not cover the technology in question. An adverse result in any litigation or defense proceedings could put one or more of our patents at risk of being invalidated, held unenforceable, or interpreted narrowly and could put our patent applications at risk of not issuing. 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. In the event of a successful claim of infringement against us, we may have to pay substantial damages, including treble damages and attorneys' fees for willful infringement, obtain one or more licenses from third parties, pay royalties or redesign our infringing products, which may be impossible or require substantial time and monetary expenditure.

Post-grant proceedings provoked by third parties or brought by the USPTO may be necessary to determine the validity or priority of inventions with respect to our patents or patent applications or those of our licensors. An unfavorable outcome could result in a loss of our current patent rights and could require us to cease using the related technology or to attempt to license rights to it from the prevailing party. Our business could be harmed if the prevailing party does not offer us a license on commercially reasonable terms, or at all. Litigation or post-grant proceedings may result in a decision adverse to our interests and, even if we are successful, may result in substantial costs and distract our management and other employees. We may not be able to prevent, alone or with our licensors, misappropriation of our trade secrets or confidential information, particularly in countries where the laws may not protect those rights as fully as in the United States.

Furthermore, because of the substantial amount of discovery required in connection with intellectual property litigation, there is a risk that some of our confidential information could be compromised by disclosure during this type of litigation. In addition, there could be public announcements of the results of hearings, motions or other interim proceedings or developments. 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.

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

Some of our patent applications have been granted or may be granted or allowed in the future. We cannot be certain that an allowed patent application will become an issued patent. There may be events that can cause the allowance of a patent application to be withdrawn. For example, after a patent application has been allowed, but prior to being issued, material that could be relevant to patentability may be identified. In such circumstances, the applicant may pull the application from allowance in order for the USPTO to review the application in view of the new material. We cannot be certain that the USPTO will re-allow the application in view of the new material. Further, periodic maintenance fees on any issued patent are due to be paid to the USPTO and foreign patent agencies in several stages over the lifetime of the patent. The USPTO and various foreign governmental patent agencies require compliance with a number of procedural, documentary, fee payment and other similar provisions during the patent application process and following the issuance of a patent. We rely on our outside counsel and other professionals or our licensing partners to pay these fees due to the USPTO and non-U.S. government patent agencies and to help us comply with other procedural, documentary and other similar requirements and we are also dependent on our licensors to take the necessary action to comply with these requirements with respect to our licensed intellectual property. While an inadvertent lapse can in many cases be cured by payment of a late fee or by other means in accordance with the applicable rules, there are situations in which noncompliance can result in abandonment or lapse of the patent or patent application, resulting in partial or complete loss of patent rights in the relevant jurisdiction. Noncompliance events that could result in abandonment or lapse of a patent or patent application include, but are not limited to, failure to respond to official actions within prescribed time limits, non-payment of fees and failure to properly legalize and submit formal documents. In such an event, our competitors might be able to enter the market, which would have a material adverse effect on our business.

Issued patents covering our product candidates or technology could be found invalid or unenforceable if challenged in court or the USPTO.

If we or one of our licensors initiate legal proceedings against a third party to enforce a patent covering one of our product candidates or our technology, the defendant could counterclaim that the patent covering our product candidate or technology, as applicable, is invalid and/or unenforceable. In patent litigation in the United States, defendant counterclaims alleging invalidity and/or unenforceability are commonplace, and there are numerous grounds upon which a third party can assert invalidity or unenforceability of a patent. Third parties may also raise similar claims before administrative bodies in the United States or abroad, even outside the context of litigation. Such mechanisms include re-examination, *inter partes* review, post-grant review and equivalent proceedings in foreign jurisdictions (such as opposition proceedings). Such proceedings could result in revocation or amendment to our patents in such a way that they no longer cover our product candidates or technology. The outcome following legal assertions of invalidity and unenforceability is unpredictable. With respect to the validity question, for example, we cannot be certain that there is no invalidating prior art, of which we, our patent counsel and the patent examiner were unaware during prosecution. If a defendant were to prevail on a legal assertion of invalidity and/or unenforceability, or if we are otherwise unable to adequately protect our rights, we would lose at least part, and perhaps all, of the patent protection on our product candidates or technology. Such a loss of patent protection could have a material adverse impact on our business and our ability to commercialize or license our technology and product candidates.

Changes to patent law in the United States and in foreign jurisdictions could diminish the value of patents in general, thereby impairing our ability to protect our products.

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 both technological and legal complexity, and is therefore costly, time-consuming and inherently uncertain. In addition, the United States continues to adapt to wide-ranging

patent reform legislation that became effective starting in 2012. Moreover, recent U.S. Supreme Court rulings have narrowed the scope of patent protection available in certain circumstances and weakened 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 the U.S. 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 that we might obtain in the future. For example, in the case *Assoc. for Molecular Pathology v. Myriad Genetics, Inc.,* the U.S. Supreme Court held that certain claims to DNA molecules are not patentable. While we do not believe that any of the patents owned or licensed by us will be found invalid based on this decision, we cannot predict how future decisions by the courts, Congress or the USPTO may impact the value of our patents. Similarly, changes in the patent laws of other jurisdictions could adversely affect our ability to obtain and effectively enforce our patent rights, which would have a material adverse effect on our business and financial condition.

We have limited foreign intellectual property rights and may not be able to protect our intellectual property rights throughout the world.

We have obtained granted patents in the United States that we consider to be important for certain of our product candidates, however, we may have less robust intellectual property rights outside the United States, and, in particular, we may not be able to pursue generic coverage of our PREDATOR platform or of our INDUKINE molecules outside of the United States. Filing, prosecuting and defending patents on 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 products and our patents or other intellectual property rights may not be effective or sufficient to prevent them from competing. Most of our patent portfolio is at the very early stage. We will need to decide whether and in which jurisdictions to pursue protection for the various inventions in our portfolio prior to applicable deadlines.

Many companies have encountered significant problems in protecting and defending intellectual property rights in foreign jurisdictions. The legal systems of certain countries, particularly certain developing countries, do not favor the enforcement of patents, trade secrets and other intellectual property protection, particularly those relating to biopharmaceutical products, 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 generally. 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.

In addition, many countries have compulsory licensing laws under which a patent owner may be compelled to grant licenses to third parties. Many countries also limit the enforceability of patents against government agencies or government contractors. In these countries, the patent owner may have limited remedies, which could materially diminish the value of such patent. If we or any of our licensors are forced to grant a license to third parties with respect to any patents relevant to our business, our competitive position may be impaired, and our business and financial condition may be adversely affected.

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

We generally enter into confidentiality and intellectual property assignment agreements with our employees, consultants, and contractors. These agreements generally provide that inventions conceived by the party in the course of rendering services to us will be our exclusive property. However, those agreements may not be honored and may not effectively assign intellectual property rights to us. Moreover, there may be some circumstances, where we are unable to negotiate for such ownership rights. Disputes regarding ownership or inventorship of intellectual property can also arise in other contexts, such as collaborations and sponsored research. If we are subject to a dispute challenging our rights in or to patents or other intellectual property, such a dispute could be expensive and time consuming. If we were unsuccessful, we could lose valuable rights in intellectual property that we regard as our own.

We may be subject to damages resulting from claims that we or our employees have wrongfully used or disclosed confidential information of our competitors or are in breach of non-competition or non-solicitation agreements with our competitors.

Many of our employees were previously employed at other pharmaceutical companies, including our competitors or potential competitors, in some cases until recently. We may be subject to claims that we or our employees have inadvertently or otherwise used or disclosed trade secrets or other confidential information of these former employers or competitors. In addition, we have been and may in the future be subject to claims that we caused an employee to breach the terms of his or her non-competition or non-solicitation agreement. Litigation may be necessary to defend against these claims. Even if we are successful in defending against these claims, litigation could result in substantial costs and could be a distraction to management. If our defense to those claims fails, in addition to paying monetary damages, we may lose valuable intellectual property rights or personnel. Any litigation or the threat thereof may adversely affect our ability to hire employees. A loss of key personnel or their work product could hamper or prevent our ability to commercialize product candidates, which could have an adverse effect on our business, results of operations and financial condition.

If we do not obtain patent term extension and data exclusivity for any of our current or future product candidates, our business may be materially harmed.

Depending upon the timing, duration and specifics of any FDA marketing approval of any of our current or future product candidates, one or more of our U.S. patents may be eligible for limited patent term extension under the Drug Price Competition and Patent Term Restoration Act of 1984, or the Hatch-Waxman Amendments. The Hatch-Waxman Amendments permit a patent extension term of up to five years as compensation for patent term lost during the FDA regulatory review process. A patent term extension cannot extend the remaining term of a patent beyond a total of 14 years from the date of product approval, only one patent may be extended and only those claims covering the approved drug, a method for using it, or a method for manufacturing it may be extended. However, we may not be granted an extension because of, for example, failing to exercise due diligence during the testing phase or regulatory review process, 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 term of any such extension is less than we request, our competitors may obtain approval of competing products following our patent expiration, and our business, financial condition, results of operations, and prospects could be materially harmed.

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

Our trademarks or trade names may be challenged, infringed, circumvented, declared generic or determined to be infringing on other marks. We rely on both registration and common law protection for our trademarks. We may not be able to protect our rights to these trademarks and trade names or may be forced to stop using these names, which we need for name recognition by potential partners or customers in our markets of interest. During the trademark registration process, we may receive Office Actions from the USPTO objecting to the registration of our trademark. Although we would be given an opportunity to respond to those objections, we may be unable to overcome such rejections. In addition, in the USPTO and in comparable agencies in many foreign jurisdictions, third parties are given an opportunity to oppose pending trademark applications and/or to seek the cancellation of registered trademarks. Opposition or cancellation proceedings may be filed against our trademarks, and our trademarks may not survive such proceedings. If we are unable to establish name recognition based on our trademarks and trade names, we may not be able to compete effectively and our business may be adversely affected.

Numerous factors may limit any potential competitive advantage provided by our intellectual property rights.

The degree of future protection afforded by our intellectual property rights, whether owned or in-licensed, is uncertain because intellectual property rights have limitations, and may not adequately protect our business, provide a barrier to entry against our competitors or potential competitors, or permit us to maintain our competitive advantage. Moreover, if a third party has intellectual property rights that cover the practice of our technology, we may not be able to fully exercise or extract value from our intellectual property rights. The factors that may limit any potential competitive advantage provided by our intellectual property rights include:

- pending patent applications that we own or license may not lead to issued patents;
- patents, should they issue, that we own or license, may not provide us with any competitive advantages, or may be challenged and held invalid or unenforceable;
- others may be able to develop and/or practice technology that is similar to our technology or aspects of our technology but that is not covered by the claims of any of our owned or in-licensed patents, should any such patents issue;

- third parties may compete with us in jurisdictions where we do not pursue and obtain patent protection;
- we (or our licensors) might not have been the first to make the inventions covered by a pending patent application that we own or license;
- we (or our licensors) might not have been the first to file patent applications covering a particular invention;
- others may independently develop similar or alternative technologies without infringing our intellectual property rights;
- we may not be able to obtain and/or maintain necessary licenses on reasonable terms or at all;
- third parties may assert an ownership interest in our intellectual property and, if successful, such disputes may preclude us from exercising exclusive rights, or any rights at all, over that intellectual property;
- we may not be able to maintain the confidentiality of our trade secrets or other proprietary information;
- we may not develop or in-license 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 and results of operation.

Risks Related to Regulatory Approval and Marketing of Our Product Candidates and Other Legal Compliance Matters

Even if we complete the necessary preclinical studies and clinical trials, the regulatory approval process is expensive, time consuming and uncertain and may prevent us from obtaining approvals for the commercialization of some or all of our product candidates. As a result, we cannot predict when or if, and in which territories, we will obtain marketing approval to commercialize a product candidate.

The research, testing, manufacturing, labeling, approval, selling, marketing, promotion and distribution of products are subject to extensive regulation by the FDA and comparable foreign regulatory authorities. We are not permitted to market our product candidates in the United States or in other countries until we receive approval of an NDA or BLA from the FDA or marketing approval from applicable regulatory authorities outside the United States. Our product candidates are in various stages of development and are subject to the risks of failure inherent in development. We have not submitted an application for or received marketing approval for any of our product candidates in the United States or in any other jurisdiction. We have no experience as a company in filing and supporting the applications necessary to gain marketing approvals and expect to rely on third-party CROs to assist us in this process.

The process of obtaining marketing approvals, both in the United States and abroad, is lengthy, expensive and uncertain. It may take many years, if approval is obtained at all, and can vary substantially based upon a variety of factors, including the type, complexity and novelty of the product candidates involved. Securing marketing approval requires the submission of extensive preclinical and clinical data and supporting information, including manufacturing information, to regulatory authorities for each therapeutic indication to establish the product candidate's safety and efficacy. The FDA or other regulatory authorities may determine that our product candidates are not safe and effective, only moderately effective or have undesirable or unintended side effects, toxicities or other characteristics that preclude our obtaining marketing approval or prevent or limit commercial use.

In addition, changes in marketing approval policies during the development period, changes in or the enactment or promulgation of additional statutes, regulations or guidance or changes in regulatory review for each submitted product application, may cause delays in the approval or rejection of an application. Regulatory authorities have substantial discretion in the approval process and varying interpretations of the data obtained from preclinical and clinical testing could delay, limit or prevent marketing approval of a product candidate. Any marketing approval we ultimately obtain may be limited or subject to restrictions or post-approval commitments that render the approved product not commercially viable.

Further, under the Pediatric Research Equity Act, a BLA or supplement to a BLA for certain biological products must contain data to assess the safety and effectiveness of the biological product in all relevant pediatric subpopulations and to support dosing and administration for each pediatric subpopulation for which the product is safe and effective, unless the sponsor receives a deferral or waiver from the FDA. A deferral may be granted for several reasons, including a finding that the product or therapeutic candidate is ready for approval for use in adults before pediatric trials are complete or that additional safety or effectiveness data needs to be collected before the pediatric trials begin. The applicable legislation in the EU also requires sponsors to either conduct clinical trials in a pediatric population in accordance with a Pediatric Investigation Plan approved by the Pediatric Committee of the European Medicines Agency, or EMA, or to obtain a waiver or deferral from the conduct of these studies by this Committee. For any of our product candidates for which we are seeking regulatory approval in the U.S. or the EU, we cannot guarantee that we will be able to obtain a waiver or alternatively complete any required studies and other

requirements in a timely manner, or at all, which could result in associated reputational harm and subject us to enforcement action.

Finally, we could be adversely affected by several significant administrative law cases decided by the U.S. Supreme Court in 2024. In *Loper Bright Enterprises v. Raimondo*, for example, the court overruled *Chevron U.S.A., Inc. v. Natural Resources Defense Council, Inc*., which for 40 years required federal courts to defer to permissible agency interpretations of statutes that are silent or ambiguous on a particular topic. The U.S. Supreme Court stripped federal agencies of this presumptive deference and held that courts must exercise their independent judgment when deciding whether an agency such as the FDA acted within its statutory authority under the Administrative Procedure Act, or the APA. Additionally, in *Corner Post, Inc. v. Board of Governors of the Federal Reserve System*, the court held that actions to challenge a federal regulation under the APA can be initiated within six years of the date of injury to the plaintiff, rather than the date the rule is finalized. The decision appears to give prospective plaintiffs a personal statute of limitations to challenge longstanding agency regulations. Another decision, *Securities and Exchange Commission v. Jarkesy*, overturned regulatory agencies' ability to impose civil penalties in administrative proceedings. These decisions could introduce additional uncertainty into the regulatory process and may result in additional legal challenges to actions taken by federal regulatory agencies, including the FDA and CMS, that we rely on. In addition to potential changes to regulations as a result of legal challenges, these decisions may result in increased regulatory uncertainty and delays and other impacts, any of which could adversely impact our business and operations.

Any delay in obtaining or failure to obtain required approvals could negatively affect our ability or that of any future collaborators to generate revenue from the particular product candidate, which likely would result in significant harm to our financial position and adversely impact our stock price.

Failure to obtain marketing approval in foreign jurisdictions would prevent our product candidates from being marketed abroad. Any approval we may be granted for our product candidates in the United States would not assure approval of our product candidates in foreign jurisdictions and any of our product candidates that may be approved for marketing in a foreign jurisdiction will be subject to risks associated with foreign operations.

In order to market and sell our products in the EU and other foreign jurisdictions, we must obtain separate marketing approvals and comply with numerous and varying regulatory requirements. The approval procedure varies among countries and can involve additional testing. The time required to obtain approval may differ substantially from that required to obtain FDA approval. The marketing approval process outside the United States generally includes all of the risks associated with obtaining FDA approval. We may not obtain approvals from regulatory authorities outside the United States on a timely basis, if at all. Approval by the FDA does not ensure approval by regulatory authorities in other countries or jurisdictions, and approval by one regulatory authority outside the United States does not ensure approval by regulatory authorities in other countries or jurisdictions or by the FDA. We may file for marketing approvals but not receive necessary approvals to commercialize our products in any market.

In many countries outside the United States, a product candidate must also be approved for reimbursement before it can be sold in that country. In some cases, the price that we intend to charge for our products, if approved, is also subject to approval. Obtaining non-U.S. regulatory approvals and compliance with non-U.S. regulatory requirements could result in significant delays, difficulties and costs for us and could delay or prevent the introduction of our product candidates in certain countries. In addition, if we fail to obtain the non-U.S. approvals required to market our product candidates outside the United States or if we fail to comply with applicable non-U.S. regulatory requirements, our target markets will be reduced and our ability to realize the full market potential of our product candidates will be harmed and our business, financial condition, results of operations and prospects may be adversely affected.

Additionally, we could face heightened risks with respect to obtaining marketing authorization in the U.K. as a result of the withdrawal of the U.K. from the EU, commonly referred to as Brexit. The U.K. is no longer part of the European Single Market and EU Customs Union. As of January 1, 2025, the Medicines and Healthcare Products Regulatory Agency, or MHRA, is responsible for approving all medicinal products destined for the United Kingdom market (i.e., Great Britain and Northern Ireland). At the same time, a new international recognition procedure, or IRP, will apply, which intends to facilitate approval of pharmaceutical products in the U.K. The IRP is open to applicants that have already received an authorization for the same product from one of the MHRA's specified Reference Regulators, or RRs. The RRs notably include EMA and regulators in the EU/European Economic Area, or EEA, member states for approvals in the EU centralized procedure and mutual recognition procedure as well as the FDA (for product approvals granted in the U.S.). However, the concrete functioning of the IRP is currently unclear. Any delay in obtaining, or an inability to obtain, any marketing approvals may force us or our collaborators to restrict or delay efforts to seek regulatory approval in the U.K. for our product candidates, which could significantly and materially harm our business.

In addition, foreign regulatory authorities may change their approval policies and new regulations may be enacted. For instance, the EU pharmaceutical legislation is currently undergoing a complete review process, in the context of the Pharmaceutical Strategy for Europe initiative, launched by the European Commission in November 2020. The European Commission's

proposal for revision of several legislative instruments related to medicinal products (potentially reducing the duration of regulatory data protection, revising the eligibility for expedited pathways, etc.) was published on April 26, 2023. The proposed revisions remain to be agreed and adopted by the European Parliament and European Council and the proposals may therefore be substantially revised before adoption, which is not anticipated before early 2026. The revisions may, however, have a significant impact on the pharmaceutical industry and our business in the long term.

We expect that we will be subject to additional risks in commercializing any of our product candidates that receive marketing approval outside the United States, including tariffs, trade barriers and regulatory requirements; economic weakness, including inflation, or political instability in particular foreign economies and markets; compliance with tax, employment, immigration and labor laws for employees living or traveling abroad; foreign currency fluctuations, which could result in increased operating expenses and reduced revenue, and other obligations incident to doing business in another country; and workforce uncertainty in countries where labor unrest is more common than in the United States.

We may not be able to obtain orphan drug designation or orphan drug exclusivity for our product candidates and, even if we do, that exclusivity may not prevent the FDA or the EMA from approving competing products.

Regulatory authorities in some jurisdictions, including the United States and Europe, may designate drugs for relatively small patient populations as orphan drugs. Under the Orphan Drug Act, the FDA may designate a product as an orphan drug if it is a drug intended to treat a rare disease or condition, which is generally defined as a patient population of fewer than 200,000 individuals annually in the United States. Generally, a product with orphan drug designation only becomes entitled to orphan drug exclusivity if it receives the first marketing approval for the indication for which it has such designation, in which case the FDA or the EMA will be precluded from approving another marketing application for the same product for that indication for the applicable exclusivity period. The applicable exclusivity period is seven years in the United States and ten years in Europe. The European exclusivity period can be reduced to six years if a product no longer meets the criteria for orphan drug designation or if the product is sufficiently profitable so that market exclusivity is no longer justified.

We may seek orphan drug designations for our product candidates and may be unable to obtain such designations. Even if we do secure such designations and orphan drug exclusivity for a product, that exclusivity may not effectively protect the product from competition because different products can be approved for the same condition. Further, the FDA can subsequently approve the same drug for the same condition if the FDA concludes that the later product is clinically superior in that it is shown to be safer, to be more effective or to make a major contribution to patient care. Finally, orphan drug exclusivity may be lost if the FDA or the EMA determines that the request for designation was materially defective or if the manufacturer is unable to assure sufficient quantity of the product to meet the needs of patients with the rare disease or condition.

The FDA may further re-evaluate the Orphan Drug Act and its regulations and policies. This may be particularly true in light of a decision from the Court of Appeals for the 11th Circuit in September 2021 finding that, for the purpose of determining the scope of exclusivity, the term “same disease or condition” means the designated “rare disease or condition” and could not be interpreted by the FDA to mean the “indication or use.” Thus, the Court of Appeals concluded that orphan drug exclusivity applies to the entire designated disease or condition rather than the “indication or use.” Although there have been legislative proposals to overrule this decision, they have not been enacted into law. On January 23, 2023, the FDA announced that, in matters beyond the scope of that court order, it will continue to apply its existing regulations tying orphan-drug exclusivity to the uses or indications for which the orphan drug was approved. We do not know if, when, or how the FDA or Congress may change the orphan drug regulations and policies in the future, and it is uncertain how any changes might affect our business. Depending on what changes the FDA may make to its orphan drug regulations and policies, our business could be adversely impacted.

In addition, to obtain orphan drug designation in the EU, we would need to demonstrate that there exists no satisfactory method of diagnosis, prevention or treatment of the condition in question that has been authorized in the EU or, if such method exists, the medicinal product will be of significant benefit to those affected by that condition. There is no assurance that we would be able to meet that standard for any of our product candidates. Further, if we do obtain orphan drug designation for a candidate product in the EU, we will not be able to maintain that designation if we are not able to show, to the satisfaction of the EU regulatory authorities, that the candidate product is of significant benefit to patients over available commercial products for the indication in the EU and any additional products that are ahead of our product candidate in clinical development for the indication.

Any product candidate for which we obtain marketing approval is subject to ongoing regulation and could be subject to restrictions or withdrawal from the market, and we may be subject to substantial penalties if we fail to comply with regulatory requirements, when and if any of our product candidates are approved.

Any product candidate for which we obtain marketing approval will be subject to continual requirements of and review by the FDA and other regulatory authorities. These requirements include submissions of safety and other post-marketing information and reports, registration and listing requirements, cGMP requirements relating to quality control and manufacturing, quality

assurance and corresponding maintenance of records and documents, and requirements regarding the distribution of samples to physicians and recordkeeping. In addition, the approval may be subject to limitations on the indicated uses for which the product may be marketed or to the conditions of approval, or contain requirements for costly post-marketing testing and surveillance to monitor the safety or efficacy of the medicine, including the requirement to implement a risk evaluation and mitigation strategy.

In addition, later discovery of previously unknown adverse events or other problems with any product for which we may obtain marketing approval and its manufacturers or manufacturing processes or failure to comply with regulatory requirements, may yield various results, including:

- restrictions on such products, manufacturers or manufacturing processes;
- restrictions on the labeling or marketing of a product;
- restrictions on distribution or use of a product;
- requirements to conduct post-marketing studies or clinical trials;
- warning letters or untitled letters;
- withdrawal of the products from the market;
- refusal to approve pending applications or supplements to approved applications that we submit;
- recall of products;
- damage to relationships with collaborators;
- unfavorable press coverage and damage to our reputation;
- fines, restitution or disgorgement of profits or revenues;
- suspension or withdrawal of marketing approvals;
- refusal to permit the import or export of our products;
- product seizure;
- injunctions or the imposition of civil or criminal penalties; and
- litigation involving patients using our products.

Post-approval restrictions apply to the approval of products in the EU. The holder of a marketing authorization is required to comply with a range of requirements applicable to the manufacturing, marketing, promotion and sale of medicinal products. These include: compliance with the EU's stringent pharmacovigilance or safety reporting rules, which can impose post-authorization studies and additional monitoring obligations; the manufacturing of authorized medicinal products, for which a separate manufacturer's license is mandatory; and the marketing and promotion of authorized drugs, which are strictly regulated in the EU and are also subject to EU Member State laws. The failure to comply with these and other EU requirements can also lead to significant penalties and sanctions.

Further, our ability to develop and market new products may be impacted by litigation challenging the FDA's approval of another company's drug product. In April 2023, the U.S. District Court for the Northern District of Texas invalidated the approval by the FDA of mifepristone, a drug product which was originally approved in 2000 and whose distribution is governed by various measures adopted under a REMS. The Court of Appeals for the Fifth Circuit declined to order the removal of mifepristone from the market but did hold that plaintiffs were likely to prevail in their claim that changes allowing for expanded access of mifepristone, which the FDA authorized in 2016 and 2021, were arbitrary and capricious. In June 2024, the Supreme Court reversed that decision after unanimously finding that the plaintiffs (anti-abortion doctors and organizations) did not have standing to bring this legal action against the FDA. On October 11, 2024, the Attorneys General of three states (Missouri, Idaho and Kansas) filed an amended complaint in the district court in Texas challenging FDA's actions. On January 16, 2025, the district court agreed to allow these states to file an amended complaint and continue to pursue this challenge. Depending on the outcome of this litigation, our ability to develop new drug product candidates and to maintain approval of existing drug products could be delayed, undermined or subject to protracted litigation.

Accordingly, if we receive marketing approval for one or more of our product candidates, we will continue to expend time, money and effort in all areas of regulatory compliance, including manufacturing, production, product surveillance and quality control. If we fail to comply with these requirements, we could have the marketing approvals for our products withdrawn by regulatory authorities and our ability to market any products could be limited, which could adversely affect our ability to achieve or sustain profitability.

Any regulatory approval to market our products will be limited by indication. If we fail to comply or are found to be in violation of FDA regulations restricting the promotion of our products for unapproved uses, we could be subject to criminal penalties, substantial fines or other sanctions and damage awards.

The regulations relating to the promotion of products for unapproved uses are complex and subject to substantial interpretation by the FDA, EMA, MHRA and other government agencies. In September 2021, the FDA published final regulations which describe the types of evidence that the agency will consider in determining the intended use of a drug product. Physicians may nevertheless prescribe our products off-label to their patients in a manner that is inconsistent with the approved label. We intend to implement compliance and training programs designed to ensure that our sales and marketing practices comply with applicable regulations. Notwithstanding these programs, the FDA or other government agencies may allege or find that our practices constitute prohibited promotion of our products for unapproved uses. We also cannot be sure that our employees will comply with company policies and applicable regulations regarding the promotion of products for unapproved uses.

Notwithstanding the regulatory restrictions on off-label promotion, the FDA and other regulatory authorities allow companies to engage in truthful, non-misleading, and non-promotional scientific communications concerning their products in certain circumstances. For example, in January 2025, the FDA published final guidance outlining its policies governing the distribution of scientific information to healthcare providers about unapproved uses of approved products. The final guidance calls for such communications to be truthful, non-misleading and scientifically sound and to include all information necessary for healthcare providers to interpret the strengths and weaknesses and validity and utility of the information about the unapproved use of the approved product. If a company engages in such communications consistent with the guidance's recommendations, the FDA indicated that it will not treat such communications as evidence of unlawful promotion of a new intended use for the approved product. We will need to carefully navigate the FDA's various regulations, guidance and policies, along with recently enacted legislation, to ensure compliance with restrictions governing promotion of our products.

In addition, under some relatively recent guidance from the FDA and the Pre-Approval Information Exchange Act signed into law as part of the Consolidated Appropriations Act of 2023, companies may also promote information that is consistent with the prescribing information and proactively speak to formulary committee members of payors regarding data for an unapproved drug or unapproved uses of an approved drug. We may engage in these discussions and communicate with healthcare providers, payors and other constituencies in compliance with all applicable laws, regulatory guidance and industry best practices. We will need to carefully navigate the FDA's various regulations, guidance and policies, along with recently enacted legislation, to ensure compliance with restrictions governing promotion of our products.

In recent years, a significant number of pharmaceutical and biotechnology companies have been the target of inquiries and investigations by various federal and state regulatory, investigative, prosecutorial and administrative entities in connection with the promotion of products for unapproved uses and other sales practices, including the Department of Justice and various U.S. Attorneys' Offices, the Office of Inspector General of the Department of Health and Human Services, the FDA, the Federal Trade Commission, or the FTC, and various state Attorneys General offices. These investigations have alleged violations of various federal and state laws and regulations, including claims asserting antitrust violations, violations of the Federal Food, Drug, and Cosmetic Act, the False Claims Act, the Prescription Drug Marketing Act and anti-kickback laws and other alleged violations in connection with the promotion of products for unapproved uses, pricing and Medicare and/or Medicaid reimbursement. Many of these investigations originate as *qui tam* actions under the False Claims Act. Under the False Claims Act, any individual can bring a claim on behalf of the government alleging that a person or entity has presented a false claim or caused a false claim to be submitted to the government for payment. The person bringing a *qui tam* suit is entitled to a share of any recovery or settlement. *Qui tam* suits, also commonly referred to as whistleblower suits, are often brought by current or former employees. In a *qui tam* suit, the government must decide whether to intervene and prosecute the case. If it declines, the individual may pursue the case alone.

If the FDA or any other governmental agency initiates an enforcement action against us or if we are the subject of a *qui tam* suit and it is determined that we violated prohibitions relating to the promotion of products for unapproved uses, we could be subject to substantial civil or criminal fines or damage awards and other sanctions such as consent decrees and corporate integrity agreements pursuant to which our activities would be subject to ongoing scrutiny and monitoring to ensure compliance with applicable laws and regulations. Any such fines, awards or other sanctions would have an adverse effect on our revenue, business, financial prospects and reputation.

We may seek certain designations for our product candidates, including Breakthrough Therapy, Fast Track and Priority Review designations, but we might not receive such designations, and even if we do, such designations may not lead to a faster development or regulatory review or approval process.

We may seek certain designations for one or more of our product candidates that could expedite review and approval by the FDA. A Breakthrough Therapy product is defined as a product that is intended, alone or in combination with one or more other products, to treat a serious condition, and preliminary clinical evidence indicates that the product may demonstrate substantial improvement over existing therapies on one or more clinically significant endpoints, such as substantial treatment effects

observed early in clinical development. For products that have been designated as Breakthrough therapies, interaction and communication between the FDA and the sponsor of the trial can help to identify the most efficient path for clinical development while minimizing the number of patients placed in ineffective control regimens.

The FDA may also designate a product for Fast Track review if it is intended, whether alone or in combination with one or more other products, for the treatment of a serious or life-threatening disease or condition, and it demonstrates the potential to address unmet medical needs for such a disease or condition. For Fast Track products, sponsors may have greater interactions with the FDA and the FDA may initiate review of sections of a Fast Track product's application before the application is complete. This rolling review may be available if the FDA determines, after preliminary evaluation of clinical data submitted by the sponsor, that a Fast Track product may be effective.

We may also seek a priority review designation for one or more of our product candidates. If the FDA determines that a product candidate is intended to treat a serious condition and, if approved, offers a significant improvement in safety or effectiveness, the FDA may designate the product candidate for priority review. Significant improvement may be illustrated by evidence of increased effectiveness in the treatment of a condition, elimination or substantial reduction of a treatment-limiting product reaction, documented enhancement of patient compliance that may lead to improvement in serious outcomes, and evidence of safety and effectiveness in a new subpopulation. A priority review designation means that the goal for the FDA to review an application is six months, rather than the standard review period of ten months.

These designations are within the discretion of the FDA. Accordingly, even if we believe that one of our product candidates meets the criteria for these designations, the FDA may disagree and instead determine not to make such designation. Further, even if we receive a designation, the receipt of such designation for a product candidate may not result in a faster development or regulatory review or approval process compared to products considered for approval under conventional FDA procedures and does not assure ultimate approval by the FDA. In addition, even if one or more of our product candidates qualifies for these designations, the FDA may later decide that the product candidates no longer meet the conditions for qualification or decide that the time period for FDA review or approval will not be shortened.

We may seek PRIME Designation in the EU for one or more of our product candidates, but we might not receive such designations and, even if we do, such designations may not lead to a faster development or regulatory review or approval process.

In the EU, we may seek PRIME designation for our product candidates in the future. PRIME is a voluntary program aimed at enhancing the EMA's role to reinforce scientific and regulatory support in order to optimize development and enable accelerated assessment of new medicines that are of major public health interest with the potential to address unmet medical needs. The program focuses on medicines that target conditions for which there exists no satisfactory method of treatment in the EU or even if such a method exists, it may offer a major therapeutic advantage over existing treatments. PRIME is limited to medicines under development and not authorized in the EU and the applicant intends to apply for an initial marketing authorization application through the centralized procedure. To be accepted for PRIME, a product candidate must meet the eligibility criteria in respect of its major public health interest and therapeutic innovation based on information that is capable of substantiating the claims.

The benefits of a PRIME designation include the appointment of a rapporteur from the Committee for Human Medicinal Products to provide continued support and help to build knowledge ahead of a marketing authorization application, early dialogue and scientific advice at key development milestones, and the potential to qualify products for accelerated review, meaning reduction in the review time for an opinion on approvability to be issued earlier in the application process. PRIME designation enables an applicant to request parallel EMA scientific advice and health technology assessment advice to facilitate timely market access. Even if we receive PRIME designation for any of our product candidates, the designation may not result in a materially faster development process, review or approval compared to conventional EMA procedures. Further, obtaining PRIME designation does not assure or increase the likelihood of EMA's grant of a marketing authorization.

Accelerated approval by the FDA, even if granted for any of our current or future product candidates, may not lead to a faster development or regulatory review or approval process and it does not increase the likelihood that our product candidates will receive marketing approval.

We may seek approval of any of our current and future product candidates using the FDA's accelerated approval pathway. A product may be eligible for accelerated approval if it treats a serious or life-threatening condition, generally provides a meaningful advantage over available therapies, and demonstrates an effect on a surrogate endpoint that is reasonably likely to predict clinical benefit. The FDA or other applicable regulatory agency makes the determination regarding whether a surrogate endpoint is reasonably likely to predict long-term clinical benefit.

Prior to seeking such accelerated approval, we will seek feedback from the FDA and otherwise evaluate our ability to seek and receive such accelerated approval. As a condition of approval, the FDA requires that a sponsor of a product receiving accelerated approval perform an adequate and well-controlled post-marketing confirmatory clinical trial or trials. These

confirmatory trials must be completed with due diligence and we may be required to evaluate different or additional endpoints in these post-marketing confirmatory trials. These confirmatory trials may require enrollment of more patients than we currently anticipate and will result in additional costs, which may be greater than the estimated costs we currently anticipate. In addition, the FDA currently requires as a condition for accelerated approval preapproval of promotional materials, which could adversely impact the timing of the commercial launch of the product.

There can be no assurance that the FDA will agree with any proposed surrogate endpoints or that we will decide to pursue or submit a BLA or NDA for accelerated approval or any other form of expedited development, review or approval for any of our current or future product candidates. Similarly, there can be no assurance that, after feedback from FDA, we will continue to pursue or apply for accelerated approval or any other form of expedited development, review or approval, even if we initially decide to do so. Furthermore, if we decide to submit an application for accelerated approval or under another expedited regulatory designation, there can be no assurance that such submission or application will be accepted or that any expedited review or approval will be granted on a timely basis, or at all.

The FDA may withdraw approval of a product candidate approved under the accelerated approval pathway if, for example, the trial required to verify the predicted clinical benefit of our product candidate fails to verify such benefit or does not demonstrate sufficient clinical benefit to justify the risks associated with the drug. The FDA may also withdraw approval if other evidence demonstrates that our product candidate is not shown to be safe or effective under the conditions of use, we fail to conduct any required post approval trial of our product candidate with due diligence or we disseminate false or misleading promotional materials relating to our product candidate. A failure to obtain accelerated approval or any other form of expedited development, review or approval for our product candidates, or withdrawal of a product candidate, would result in a longer time period for commercialization of such product candidate, could increase the cost of development of such product candidate and could harm our competitive position in the marketplace.

Further, there can be no assurance that we will satisfy all FDA requirements, including new provisions, that govern accelerated approval. For example, with passage of the FDORA in December 2022, Congress modified certain provisions governing accelerated approval of drug and biologic products. Specifically, the new legislation authorized the FDA to require a sponsor to have its confirmatory clinical trial underway before accelerated approval is awarded and to submit progress reports on its post-approval studies to FDA every six months until the study is completed. Moreover, FDORA established expedited procedures authorizing FDA to withdraw an accelerated approval if certain conditions are met, including where a required confirmatory study fails to verify and describe the predicted clinical benefit or where evidence demonstrates the product is not shown to be safe or effective under the conditions of use. The FDA may also use such procedures to withdraw an accelerated approval if a sponsor fails to conduct any required post-approval study of the product with due diligence, including with respect to "conditions specified by the Secretary." The new procedures include the provision of due notice and an explanation for a proposed withdrawal, and opportunities for a meeting with the Commissioner or the Commissioner's designee and a written appeal, among other things. We will need to fully comply with these and other requirements in connection with the development and approval of any product candidate that qualifies for accelerated approval.

More recently, in March 2023, the FDA issued draft guidance that outlines its current thinking and approach to accelerated approval. The FDA indicated that the accelerated approval pathway is commonly used for approval of oncology drugs due to the serious and life-threatening nature of cancer. Although single-arm trials have been commonly used to support accelerated approval, a randomized controlled trial is the preferred approach as it provides a more robust efficacy and safety assessment and allows for direct comparisons to an available therapy. To that end, the FDA outlined considerations for designing, conducting, and analyzing data for trials intended to support accelerated approvals of oncology therapeutics. Subsequently, in December 2024 and January 2025, the FDA issued additional draft guidances relating to accelerated approval. These guidances describe FDA's views on what it means to conduct a confirmatory trial with due diligence and how the agency plans to interpret whether such a study needs to be underway at the time of approval. While these guidances are currently only in draft form and will ultimately not be legally binding even when finalized, sponsors typically observe the FDA's guidance closely to ensure that their investigational products qualify for accelerated approval.

In the EU, a "conditional" marketing authorization may be granted in cases where all the required safety and efficacy data are not yet available. A conditional marketing authorization is subject to conditions to be fulfilled for generating missing data or ensuring increased safety measures. A conditional marketing authorization is valid for one year and has to be renewed annually until fulfillment of all relevant conditions. Once the applicable pending studies are provided, a conditional marketing authorization can become a "standard" marketing authorization. However, if the conditions are not fulfilled within the timeframe set by the EMA, the marketing authorization will cease to be renewed.

We and our contract manufacturers are subject to significant regulation. The manufacturing facilities on which we rely may not continue to meet regulatory requirements, which could materially harm our business.

All entities involved in the preparation of product candidates for clinical trials or commercial sale, including any contract manufacturers, are subject to extensive regulation. Components of a finished therapeutic product approved for commercial sale

or used in late-stage clinical trials must be manufactured in accordance with cGMP. 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 manufacturer must supply all necessary documentation in support of a BLA or an NDA on a timely basis and must adhere to the FDA's current Good Laboratory Practice and cGMP regulations enforced 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 pass a pre-approval inspection for compliance with the applicable regulations as a condition of regulatory approval of any product candidate. In addition, the regulatory authorities may, at any time, audit or inspect a manufacturing facility involved with the preparation of our product candidates or the associated quality systems for compliance with the regulations applicable to the activities being conducted. If these facilities do not pass a pre-approval plant inspection, FDA approval of the products will not be granted.

The regulatory authorities also may, at any time following approval of a product for sale, audit our manufacturing facilities or those of our third-party contractors. If any such inspection or audit identifies 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 trial or commercial sales or the temporary or permanent closure of a facility. Any such remedial measures imposed upon us or third parties with whom we contract could materially harm our business.

If we or any of our third-party manufacturers fail to maintain regulatory compliance, the FDA can impose regulatory sanctions including, among other things, refusal to approve a pending application for a new product, or revocation of a pre-existing approval. Any such consequence would severely harm our business, financial condition and results of operations.

We intend in the future to conduct clinical trials for certain of our product candidates at sites outside the United States. The FDA may not accept data from trials conducted in such locations and the conduct of trials outside the United States could subject us to additional delays and expense.

We intend in the future to conduct one or more of our clinical trials with trial sites that are located outside the United States. Although the FDA may accept data from clinical trials conducted outside the United States, acceptance of these data is subject to certain conditions imposed by the FDA. For example, the clinical trial must be well designed and conducted and performed by qualified investigators in accordance with good clinical practice. The FDA must be able to validate the data from the trial through an onsite inspection if necessary. The trial population must also have a similar profile to the U.S. population, and the data must be applicable to the U.S. population and U.S. medical practice in ways that the FDA deems clinically meaningful, except to the extent the disease being studied does not typically occur in the United States. In addition, while these clinical trials are subject to the applicable local laws, the FDA acceptance of the data will be dependent upon its determination that the trials also complied with all applicable U.S. laws and regulations. There can be no assurance that the FDA will accept data from clinical trials conducted outside of the United States. If the FDA does not accept the data from any trial that we conduct outside the United States, 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 our product candidates.

In addition, the conduct of clinical trials outside the United States could have a significant adverse impact on us or the trial results. Risks inherent in conducting international clinical trials include:

- clinical practice patterns and standards of care that vary widely among countries;
- non-U.S. regulatory authority requirements that could restrict or limit our ability to conduct our clinical trials;
- administrative burdens of conducting clinical trials under multiple non-U.S. regulatory authority schema;
- foreign exchange rate fluctuations; and
- diminished protection of intellectual property in some countries.

Inadequate funding for the FDA, the SEC and other government agencies, including from government shut downs, or other disruptions to these agencies' operations, could hinder their ability to hire and retain key leadership and other personnel, prevent new products and services from being developed or commercialized in a timely manner or otherwise prevent those agencies from performing normal business functions on which the operation of our business may rely, which could negatively impact our business.

The ability of the FDA to review and approve new products can be affected by a variety of factors, including government budget and funding levels, ability to hire and retain key personnel and accept the payment of user fees, and statutory, regulatory and policy changes. Average review times at the agency have fluctuated in recent years as a result. Disruptions at the FDA and

other agencies may also slow the time necessary for new product candidates to be reviewed and/or approved by necessary government agencies, which would adversely affect our business. In addition, government funding of the U.S. Securities and Exchange Commission, or the SEC, and other government agencies on which our operations may rely, including those that fund research and development activities, is subject to the political process, which is inherently fluid and unpredictable.

Disruptions at the FDA, EMA and other agencies may also slow the time necessary for new drugs to be reviewed and/or approved by necessary government agencies, which would adversely affect our business. For example, in recent years, including in 2018 and 2019, the U.S. government shut down several times and certain regulatory agencies, such as the FDA and the SEC, had to furlough critical employees and stop critical activities. In addition, disruptions may also be caused by events similar to the COVID-19 pandemic. During the COVID-19 pandemic, a number of companies announced receipt of complete response letters due to the FDA's inability to complete required inspections for their applications. In the event of a similar public health emergency in the future, the FDA may not be able to continue its current pace and review timelines could be extended. Regulatory authorities outside the United States facing similar circumstances may adopt similar restrictions or other policy measures in response to a similar public health emergency and may also experience delays in their regulatory activities.

Further, with the change in presidential administrations in 2025, there is substantial uncertainty as to how, if at all, the new administration will seek to modify or revise the requirements and policies of the FDA and other regulatory agencies with jurisdiction over our product candidates. There is also uncertainty as to how other measures being implemented by the Trump Administration across the government will affect our activities and those of the FDA and its operations. For example, the potential loss of FDA personnel could lead to further disruptions and delays in FDA review of our product candidates. Similarly, efforts by the new administration to substantially reduce research funding by the National Institutes of Health of medical research could have substantial direct or indirect impacts on our research activities.

Accordingly, if a prolonged government shutdown or other disruption occurs, it could significantly impact the ability of the FDA to timely review and process our regulatory submissions, which could have a material adverse effect on our business. Future shutdowns or other disruptions could also affect other government agencies such as the SEC, which may also impact our business by delaying review of our public filings, to the extent such review is necessary, and our ability to access the public markets.

Current and future legislation may increase the difficulty and cost for us to obtain reimbursement for any of our candidate products that do receive marketing approval.

In the United States and foreign jurisdictions, there have been a number of legislative and regulatory changes and proposed changes regarding the healthcare system that could prevent or delay marketing approval of our product candidates, restrict or regulate post-approval activities and affect our ability to profitably sell any product candidates for which we obtain marketing approval. We expect that current laws, as well as other healthcare reform measures that may be adopted in the future, may result in more rigorous coverage criteria and in additional downward pressure on the price that we may receive for any approved products. If reimbursement of our products is unavailable or limited in scope, our business could be materially harmed.

The ACA substantially changed the way healthcare is financed by both governmental and private insurers and continues to significantly impact the U.S. pharmaceutical industry. Since enactment of the ACA, there have been numerous legal challenges and Congressional actions to repeal and replace provisions of the law. For example, with enactment of the TCJA in 2017, Congress repealed the "individual mandate." The repeal of this provision, which requires most Americans to carry a minimal level of health insurance, became effective in 2019. Further, in June 2021, the U.S. Supreme Court dismissed a legal action after finding that the plaintiffs do not have standing to challenge the constitutionality of the ACA. Litigation and legislation over the ACA are likely to continue, with unpredictable and uncertain results.

During the first Trump Administration, the Congress and administration sought to overturn the ACA and related measures. Shortly after taking office in January 2025, President Trump revoked numerous executive orders issued by President Biden, including at least two executive orders (e.g., EO 14009, Strengthening Medicaid and the Affordable Care Act, and EO 14070, Continuing to Strengthen Americans' Access to Affordable, Quality Health Coverage) where were designed to further implement the ACA. We anticipate similar efforts to undermine the ACA, and the accompanying uncertainty, for the foreseeable future.

In addition, other legislative changes have been proposed and adopted since the ACA was enacted. In August 2011, the Budget Control Act of 2011, among other things, created measures for spending reductions by Congress. A Joint Select Committee on Deficit Reduction, tasked with recommending a targeted deficit reduction of at least $1.2 trillion for the years 2013 through 2021, was unable to reach required goals, thereby triggering the legislation's automatic reduction to several government programs. These changes included aggregate reductions to Medicare payments to providers of up to 2% per fiscal year, which went into effect in April 2013 and will remain in effect through 2032 under the CARES Act. The American Taxpayer Relief Act of 2012, among other things, reduced Medicare payments to several providers and increased the statute of limitations period for the government to recover overpayments to providers from three to five years. These laws may result in additional

reductions in Medicare and other healthcare funding and otherwise affect the prices we may obtain for any of our product candidates for which we may obtain regulatory approval or the frequency with which any such product candidate is prescribed or used. The Consolidated Appropriations Act, which was signed into law by President Biden in December 2022, made several changes to sequestration of the Medicare program. Section 1001 of the Consolidated Appropriations Act delays the 4% Statutory Pay-As-You-Go Act of 2010, or PAYGO, sequester for two years, through the end of calendar year 2024. Triggered by enactment of the American Rescue Plan Act of 2021, the 4% cut to the Medicare program would have taken effect in January 2023. The Consolidated Appropriations Act's health care offset title includes Section 4163, which extends the 2% Budget Control Act of 2011 Medicare sequester for six months into fiscal year 2032 and lowers the payment reduction percentages in fiscal years 2030 and 2031.

In the EU, on December 13, 2021, Regulation No 2021/2282 on Health Technology Assessment, or HTA, amending Directive 2011/24/EU, was adopted. While the Regulation entered into force in January 2022, it will only begin to apply from January 2025 onwards, with preparatory and implementation-related steps to take place in the interim. Once applicable, it will have a phased implementation depending on the concerned products. The Regulation intends to boost cooperation among EU member states in assessing health technologies, including new medicinal products as well as certain high-risk medical devices, and provide the basis for cooperation at the EU level for joint clinical assessments in these areas. It will permit EU member states to use common HTA tools, methodologies, and procedures across the EU, working together in four main areas, including joint clinical assessment of the innovative health technologies with the highest potential impact for patients, joint scientific consultations whereby developers can seek advice from HTA authorities, identification of emerging health technologies to identify promising technologies early, and continuing voluntary cooperation in other areas. Individual EU member states will continue to be responsible for assessing non-clinical (e.g., economic, social, ethical) aspects of health technology, and making decisions on pricing and reimbursement.

Current and future legislative efforts may limit the costs for our products, if and when they are licensed for marketing, and that could materially impact our ability to generate revenues.

The prices of prescription pharmaceuticals have also been the subject of considerable discussion in the United States. There have been several recent U.S. congressional inquiries, as well as proposed and enacted state and federal legislation designed to, among other things, bring more transparency to pharmaceutical pricing, review the relationship between pricing and manufacturer patient programs, and reduce the costs of pharmaceuticals under Medicare and Medicaid. In 2020, President Trump issued several executive orders intended to lower the costs of prescription products and certain provisions in these orders have been incorporated into regulations. These regulations include an interim final rule implementing a most favored nation model for prices that would tie Medicare Part B payments for certain physician-administered pharmaceuticals to the lowest price paid in other economically advanced countries, effective January 1, 2021. That rule, however, has been subject to a nationwide preliminary injunction and, on December 29, 2021, the Center for Medicare & Medicaid Services, or CMS, issued a final rule to rescind it. With issuance of this rule, CMS stated that it will explore all options to incorporate value into payments for Medicare Part B pharmaceuticals and improve beneficiaries' access to evidence-based care.

In addition, in October 2020, HHS and the FDA published a final rule allowing states and other entities to develop a Section 804 Importation Program, or SIP, to import certain prescription drugs from Canada into the United States. That regulation was challenged in a lawsuit by the Pharmaceutical Research and Manufacturers of America, or PhRMA, but the case was dismissed by a federal district court in February 2023 after the court found that PhRMA did not have standing to sue HHS. Seven states (Colorado, Florida, Maine, New Hampshire, New Mexico, Texas and Vermont) have passed laws allowing for the importation of drugs from Canada. North Dakota and Virginia have passed legislation establishing working groups to examine the impact of a state importation program. As of May 2024, five states (Colorado, Florida, Maine, New Hampshire and New Mexico) had submitted Section 804 Importation Program proposals to the FDA, and on January 5, 2023, the FDA approved Florida's plan for Canadian drug importation. That state now has authority to import certain drugs from Canada for a period of two years once certain conditions are met. Florida will first need to submit a pre-import request for each drug selected for importation, which must be approved by the FDA. The state will also need to relabel the drugs and perform quality testing of the products to meet FDA standards.

Further, on November 20, 2020, HHS finalized a regulation removing safe harbor protection for price reductions from pharmaceutical manufacturers to plan sponsors under Part D, either directly or through pharmacy benefit managers, unless the price reduction is required by law. The implementation of the rule has been delayed by the Biden administration until January 1, 2026 by the Infrastructure Investment and Jobs Act. The final rule would eliminate the current safe harbor for Medicare drug rebates and create new safe harbors for beneficiary point-of-sale discounts and pharmacy benefit manager service fees. It originally was set to go into effect on January 1, 2022, but with the passage of the Inflation Reduction Act of 2022, or the IRA, has been delayed by Congress to January 1, 2032.

On August 16, 2022, the IRA was signed into law by President Biden. The new legislation has implications for Medicare Part D, which is a program available to individuals who are entitled to Medicare Part A or enrolled in Medicare Part B to give them

the option of paying a monthly premium for outpatient prescription drug coverage. 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 (beginning in 2025). The IRA permits the Secretary of HHS to implement many of these provisions through guidance, as opposed to regulation, for the initial years.

Specifically, with respect to price negotiations, Congress authorized Medicare to negotiate lower prices for certain costly single-source drug and biologic products that do not have competing generics or biosimilars and are reimbursed under Medicare Part B and Part D. CMS may negotiate prices for ten high-cost drugs paid for by Medicare Part D starting in 2026, followed by 15 Part D drugs in 2027, 15 Part B or Part D drugs in 2028, and 20 Part B or Part D drugs in 2029 and beyond. This provision applies to drug products that have been approved for at least nine years and biologics that have been licensed for 13 years, but it does not apply to drugs and biologics that have been approved for a single rare disease or condition. Nonetheless, since CMS may establish a maximum price for these products in price negotiations, we would be fully at risk of government action if our products are the subject of Medicare price negotiations. Moreover, given the risk that could be the case, these provisions of the IRA may also further heighten the risk that we would not be able to achieve the expected return on our drug products or full value of our patents protecting our products if prices are set after such products have been on the market for nine years.

The first cycle of negotiations for the Medicare Drug Price Negotiation Program commenced in the summer of 2023. On August 15, 2024, the HHS published the results of the first Medicare drug price negotiations for ten selected drugs that treat a range of conditions, including diabetes, chronic kidney disease, and rheumatoid arthritis. The prices of these ten drugs will become effective January 1, 2026. On January 17, 2025, CMS announced its selection of 15 additional drugs covered by Part D for the second cycle of negotiations. Thereafter, following the change in administrations, CMS issued a public statement on January 29, 2025, declaring that lowering the cost of prescription drugs is a top priority of the new administration and CMS is committed to considering opportunities to bring greater transparency in the negotiation program. The second cycle of negotiations with participating drug companies will occur during 2025, and any negotiated prices for this second set of drugs will be effective starting January 1, 2027.

Further, the legislation subjects drug manufacturers to civil monetary penalties and a potential excise tax for failing to comply with the legislation by offering a price that is not equal to or less than the negotiated "maximum fair price" under the law or for taking price increases that exceed inflation. The legislation also requires manufacturers to pay rebates for drugs in Medicare Part D whose price increases exceed inflation. The new law also caps Medicare out-of-pocket drug costs at an estimated $4,000 a year in 2024 and, thereafter beginning in 2025, at $2,000 a year. In addition, the IRA potentially raises legal risks with respect to individuals participating in a Medicare Part D prescription drug plan who may experience a gap in coverage if they required coverage above their initial annual coverage limit before they reached the higher threshold, or "catastrophic period" of the plan. Individuals requiring services exceeding the initial annual coverage limit and below the catastrophic period, must pay 100% of the cost of their prescriptions until they reach the catastrophic period. Among other things, the IRA contains many provisions aimed at reducing this financial burden on individuals by reducing the co-insurance and co-payment costs, expanding eligibility for lower income subsidy plans, and price caps on annual out-of-pocket expenses, each of which could have potential pricing and reporting implications.

On June 6, 2023, Merck & Co. filed a lawsuit against the HHS and CMS asserting that, among other things, the IRA's Drug Price Negotiation Program for Medicare constitutes an uncompensated taking in violation of the Fifth Amendment of the Constitution. Subsequently, a number of other parties, including the U.S. Chamber of Commerce, Bristol Myers Squibb Company, the PhRMA, Astellas, Novo Nordisk, Janssen Pharmaceuticals, Novartis, AstraZeneca and Boehringer Ingelheim, also filed lawsuits in various courts with similar constitutional claims against the HHS and CMS. There have been various decisions by the courts considering these cases since they were filed. The HHS has generally won the substantive disputes in these cases, and various federal district court judges have expressed skepticism regarding the merits of the legal arguments being pursued by the pharmaceutical industry. Certain of these cases are now on appeal, and oral arguments took place on October 30, 2024. We expect that litigation involving these and other provisions of the IRA will continue, with unpredictable and uncertain results.

Accordingly, while it is currently unclear how the IRA will be effectuated, we cannot predict with certainty what impact any federal or state health reforms will have on us, but such changes could impose new or more stringent regulatory requirements on our activities or result in reduced reimbursement for our products, any of which could adversely affect our business, results of operations and financial condition.

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

increasingly using bidding procedures to determine what pharmaceutical products and which suppliers will be included in their prescription drug and other health care programs. These measures could reduce the ultimate demand for our products, once approved, or put pressure on our product pricing. We expect that additional state and federal healthcare reform measures will be adopted in the future, any of which could limit the amounts that federal and state governments will pay for healthcare products and services, which could result in reduced demand for our product candidates or additional pricing pressures. This may be increasingly true with respect to products approved pursuant to the accelerated approval pathway. State Medicaid programs and other payers are developing strategies and implementing significant coverage barriers, or refusing to cover these products outright, arguing that accelerated approval drugs have insufficient or limited evidence despite meeting the FDA's standards for accelerated approval.

Finally, outside the United States, in some nations, including those of the European Union, the pricing of prescription pharmaceuticals is subject to governmental control and access. In these countries, pricing negotiations with governmental authorities can take considerable time after the receipt of marketing approval for a product. To obtain reimbursement or pricing approval in some countries, we or our collaborators may be required to conduct a clinical trial that compares the cost-effectiveness of our product to other available therapies. If reimbursement of our products is unavailable or limited in scope or amount, or if pricing is set at unsatisfactory levels, our business could be materially harmed.

We may be subject to certain healthcare laws and regulations, which could expose us to criminal sanctions, civil penalties, contractual damages, reputational harm, fines, disgorgement, exclusion from participation in government healthcare programs, curtailment or restricting of our operations, and diminished profits and future earnings.

Healthcare providers, third-party payors and others will play a primary role in the recommendation and prescription of any products for which we obtain marketing approval. Our current and future arrangements with healthcare providers and third-party payors will expose us to broadly applicable fraud and abuse and other healthcare laws and regulations that may constrain the business or financial arrangements and relationships through which we research as well as market, sell and distribute any products for which we obtain marketing approval. Potentially applicable U.S. federal and state healthcare laws and regulations include the following:

Anti-Kickback Statute. The federal Anti-Kickback Statute prohibits, among other things, persons and entities from knowingly and willfully soliciting, offering, receiving or providing remuneration, directly or indirectly, in cash or in kind, to induce or reward 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 federal healthcare programs such as Medicare and Medicaid.

False Claims Laws. The federal false claims laws, including the civil False Claims Act, impose criminal and civil penalties, including those from 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.

HIPAA. The federal Health Insurance Portability and Accountability Act of 1996, or HIPAA, imposes criminal and civil liability for, among other things, executing or attempting to execute a scheme to defraud any healthcare benefit program.

HIPAA and HITECH. HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act, or the HITECH Act, also imposes obligations on certain types of individuals and entities, including mandatory contractual terms, with respect to safeguarding the privacy, security and transmission of individually identifiable health information.

False Statements Statute. The federal false statements statute prohibits knowingly and willfully falsifying, concealing or covering up a material fact or making any materially false statement in connection with the delivery of or payment for healthcare benefits, items or services.

Transparency Requirements. The federal Physician Payments Sunshine Act requires certain manufacturers of drugs, devices, biologics, and medical supplies for which payment is available under Medicare, Medicaid, or the Children's Health Insurance Program, with specific exceptions, to report annually to HHS information related to payments and other transfers of value made to physicians (defined to include doctors, dentists, optometrists, podiatrists, and chiropractors) and teaching hospitals, as well as ownership and investment interests by physicians and their immediate family members. As of January 1, 2022, applicable manufacturers are also required to report such information regarding its payments and other transfers of value to physician assistants, nurse practitioners, clinical nurse specialists, anesthesiologist assistants, certified registered nurse anesthetists and certified nurse midwives during the previous year.

Analogous State and Foreign Laws. Analogous state laws and regulations, such as state anti-kickback and false claims laws, and transparency 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, and some state laws require pharmaceutical companies to comply with the pharmaceutical industry's voluntary compliance guidelines and the relevant compliance guidance promulgated by the federal government, in addition to requiring manufacturers to report information related to payments to

physicians and other healthcare providers or marketing expenditures. Many state laws also govern the privacy and security of health information in some circumstances, many of which differ from each other in significant ways and often are not preempted by HIPAA, thus complicating compliance efforts. Foreign laws also govern the privacy and security of health information in many circumstances.

The provision of benefits or advantages to physicians to induce or encourage the prescription, recommendation, endorsement, purchase, supply, order or use of medicinal products is prohibited in the European Union. Payments made to physicians in certain European Union Member States must be publicly disclosed. Moreover, agreements with physicians often must be the subject of prior notification and approval by the physician's employer, his or her competent professional organization and/or the regulatory authorities of the individual European Union Member States. These requirements are provided in the national laws, industry codes or professional codes of conduct applicable in the European Union Member States. Failure to comply with these requirements could result in reputational risk, public reprimands, administrative penalties, fines or imprisonment.

Efforts to ensure that our business arrangements with third parties, and our business generally, will comply with applicable healthcare laws and regulations will involve substantial costs. It is possible that governmental authorities will conclude that our business practices may not comply with current or future statutes, regulations or case law involving applicable fraud and abuse or other healthcare laws and regulations. If our operations are found to be in violation of any of these laws or any other governmental regulations that may apply to us, we may be subject to significant civil, criminal and administrative penalties, damages, fines, imprisonment, exclusion of products from government funded healthcare programs, such as Medicare and Medicaid, disgorgement, contractual damages, and reputational harm, any of which could substantially disrupt our operations. If any of the physicians or other providers or entities with whom we expect to do business is found not to be in compliance with applicable laws, they may be subject to criminal, civil or administrative sanctions, including exclusions from government funded healthcare programs.

Compliance with state, national and international privacy and data security requirements could result in additional costs and liabilities to us or inhibit our ability to collect and process data globally, and the failure to comply with such requirements could subject us to a variety of harms, including significant fines and penalties, litigation and reputational damage, any of which may have a material adverse effect on our business, financial condition or results of operations.

We are subject to data privacy and protection laws and regulations, which among other things, impose certain requirements relating to the privacy, security and transmission of personal information, including comprehensive regulatory systems in the U.S., EU and United Kingdom. The regulatory framework for the collection, use, safeguarding, sharing, transfer and other processing of information worldwide is rapidly evolving and is likely to remain uncertain for the foreseeable future. Failure to comply with any of these laws and regulations could result in enforcement action against us, including fines, claims for damages by affected individuals, damage to our reputation and loss of goodwill, any of which could have a material adverse effect on our business, financial condition, results of operations or prospects.

In the United States, there are numerous federal and state laws and regulations related to the privacy and security of personal information that may be applicable to our current and future activities, and a wide range of enforcement agencies at both the state and federal levels that can review companies for privacy and data security concerns based on general consumer protection laws. The FTC and state Attorneys General are all aggressive in reviewing privacy and data security protections for consumers. New laws also are being considered at both the state and federal levels. For example, the FTC has been particularly focused on the unpermitted processing of health and genetic data through its recent enforcement actions and is expanding the types of privacy violations that it interprets to be "unfair" under Section 5 of the Federal Trade Commission Act, as well as the types of activities it views to trigger the Health Breach Notification Rule (which the FTC also has the authority to enforce). The agency is also in the process of developing rules related to commercial surveillance and data security that may impact our business. We will need to account for the FTC's evolving rules and guidance for proper privacy and data security practices in order to mitigate our risk for a potential enforcement action, which may be costly. If we are subject to a potential FTC enforcement action, we may be subject to a settlement order that requires us to adhere to very specific privacy and data security practices, which may impact our business. We may also be required to pay fines as part of a settlement (depending on the nature of the alleged violations). If we violate any consent order that we reach with the FTC, we may be subject to additional fines and compliance requirements.

In addition to existing laws, a broad range of legislative measures have been introduced at both the federal and state levels. For example, the California Consumer Privacy Act, or CCPA, which went into effect on January 1, 2020, imposed many requirements on businesses that process the personal information of California residents, including requiring businesses to provide notice to data subjects regarding the information collected about them and how such information is used and shared, and providing data subjects the right to request access to such personal information and, in certain cases, request the erasure of such personal information. Additionally, in November 2020, California voters approved a new privacy law, the California Privacy Rights Act, or CPRA, which expands the CCPA to incorporate additional provisions, including requiring that the use, retention, and sharing of personal information of California residents be reasonably necessary and proportionate to the purposes

of collection or processing, granting additional protections for sensitive personal information, and requiring greater disclosures related to notice to residents regarding retention of information. Most CPRA provisions took effect on January 1, 2023, though the obligations apply to any personal information collected after January 1, 2022.

In addition to California, at least 18 other states have passed comprehensive privacy laws similar to the CCPA and CPRA. These laws are either in effect or will go into effect sometime before the end of 2026. Like the CCPA and CPRA, these laws create obligations related to the processing of personal information, as well as special obligations for the processing of "sensitive" data (which includes health data in some cases). Some of the provisions of these laws may apply to our business activities. There are also states that are considering or have already passed comprehensive privacy laws during the 2023 legislative sessions that will go into effect in 2024 and beyond. There are also states that are specifically regulating health information that may affect our business. For example, Washington state recently passed a health privacy law that will regulate the collection and sharing of health information, and the law also has a private right of action, which further increases the relevant compliance risk. These laws may impact our business activities, including our identification of research subjects, relationships with business partners and ultimately the marketing and distribution of our products.

Plaintiffs' lawyers are also increasingly using privacy-related statutes at both the state and federal level to bring lawsuits against companies for their data-related practices. In particular, there have been a significant number of cases filed against companies for their use of pixels and other web trackers. These cases often allege violations of the California Invasion of Privacy Act and other state laws regulating wiretapping, as well as the federal Video Privacy Protection Act. The rise in these types of lawsuits creates potential risk for our business.

A wide range of enforcement agencies at both the state and federal levels can review companies for privacy and data security concerns based on general consumer protection laws. For example, the FTC and state Attorneys General are aggressive in reviewing privacy and data security protections for consumers. In addition to the risks associated with enforcement activities, there also is the threat of consumer class actions related to these laws and the overall protection of personal data. Even if we are not determined to have violated the law, government investigations into these issues typically require the expenditure of significant resources and generate negative publicity, which could harm our reputation and our business.

Similar to the laws in the United States, there are significant privacy and data security laws that apply in Europe and other countries. For example, the collection, use, disclosure, transfer, or other processing of personal data, including personal health data, regarding individuals who are located in the European Economic Area, or the EEA, is subject to the EU General Data Protection Regulation, or the GDPR, which took effect across all member states of the EEA in May 2018. The GDPR is wide-ranging in scope and imposes numerous requirements on companies that process personal data, including strict rules on the transfer of personal data to countries outside the European Union, including the United States. The GDPR also permits data protection authorities to require destruction of improperly gathered or used personal information and/or impose substantial fines for violations of the GDPR, which can be up to four percent of annual global revenues or 20 million Euros, whichever is greater, and it also confers a private right of action on data subjects and consumer associations to lodge complaints with supervisory authorities, seek judicial remedies, and obtain compensation for damages resulting from violations of the GDPR. In addition, the GDPR provides that European Union member states may make their own further laws and regulations limiting the processing of personal data, including genetic, biometric or health data. As a result, there is increased scrutiny on the extent to which clinical trial sites located in the EEA should apply the GDPR to transfers of personal data from such sites to countries that are considered to lack an adequate level of data protection, such as the United States. There are also open questions about how personal data will be protected in the United Kingdom and whether personal information can transfer from the EU to the United Kingdom.

In October 2022, President Biden signed an executive order to implement the EU-U.S. Data Privacy Framework, which serves as a replacement to the EU-U.S. Privacy Shield. The European Commission adopted the adequacy decision on July 10, 2023. The adequacy decision permits U.S. companies who self-certify to the EU-U.S. Data Privacy Framework to rely on it as a valid data transfer mechanism for data transfers from the European Union to the United States. However, some privacy advocacy groups have already suggested that they will be challenging the EU-U.S. Data Privacy Framework. If these challenges are successful, or there are other developments involving the arrangements that underly this framework, they may not only impact the EU-U.S. Data Privacy Framework, but also further limit the viability of the standard contractual clauses and other data transfer mechanisms. The uncertainty around this issue has the potential to impact our business.

These evolving compliance and operational requirements impose significant costs that are likely to increase over time. Preparing for and complying with such requirements is rigorous and time intensive. It requires significant resources and a review of our technologies, systems and practices, as well as those of any third-party collaborators, service providers, contractors or consultants that process or transfer personal data, and may require us to modify our data processing practices and policies, divert resources from other initiatives and projects, and restrict the way products and services involving data are offered. Further, current and future laws or regulations associated with the enhanced protection of certain types of sensitive data, such as healthcare data or other personal information from our clinical trials, could require us to change our business

practices and put in place additional compliance mechanisms, interrupt or delay our development, regulatory and commercialization activities and increase our cost of doing business, and could lead to government enforcement actions, private litigation and significant fines and penalties against us. Any of these events could have a material adverse effect on our business, financial condition, results of operations and prospects.

We are subject to U.S. and certain foreign export control, import, sanctions, anti-corruption, and anti-money laundering laws with respect to our operations and non-compliance with such laws can subject us to criminal and/or civil liability and harm our business.

We are subject to export control and import laws and regulations, including the U.S. Export Administration Regulations, U.S. Customs regulations, various economic and trade sanctions regulations administered by the U.S. Treasury Department's Office of Foreign Assets Control, the U.S. Foreign Corrupt Practices Act of 1977, as amended, or the FCPA, the U.S. domestic bribery statute contained in 18 U.S.C. § 201, the U.S. Travel Act, the USA PATRIOT Act, and other state and national anti-bribery and anti-money laundering laws in countries in which we conduct activities. Anti-corruption laws are interpreted broadly and prohibit companies and their employees, agents, third-party intermediaries, joint venture partners and collaborators from authorizing, promising, offering or providing, directly or indirectly, improper payments or benefits to recipients in the public or private sector. We may have direct or indirect interactions with officials and employees of government agencies or government-affiliated hospitals, universities and other organizations. In addition, we may engage third party intermediaries to promote our clinical research activities abroad and/or to obtain necessary permits, licenses, and other regulatory approvals. We can be held liable for the corrupt or other illegal activities of these third-party intermediaries, our employees, representatives, contractors, partners and agents, even if we do not explicitly authorize or have actual knowledge of such activities.

Noncompliance with the laws and regulations described above could subject us to whistleblower complaints, investigations, sanctions, settlements, prosecution, other enforcement actions, disgorgement of profits, significant fines, damages, other civil and criminal penalties or injunctions, suspension and/or debarment from contracting with certain persons, the loss of export privileges, reputational harm, adverse media coverage and other collateral consequences. If any subpoenas, investigations or other enforcement actions are launched, or governmental or other sanctions are imposed, or if we do not prevail in any possible civil or criminal litigation, our business, results of operations and financial condition could be materially harmed. In addition, responding to any action will likely result in a materially significant diversion of management's attention and resources and significant defense and compliance costs and other professional fees. In certain cases, enforcement authorities may even cause us to appoint an independent compliance monitor which can result in added costs and administrative burdens.

Changes in U.S. and international trade policies, particularly with respect to China, may adversely impact our business and operating results.

The U.S. government has recently made statements and taken certain actions that may lead to potential changes to U.S. and international trade policies, including imposing several rounds of tariffs and export control restrictions affecting certain products manufactured in China. In March 2018, the Trump administration announced the imposition of tariffs on steel and aluminum entering the United States and in June 2018, the Trump administration announced further tariffs targeting goods imported from China. Recently both China and the United States have each imposed tariffs indicating the potential for further trade barriers, including the U.S. Commerce Department adding numerous Chinese entities to its "unverified list," which requires U.S. exporters to go through more procedures before exporting goods to such entities. It is unknown whether and to what extent new tariffs, export controls, or other new laws or regulations will be adopted, or the effect that any such actions would have on us or our industry, and it is unclear whether the Biden administration will work to reverse these measures or pursue similar policy initiatives.

Trade tensions and conflicts between the United States and China have been escalating in recent years and, as such, we are exposed to the possibility of product supply disruption and increased costs and expenses in the event of changes to the laws, rules, regulations and policies of the governments of the United States or China, or due to geopolitical unrest and unstable economic conditions. Certain Chinese biotechnology companies may become subject to trade restrictions, sanctions, other regulatory requirements or proposed legislation by the U.S. government, which could restrict or even prohibit our ability to work with such entities, thereby potentially disrupting their supply of material to us. For example, in February 2024, U.S. lawmakers called for investigations into and the imposition of possible economic sanctions against Chinese biotechnology companies WuXi AppTec and WuXi Biologics, or collectively WuXi, over alleged ties to the Chinese military.

In addition, in September 2024, the U.S. House or Representatives passed the BIOSECURE Act (H.R. 7085), and the Senate has advanced a substantially similar bill, which legislation, if passed by the Senate and enacted into law, would restrict the ability of U.S. biotechnology companies like us to purchase services or products from, or otherwise collaborate with, specifically named Chinese biotechnology companies, including WuXi, and authorizes the U.S. government to impose such restrictions on entities' transactions with additional Chinese biotechnology companies as a condition of U.S. government contract, grant and loan funding. If these bills become law, or similar laws are passed, they would have the potential to severely restrict the ability of companies to contract with certain Chinese biotechnology companies of concern without losing the ability

to contract with, or otherwise received funding from, the U.S. government. Such disruptions could have adverse effects on the development of our product candidates and our business operations.

Any unfavorable government policies on international trade, such as export controls, capital controls or tariffs, may increase the cost of manufacturing our product candidates and platform materials, affect the demand for our drug products (if and once approved), the competitive position of our product candidates, and import or export of raw materials and finished product candidate used in our and our collaborators' preclinical studies and clinical trials, particularly with respect to any product candidates and materials that we import from China. If any new tariffs, export controls, legislation and/or regulations are implemented, or if existing trade agreements are renegotiated or, in particular, if either the U.S. or Chinese government takes retaliatory trade actions due to the recent trade tension, such changes could have an adverse effect on our business, financial condition and results of operations.

If we fail to comply with environmental, health and safety laws and regulations, we could become subject to fines or penalties or incur costs that could harm our business.

We are subject to numerous environmental, health and safety laws and regulations, including those governing laboratory procedures and the handling, use, storage, treatment and disposal of hazardous materials and wastes. From time to time and in the future, our operations may involve the use of hazardous and flammable materials, including chemicals and biological materials, and may also produce hazardous waste products. Even if we contract with third parties for the disposal of these materials and waste products, we cannot completely eliminate the risk of contamination or injury resulting from these materials. In the event of contamination or injury resulting from the use or disposal of our hazardous materials, we could be held liable for any resulting damages, and any liability could exceed our resources. We also could incur significant costs associated with civil or criminal fines and penalties for failure to comply with such laws and regulations.

We maintain workers' compensation insurance to cover us for costs and expenses we may incur due to injuries to our employees resulting from the use of hazardous materials, however this insurance may not provide adequate coverage against potential liabilities. We do not maintain insurance for environmental liability or toxic tort claims that may be asserted against us.

In addition, we may incur substantial costs in order to comply with current or future environmental, health and safety laws and regulations. Current or future environmental laws and regulations may impair our research, development or production efforts. In addition, failure to comply with these laws and regulations may result in substantial fines, penalties or other sanctions.

Our employees, independent contractors, CROs, consultants, commercial partners, vendors and principal investigators may engage in misconduct or other improper activities, including non-compliance with regulatory standards and requirements.

We are exposed to the risk of fraud or other misconduct by our employees, independent contractors, CROs, consultants, commercial partners, vendors and, if we commence clinical trials, our principal investigators. Misconduct by these parties could include intentional failures to comply with FDA regulations or the regulations applicable in the European Union and other jurisdictions, provide accurate information to the FDA, the European Commission and other regulatory authorities, comply with healthcare fraud and abuse laws and regulations in the United States and abroad, report financial information or data accurately, or disclose unauthorized activities to us. In particular, sales, marketing and business arrangements in the healthcare industry are subject to extensive laws and regulations intended to prevent fraud, misconduct, kickbacks, self-dealing and other abusive practices. These laws and regulations restrict or prohibit a wide range of pricing, discounting, marketing and promotion, sales commission, customer incentive programs and other business arrangements.

Such misconduct also could involve the improper use of information obtained in the course of clinical trials or interactions with the FDA or other regulatory authorities, which could result in regulatory sanctions and cause serious harm to our reputation. Even with appropriate policies and procedures, it is not always possible to identify and deter misconduct, and the precautions we take to detect and prevent such activity may not be effective in controlling unknown or unmanaged risks or losses or in protecting us from government investigations or other actions or lawsuits stemming from a failure to comply with these laws or regulations. If any such actions are instituted against us, and we are not successful in defending ourselves or asserting our rights, those actions could have a significant impact on our business, financial condition, results of operations and prospects, including the imposition of significant fines or other sanctions.

Risks Related to Our Business Operations, Employee Matters and Managing Growth

Our future success depends on our ability to retain key employees, consultants and advisors and to attract, retain and motivate qualified personnel.

We are highly dependent on the management, research and development, clinical, financial and business development expertise of our executive officers, as well as the other members of our scientific and clinical teams. Although we have employment offer letters which outline the terms of employment with each of our executive officers, each of them may terminate their

employment with us at any time. As such, these employment offer letters do not guarantee our retention of our executive officers for any period of time. We do not maintain "key person" insurance for any of our employees.

Recruiting and retaining qualified scientific and clinical personnel and, if we are successful in obtaining marketing approval for our product candidates, sales and marketing personnel, is critical to our success. The loss of the services of our executive officers or other key employees could impede the achievement of our research, development and commercialization objectives and seriously harm our ability to successfully implement our business strategy. Furthermore, replacing executive officers and other key employees may be difficult and may take an extended period of time because of the limited number of individuals in our industry with the breadth of skills and experience required to successfully develop, gain regulatory approval for and commercialize our product candidates. We are based in the Boston area, a region that is home to many other biopharmaceutical companies as well as many academic and research institutions, resulting in fierce competition for qualified personnel. Furthermore, to the extent we hire personnel from competitors, we may be subject to allegations that they have been improperly solicited or that they have divulged proprietary or other confidential information, or that their former employers own their research output. We also experience competition for the hiring of scientific and clinical personnel from universities and research institutions. In addition, we rely on consultants and advisors, including scientific and clinical advisors, to assist us in formulating our research and development strategy. Our consultants and advisors may be employed by employers other than us and may have commitments under consulting or advisory contracts with other entities that may limit their availability to us. If we are unable to continue to attract and retain high quality personnel, our ability to pursue our growth strategy will be limited, and could harm our business, prospects, financial condition and results of operations.

We expect to grow our organization, and as a result, we may encounter difficulties in managing our growth, which could disrupt our operations.

As of December 31, 2024, we had 46 employees. Over the next few years, assuming we are able to raise sufficient capital, we expect to experience significant growth in the number of our employees and the scope of our operations, particularly in the areas of clinical development, regulatory affairs, finance and, if any of our product candidates receive marketing approval, sales, marketing and distribution. Our management may need to divert a disproportionate amount of its attention away from our day-to-day activities to devote time to managing these growth activities. To manage these growth activities, we must continue to implement and improve our managerial, operational and financial systems, expand our facilities and continue to recruit and train additional qualified personnel. Due to our limited financial resources and the limited experience of our management team in managing a company with such anticipated growth, we may not be able to effectively manage the expansion of our operations or recruit and train additional qualified personnel. Our inability to effectively manage the expansion of our operations may result in weaknesses in our infrastructure, give rise to operational mistakes, loss of business opportunities, loss of employees and reduced productivity among remaining employees. Our expected growth could require significant capital expenditures and may divert financial resources from other projects, such as the development of additional product candidates. If our management is unable to effectively manage our expected growth, our expenses may increase more than expected, our potential ability to generate revenue could be reduced and we may not be able to implement our business strategy.

Our business could be negatively affected by cyberattacks or a deficiency in our cybersecurity.

A cyberattack or similar incident could occur and result in information theft, data corruption, operational disruption, damage to our reputation, or financial loss. We are increasingly dependent on information technology systems and infrastructure, including mobile technologies, to operate our business. Our technologies, systems, networks, or other proprietary information, and those of our vendors, suppliers and other business partners, may become the target of cyberattacks or information security breaches that could result in the unauthorized release, gathering, monitoring, misuse, loss, or destruction of proprietary and other information, or could otherwise lead to the disruption of our business operations. The risk of a security breach or disruption, particularly through cyberattacks or cyber intrusion, including by computer hackers, foreign governments, and cyber terrorists, has generally increased as the number, intensity and sophistication of attempted attacks and intrusions from around the world have increased. Moreover, certain cyber incidents, such as surveillance, may remain undetected for an extended period and could lead to disruptions in critical systems or the unauthorized release of confidential or otherwise protected information. These events could lead to financial loss due to remedial actions, loss of business, disruption of operations, damage to our reputation, or potential liability. Our systems and insurance coverage for protecting against cybersecurity risks may not be sufficient. Furthermore, as cyberattacks continue to evolve, we may be required to expend significant additional resources to continue to modify or enhance our protective measures or to investigate and remediate any vulnerability to cyberattacks.

Our internal computer systems, or those used by our third-party research institution collaborators, CROs or other contractors or consultants, may fail or suffer security breaches.

Despite the implementation of security measures, our internal computer systems and those of our CROs and other contractors, vendors, and consultants may be vulnerable to damage from cybersecurity risks, including attempts to gain unauthorized access to and to harm sensitive or confidential information and networks, insider threats, and ransomware. These vulnerabilities may be heightened as a result of flexible work arrangements, including hybrid or remote work policies implemented by us and our

third-party contractors, that were first adopted in response to the COVID-19 pandemic and have continued by many businesses in an effort to attract and retain talent.

Investigations into and remedial efforts in connection with any security incidents, even those with immaterial impact, can be costly and time-consuming and could be material, or cause significant disruption, to our business. For example, the loss of clinical trial data from ongoing or future clinical trials could result in delays in our regulatory approval efforts and significantly increase our costs to recover or reproduce the data. Likewise, we rely on third parties for research and development, the manufacture and supply of drug product and drug substance and to conduct clinical trials. We depend on these third parties to implement adequate controls and safeguards to protect against and report cybersecurity incidents. If they fail to do so, we may suffer financial and other harm, including to our information, operations, performance, and reputation. To the extent that any disruption or security breach were to result in a loss of, or damage to, our data or systems, or inappropriate disclosure of confidential or proprietary information, we could incur liability and the further development and commercialization of our product candidates could be delayed.

Cybersecurity threats, both on premises and in the cloud, are evolving and include, but are not limited to: malicious software, destructive malware, ransomware, attempts to gain unauthorized access to systems or data, disruption to operations, critical systems or denial of service attacks; unauthorized release of confidential, personal or otherwise protected information; corruption of data, networks or systems; harm to individuals; and loss of assets. In addition, we could be impacted by cybersecurity threats or other disruptions or vulnerabilities found in products or services we use that are provided to us by third parties. The techniques used by criminal elements to attack computer systems are sophisticated, change frequently and may originate from less regulated and remote areas of the world. As a result, we may not be able to address these techniques proactively or implement adequate preventative measures. These events, if not prevented or effectively mitigated, could damage our reputation, require remedial actions and lead to loss of business, regulatory actions, potential liability and other financial losses.

Certain data breaches must also be reported to affected individuals and various government and/or regulatory agencies, and in some cases to the media, under provisions of HIPAA, as amended by HITECH, other U.S. federal and state law, and requirements of non-U.S. jurisdictions, including the European Union Data Protection Directive, and financial penalties may also apply.

Our insurance policies may not be adequate to compensate us for the potential losses arising from breaches, failures or disruptions of our infrastructure, catastrophic events and disasters or otherwise. In addition, such insurance may not be available to us in the future on economically reasonable terms, or at all. Further, our insurance may not cover all claims made against us and defending a suit, regardless of its merit, could be costly and divert management's attention.

Business disruptions and unfavorable economic conditions could seriously harm our business, future revenue and financial condition, and could increase our costs and expenses.

We depend on our employees, consultants, contract manufacturers, and CROs, and other parties, for the continued operation of our business. Our or their operations could be significantly disrupted by earthquakes, power shortages, telecommunications failures, water shortages, floods, hurricanes, typhoons, fires, ice and snowstorms, extreme weather conditions, medical epidemics or pandemics, wars or other armed conflicts, geopolitical tensions or trade wars, terrorist attacks, and other natural or man-made disasters or business interruptions, for which we are, and they may be, predominantly self-insured. Because we rely on third-party contract manufacturers to produce our product candidates, our ability to obtain clinical supplies of our 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.

In addition, unfavorable economic conditions both inside and outside the U.S., including, without limitation, heightened inflation, capital market volatility, interest rate and currency rate fluctuations, any potential economic slowdown or recession, banking disruptions, public health crises such as the COVID-19 pandemic and geopolitical events, including trade wars or civil or political unrest (such as the ongoing war between Ukraine and Russia and conflict in the Middle East), have resulted in a significant disruption of global financial markets. If the disruption persists or deepens, we could experience an increase in our costs and expenses, including an increase in financing costs, and restrictions on our access to potential sources of future capital. If we are unable to raise additional capital when needed or on attractive terms, our business, financial condition, stock price and results of operations could be adversely affected, and we could be forced to delay, reduce or altogether terminate one or more current or future research and development programs. Further, we hold our cash and cash equivalents that we use to meet our working capital and operating expense needs in deposit accounts at multiple financial institutions, and if a financial institution in which we hold such funds fails or is subject to significant adverse conditions in the financial or credit markets, we could be subject to a risk of loss of all or a portion of any uninsured funds or be subject to a delay in accessing all or a portion of such uninsured funds. Any such loss or lack of access to these funds could adversely impact our short-term liquidity and ability to meet our operating expense obligations. In addition, there is a risk that one or more of our current service providers,

manufacturers and other partners may not survive such difficult economic times, which could directly affect our ability to attain our operating goals. Any of the foregoing could harm our business, future revenue and financial condition.

A variety of risks associated with marketing our product candidates internationally, if approved, could materially adversely affect our business.

We may seek regulatory approval of our product candidates outside of the United States and, accordingly, we expect that we will be subject to additional risks related to operating in foreign countries if we obtain the necessary approvals, including:

- regulatory requirements in foreign countries that differ from those in the United States;
- unexpected changes in tariffs, trade barriers, price and exchange controls and other regulatory requirements;
- economic weakness, including inflation, or political instability in particular foreign economies and markets;
- compliance with tax, employment, immigration and labor laws for employees living or traveling abroad;
- foreign taxes, including withholding of payroll taxes;
- foreign currency fluctuations, which could result in increased operating expenses and reduced revenue, and other obligations incident to doing business in another country;
- complexities associated with managing multiple payor reimbursement regimes, government payors or patient self-pay systems;
- difficulties staffing and managing foreign operations;
- workforce uncertainty in countries where labor unrest is more common than in the United States;
- potential liability under the FCPA or comparable foreign regulations;
- challenges enforcing our contractual and intellectual property rights, especially in those foreign countries that do not respect and protect intellectual property rights to the same extent as the United States;
- production shortages resulting from any events affecting raw material supply or manufacturing capabilities abroad; and
- business interruptions resulting from geo-political actions, including war and terrorism.

Any of these factors could harm our future international expansion and operations and, consequently, our results of operations.

We may engage in strategic transactions that could impact our liquidity, increase our expenses and present significant distractions to our management.

From time to time, we may consider strategic transactions, such as acquisitions of companies, asset purchases and out-licensing or in-licensing of intellectual property, products or technologies. Additional potential transactions that we may consider in the future include a variety of business arrangements, including spin-offs, strategic partnerships, joint ventures, restructurings, divestitures, business combinations and investments. Any future transactions could increase our near and long-term expenditures, result in potentially dilutive issuances of our equity securities, including our common stock, or the incurrence of debt, contingent liabilities, amortization expenses or acquired in-process research and development expenses, any of which could affect our financial condition, liquidity and results of operations. Future acquisitions may also require us to obtain additional financing, which may not be available on favorable terms or at all. These transactions may never be successful and may require significant time and attention of management. In addition, the integration of any business that we may acquire in the future may disrupt our existing business and may be a complex, risky and costly endeavor for which we may never realize the full benefits of the acquisition. Accordingly, although there can be no assurance that we will undertake or successfully complete any additional transactions of the nature described above, any additional transactions that we do complete could have a material adverse effect on our business, results of operations, financial condition and prospects.

Risks Related to Ownership of Our Common Stock and Our Status as a Public Company

The price of our common stock could be subject to volatility related or unrelated to our operations.

Our stock price is likely to be volatile. For example, from January 1, 2024, until March 5, 2025, our stock price has ranged from $1.03 to $8.19. The stock market in general and the market for biotechnology and pharmaceutical companies in particular have experienced extreme volatility that has often been unrelated to the operating performance of particular companies. As a result of this volatility, investors may not be able to sell their common stock at an attractive price or at all. The market price for our common stock may be influenced by many factors, including:

- adverse results from preclinical studies;

- the commencement, enrollment or results of any clinical trials we may conduct, or changes in the development status of our product candidates;
- adverse results from, delays in initiating or completing, or termination of clinical trials;
- unanticipated serious safety concerns related to the use of our product candidates;
- clinical trial results from, or regulatory approval of, a competitor's product candidate;
- adverse regulatory decisions, including failure to receive regulatory approval of our product candidates;
- any delay in our regulatory filings for our product candidates and any adverse development or perceived adverse development with respect to the applicable regulatory authority's review of such filings, including without limitation the FDA's issuance of a "refusal to file" letter or a request for additional information;
- lower than expected market acceptance of our product candidates following approval for commercialization;
- adverse developments concerning our manufacturers;
- our inability to obtain adequate product supply for any approved product or inability to do so at acceptable prices;
- introduction of new products or services by our competitors;
- changes in financial estimates by us or by any securities analysts who might cover our stock;
- conditions or trends in our industry;
- our cash position;
- sales of our common stock by us or our stockholders in the future;
- adoption of new accounting standards;
- ineffectiveness of our internal controls;
- changes in the market valuations of similar companies;
- stock market price and volume fluctuations of comparable companies and, in particular, those that operate in the biotechnology and pharmaceutical industry;
- publication of research reports about us or our industry or positive or negative recommendations or withdrawal of research coverage by securities analysts;
- announcements by us or our competitors of significant acquisitions, strategic partnerships or divestitures;
- announcements of investigations or regulatory scrutiny of our operations or lawsuits filed against us;
- investors' general perception of our company and our business;
- recruitment or departure of key personnel;
- overall performance of the equity markets;
- trading volume of our common stock;
- disputes or other developments relating to proprietary rights, including patents, litigation matters and our ability to obtain patent protection for our technologies and product candidates;
- significant lawsuits, including patent or stockholder litigation;
- proposed changes to healthcare laws or pharmaceutical pricing in the United States or foreign jurisdictions, or speculation regarding such changes;
- general political and economic conditions; and
- other events or factors, many of which are beyond our control.

In addition, in the past, stockholders have initiated class action lawsuits against pharmaceutical and biotechnology companies following periods of volatility in the market prices of these companies' stock. This risk is especially relevant for us because biopharmaceutical companies have experienced significant stock price volatility in recent years. Such litigation, if instituted against us, could cause us to incur substantial costs and divert management's attention and resources from our business.

If securities or industry analysts do not publish or cease publishing research or reports about our company, or if they issue unfavorable or inaccurate research regarding our business, our share price and trading volume could decline.

The trading market for our common stock relies, in part, on the research and reports that securities or industry analysts publish about us or our business. We do not have research control over these analysts. There can be no assurance that existing analysts will continue to cover us or that new analysts will begin to cover us. There is also no assurance that any covering analysts with provide favorable coverage. Although we have obtained coverage, if one or more of the analysts covering us downgrades our stock or publishes unfavorable or inaccurate research about our business, our stock price may decline. If one or more of these analysts ceases coverage of our company or fails to publish reports on us regularly, demand for our stock could decrease, which might cause our stock price and trading volume to decline.

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

Our executive officers, directors, holders of 5% or more of our common stock and their respective affiliates beneficially own a significant portion of our outstanding common stock.

As a result of their share ownership, these stockholders, if they act together, have the ability to influence our management and policies and are able to significantly affect the outcome of matters requiring stockholder approval such as elections of directors, amendments of our organizational documents or approvals 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.

In addition, this concentration of ownership might adversely affect the market price of our common stock by:

- delaying, deferring or preventing a change of control of us;
- impeding a merger, consolidation, takeover or other business combination involving us; or
- discouraging a potential acquirer from making a tender offer or otherwise attempting to obtain control of us.

We have broad discretion regarding use of our cash and cash equivalents, and we may use them in ways that do not enhance our operating results or the market price of our common stock.

Our management has broad discretion in the application of our cash and cash equivalents. We could utilize our cash and cash equivalents in ways our stockholders may not agree with or that do not yield a favorable return, if any, and our management might not apply our cash and cash equivalents in ways that ultimately increase the value of our stockholders' investments. If we do not utilize our cash and cash equivalents in ways that enhance stockholder value, we may fail to achieve expected financial results, which could cause our stock price to decline.

We do not intend to pay dividends on our common stock so any returns will be limited to the value of our 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. In addition, the terms of the K2HV Loan Agreement and any future debt agreements may preclude us from paying dividends. Any return to stockholders will therefore be limited in the foreseeable future to the appreciation of their stock.

We have incurred and will continue to incur increased costs as a result of operating as a public company, and our management has devoted and will continue to be required to devote substantial time to new compliance initiatives and corporate governance practices.

As a public company, we incur significant legal, accounting and other expenses that we did not previously incur as a private company. The Sarbanes-Oxley Act of 2002, or the Sarbanes-Oxley Act, the Dodd-Frank Wall Street Reform and Consumer Protection Act, Nasdaq listing requirements, and other applicable securities rules and regulations impose various requirements on public companies, including establishment and maintenance of effective disclosure and financial controls and corporate governance practices. Our management and other personnel have and will need to continue to devote a substantial amount of time to these compliance initiatives. Moreover, these rules and regulations will increase our legal and financial compliance costs, particularly as we hire additional financial and accounting employees to meet public company internal control and financial reporting requirements and will make some activities more time-consuming and costly compared to when we were a private company.

We are continually evaluating these rules and regulations and cannot predict or estimate the amount of additional costs we may incur or the timing of such costs. These rules and regulations are often subject to varying interpretations, in many cases due to their lack of specificity, and, as a result, their application in practice may evolve over time as new guidance is provided by regulatory and governing bodies. This could result in continuing uncertainty regarding compliance matters and higher costs necessitated by ongoing revisions to disclosure and governance practices. We intend to invest resources to comply with

evolving laws, regulations and standards, and this investment may result in increased general and administrative expenses and a diversion of management's time and attention from revenue-generating activities to compliance activities. If notwithstanding our efforts to comply with new laws, regulations and standards, we fail to comply, regulatory authorities may initiate legal proceedings against us and our business may be harmed.

Pursuant to Section 404 of the Sarbanes-Oxley Act, or Section 404, we are required to furnish a report by our management on our internal control over financial reporting. However, while we remain an emerging growth company or a smaller reporting company with less than $100.0 million in annual revenue, we will not be required to include an attestation report on internal control over financial reporting issued by our independent registered public accounting firm. To achieve compliance with Section 404 within the prescribed period, we are engaged in a process to document and evaluate our internal control over financial reporting, which is both costly and challenging. In this regard, we will need to continue to dedicate internal resources, including through hiring additional financial and accounting personnel, potentially engage outside consultants and adopt a detailed work plan to assess and document the adequacy of internal control over financial reporting, continue steps to improve control processes as appropriate, validate through testing that controls are functioning as documented and implement a continuous reporting and improvement process for internal control over financial reporting. Despite our efforts, there is a risk that we will not be able to conclude, within the prescribed timeframe or at all, that our internal control over financial reporting is effective as required by Section 404. If we identify one or more material weaknesses in our internal control over financial reporting, it could result in an adverse reaction in the financial markets due to a loss of confidence in the reliability of our financial statements.

In the past, we have identified material weaknesses in our internal control over financial reporting, and if we are unable to implement and maintain effective internal control over financial reporting in the future, investors may lose confidence in the accuracy and completeness of our financial reports, and the market price of our common stock may be materially adversely affected.

In the past, we have identified material weaknesses in our internal control over financial reporting. All material weaknesses previously identified were fully remediated in the first quarter of 2024.

If, in the future we have a material weakness in our internal controls over financial reporting, we may not detect errors on a timely basis and our consolidated financial statements may be materially misstated. We or our independent registered public accounting firm may not be able to conclude on an ongoing basis that we have effective internal control over financial reporting, which could harm our operating results, cause investors to lose confidence in our reported financial information and cause the trading price of our stock to fall. In addition, as a public company we are required to file accurate and timely quarterly and annual reports with the SEC under the Exchange Act. Any failure to report our financial results on an accurate and timely basis could result in sanctions, lawsuits, delisting of our shares from the Nasdaq Global Select Market or other adverse consequences that would materially harm our business. In addition, we could become subject to investigations by the stock exchange on which our securities are listed, the SEC, and other regulatory authorities, and become subject to litigation from investors and stockholders, which could harm our reputation and our financial condition, or divert financial and management resources from our core business

If we fail to maintain an effective system of internal control over financial reporting, we may not be able to accurately report our financial results or prevent fraud. As a result, stockholders could lose confidence in our financial and other public reporting, which would harm our business and the trading price of our common stock.

Effective internal control over financial reporting is necessary for us to provide reliable financial reports and, together with adequate disclosure controls and procedures, is designed to prevent fraud. Any failure to implement required new or improved controls, or difficulties encountered in their implementation could cause us to fail to meet our reporting obligations. In addition, any testing by us conducted in connection with Section 404, or any subsequent testing by our independent registered public accounting firm, may reveal deficiencies in our internal control over financial reporting that are deemed to be material weaknesses or that may require prospective or retroactive changes to our financial statements or identify other areas for further attention or improvement. As discussed above, we have identified material weaknesses in the past which have since been remediated. However, our remediation of previous material weaknesses may not prevent any future deficiency in our internal control over financial reporting. Inferior internal controls could, also cause investors to lose confidence in our reported financial information, which could harm our business and have a negative effect on the trading price of our stock.

We are required to disclose changes made in our internal controls and procedures on a quarterly basis, and our management is required to assess the effectiveness of these controls annually. However, for as long as we are an emerging growth company under the Jumpstart Our Business Startups Act, or the JOBS Act, enacted in April 2012 or a smaller reporting company with less than $100.0 million in annual revenue, our independent registered public accounting firm will not be required to attest to the effectiveness of our internal control over financial reporting pursuant to Section 404. We could be an emerging growth company for up to five years. An independent assessment of the effectiveness of our internal control over financial reporting could detect problems that our management's assessment might not. Undetected material weaknesses in our internal control

over financial reporting could lead to financial statement restatements and require us to incur the expense of remediation, which could have a negative effect on the trading price of our stock.

Our disclosure controls and procedures may not prevent or detect all errors or acts of fraud.

We are subject to certain reporting requirements of the Exchange Act. Our disclosure controls and procedures are designed to reasonably assure that information required to be disclosed by us in reports we file or submit under the Exchange Act is accumulated and communicated to management, recorded, processed, summarized and reported within the time periods specified in the rules and forms of the SEC. We believe that any disclosure controls and procedures or internal control over financial reporting, no matter how well conceived and operated, can provide only reasonable, not absolute, assurance that the objectives of the control system are met. These inherent limitations include the realities that judgments in decision-making can be faulty, and that breakdowns can occur because of simple error or mistake. Additionally, controls can be circumvented by the individual acts of some persons, by collusion of two or more people or by an unauthorized override of the controls. Accordingly, because of the inherent limitations in our control system, misstatements or insufficient disclosures due to error or fraud may occur and not be detected.

Provisions in our corporate charter documents and under Delaware law could make an acquisition of our company, which may be beneficial to our stockholders, more difficult and may prevent attempts by our stockholders to replace or remove our current directors and members of management.

Provisions in our restated certificate of incorporation, or our certificate of incorporation, and our second amended and restated bylaws, or our bylaws, may discourage, delay or prevent a merger, acquisition or other change in control of our company that stockholders may consider favorable, including transactions in which our stockholders might otherwise receive a premium for their shares. These provisions could also limit the price that investors might be willing to pay in the future for shares of our common stock, thereby depressing the market price of our common stock. In addition, because our board of directors is responsible for appointing the members of our management team, these provisions may frustrate or prevent any attempts by our stockholders to replace or remove our current management by making it more difficult for stockholders to replace members of our board of directors. Among other things, these provisions:

- establish a classified board of directors such that only one of three classes of directors is elected each year;
- allow the authorized number of our directors to be changed only by resolution of our board of directors;
- limit the manner in which stockholders can remove directors from our board of directors;
- establish advance notice requirements for stockholder proposals that can be acted on at stockholder meetings and nominations to our board of directors;
- require that stockholder actions must be effected at a duly called stockholder meeting and prohibit actions by our stockholders by written consent;
- limit who may call stockholder meetings;
- authorize our board of directors to issue preferred stock without stockholder approval, which could be used to institute a “poison pill” that would work to dilute the stock ownership of a potential hostile acquirer, effectively preventing acquisitions that have not been approved by our board of directors; and
- require the approval of the holders of at least two-thirds of the votes that all our stockholders would be entitled to cast to amend or repeal specified provisions of our certificate of incorporation or bylaws.

Moreover, because we are incorporated in Delaware, we are governed by the provisions of Section 203 of the Delaware General Corporation Law, or the DGCL, which prohibits a person who owns in excess of 15% of our outstanding voting stock from merging or combining with us for a period of three years after the date of the transaction in which the person acquired in excess of 15% of our outstanding voting stock, unless the merger or combination is approved in a prescribed manner.

Our restated certificate of incorporation designates the Court of Chancery of the State of Delaware and the federal district courts of the United States of America as the sole and exclusive forum for certain types of actions and proceedings that may be initiated by our stockholders, which could limit our stockholders’ ability to obtain a favorable judicial forum for disputes with us or our directors, officers and employees and increase the costs to our stockholders of bringing such claims.

Our restated certificate of incorporation provides that, unless we consent in writing to the selection of an alternative forum, the Court of Chancery of the State of Delaware (or, if the Court of Chancery of the State of Delaware does not have jurisdiction, the federal district court for the District of Delaware) will be the sole and exclusive forum for the following types of actions or proceedings under Delaware statutory or common law:

- any derivative action or proceeding brought on our behalf;

- any action asserting a claim of breach of a fiduciary duty owed by any of our directors, officers, employees or stockholders to our company or our stockholders;
- any action asserting a claim arising pursuant to any provision of the DGCL or as to which the DGCL confers jurisdiction on the Court of Chancery of the State of Delaware; or
- any action asserting a claim arising pursuant to any provision of our certificate of incorporation or bylaws (in each case, as they may be amended from time to time) or governed by the internal affairs doctrine.

These choice of forum provisions will not apply to suits brought to enforce a duty or liability created by the Exchange Act. Furthermore, Section 22 of the Securities Act creates concurrent jurisdiction for federal and state courts over all such Securities Act actions, and investors cannot waive compliance with the federal securities laws and the rules and regulations thereunder. Accordingly, both state and federal courts have jurisdiction to entertain such claims. To prevent having to litigate claims in multiple jurisdictions and the threat of inconsistent or contrary rulings by different courts, among other considerations, our restated certificate of incorporation provides that, unless we consent in writing to the selection of an alternative forum, the federal district courts of the United States of America shall, to the fullest extent permitted by law, be the sole and exclusive forum for the resolution of any claims arising under the Securities Act. While the Delaware courts have determined that such choice of forum provisions are facially valid, a stockholder may nevertheless seek to bring a claim in a venue other than those designated in the exclusive forum provisions. In such instance, we would expect to vigorously assert the validity and enforceability of the exclusive forum provisions of our restated certificate of incorporation. This may require significant additional costs associated with resolving such action in other jurisdictions and there can be no assurance that the provisions will be enforced by a court in those other jurisdictions.

These exclusive forum provisions may limit the ability of our stockholders to bring a claim in a judicial forum that such stockholders find favorable for disputes with us or our directors, officers or employees, and increase the costs to such stockholders of bringing such a claim, either of which may discourage such lawsuits against us and our directors, officers and employees. If a court were to find either exclusive forum provision contained in our restated certificate of incorporation to be inapplicable or unenforceable in an action, we may incur further significant additional costs associated with resolving such action in other jurisdictions, all of which could materially adversely affect our business, financial condition and operating results.

Item 1B. Unresolved Staff Comments

None.

Item 1C. Cybersecurity

We have certain processes for the identification, assessment, and mitigation of cybersecurity risks which are incorporated into our overall risk management processes in coordination with our information technology function. Such processes include physical, procedural and technical safeguards, and routine review of our policies and procedures to identify risks and improve our practices. We conduct cybersecurity training and testing for all of our employees covering timely and relevant topics, including social engineering, phishing, password protection, confidential data protection, and mobile security, and we educate employees on the importance of reporting all incidents immediately. We also use technology-based tools to mitigate cybersecurity risks and to bolster our employee-based cybersecurity programs. We engage third-party consultants to enhance our cybersecurity oversight and conduct penetration testing and vulnerability assessments. Further, we consider the cybersecurity practices of our third-party service providers, including through a general security assessment and contractual requirements, as appropriate, before engaging them in order to help protect us from any related vulnerabilities.

We do not believe that there are currently any risks from known cybersecurity threats that are reasonably likely to materially affect us or our business strategy, results of operations or financial condition. For more information about the cybersecurity risks we face, see the risk factors entitled “Our business could be negatively affected by cyberattacks or a deficiency in our cybersecurity” and “Our internal computer systems, or those used by our third-party research institution collaborators, CROs or other contractors or consultants, may fail or suffer security breaches” in the section titled *“Risk Factors”* in Part 1, Item 1A of this Annual Report.

Our Director of Operations leads the operational oversight of the company-wide cybersecurity strategy, policy, standards and processes. The Director of Operations role is currently held by an individual who has over two decades of professional IT management experience and possesses the requisite education, skills and experience expected to perform such a duty. In addition, our Director of Operations as well as leaders from our operations, finance, and legal departments, are responsible for documenting, reviewing, and assessing our cybersecurity processes, monitoring for cybersecurity incidents, and periodically reporting on cybersecurity risks and risk management to the audit committee of our board of directors. The audit committee of the board of directors provides oversight of our cybersecurity risk as part of its periodic review of enterprise risk management. The audit committee provides regular updates to our board of directors regarding such oversight, including updates on the status

of ongoing cybersecurity projects, the results of cybersecurity risk assessments, and the emerging cybersecurity threat landscape. Additionally, the board of directors reviews our enterprise risk management processes periodically and is notified by management between management updates regarding significant new cybersecurity threats or incidents.

Item 2. Properties

Our principal facilities consist of office and laboratory space. We currently occupy 25,778 square feet of office and laboratory space in Watertown, Massachusetts under a lease that expires in May 2030. We believe that our existing facilities will be adequate and suitable for our needs for the foreseeable future.

Item 3. Legal Proceedings

We are not currently a party to any material legal proceedings.

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 and Holders

Our common stock trades on The Nasdaq Global Select Market under the symbol HOWL. As of March 5, 2025, we had approximately 19 holders of record of our common stock. This number does not include beneficial owners whose shares were held by nominees in street name.

Dividend Policy

We have never declared or paid cash dividends on our capital stock. We currently intend to retain all available funds and any future earnings, if any, to fund the development and expansion of our business and we do not anticipate paying any cash dividends in the foreseeable future. Any future determination to pay dividends will be made at the discretion of our board of directors and will depend on various factors, including applicable laws, our results of operations, financial condition, future prospects, then applicable contractual restrictions and any other factors deemed relevant by our board of directors. Investors should not purchase our common stock with the expectation of receiving cash dividends.

Recent Sales of Unregistered Securities

None.

Purchase of Equity Securities

We did not purchase any of our registered equity securities during the period covered by this Annual Report.

Item 6. [Reserved]

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

The following discussion and analysis is meant to provide material information relevant to an assessment of the financial condition and results of operations of our company, including an evaluation of the amounts and uncertainties of cash flows from operations and from outside resources, so as to allow investors to better view our company from management's perspective. The following discussion and analysis of our financial condition and results of operations should be read together with our consolidated financial statements and related notes appearing elsewhere in this Annual Report. In addition to historical information, the discussion and analysis contains forward-looking statements that involve risks, uncertainties and assumptions. Our actual results may differ materially from those anticipated in these forward-looking statements as a result of certain factors. We discuss factors we believe could cause or contribute to these differences below and elsewhere in this Annual Report, including those factors set forth in the section entitled "Cautionary Note Regarding Forward-Looking Statements and Industry Data" and in the section entitled "Risk Factors" in Part I, Item 1A of this Annual Report.

Overview

We are an innovative biopharmaceutical company pioneering the development of therapeutics engineered to stimulate the body's immune system for the treatment of cancer and other immune-mediated conditions. We are leveraging our proprietary PREDATOR platform to design conditionally activated molecules that stimulate both adaptive and innate immunity with the goal of addressing the limitations of conventional proinflammatory immune therapies. Our molecules, which we refer to as INDUKINE molecules, are intended to activate selectively in the tumor microenvironment, or TME. Our most advanced product candidates, WTX-124 and WTX-330, are systemically delivered, conditionally activated Interleukin-2 and Interleukin-12, respectively, INDUKINE molecules for the treatment of multiple tumor types.

We are currently evaluating WTX-124 in a Phase 1/1b clinical trial as a monotherapy and in combination with Merck & Co., Inc.'s anti-PD-1 therapy KEYTRUDA (pembrolizumab) in patients with immunotherapy sensitive advanced or metastatic solid tumors who have failed standard of care treatment, including checkpoint inhibitor therapy. In June 2024, we reported updated interim data from the monotherapy dose-escalation arms of the Phase 1/1b clinical trial, selected a recommended dose for expansion and initiated monotherapy dose expansion arms, and reported initial data from the combination dose escalation cohorts of the Phase 1/1b clinical trial. We have targeted full enrollment in the monotherapy dose expansion arm in the first half of 2025 and in the combination expansion arm in the second half of 2025. We plan to meet with regulatory authorities to discuss potential registrational pathways in the second half of 2025 and to release a monotherapy and combination therapy clinical data update in the fourth quarter of 2025.

We have evaluated WTX-330 in a Phase 1 clinical trial for the treatment of immunotherapy resistant advanced or metastatic solid tumors or lymphoma, to be followed by expansion arms in relapsed/refractory tumors following treatment with checkpoint inhibitors or tumors for which checkpoint inhibitors are not approved. We announced the initiation of patient dosing in February 2023. We reported initial data from the Phase 1 clinical trial in June 2024. In March 2024, we received alignment from the U.S. Food and Drug Administration, or the FDA, on the comparability path for WTX-330 for an improved manufacturing process. In December 2024, we submitted an amended investigational new drug application, or IND, for WTX-330, and we expect to initiate a Phase 1/2 dose- and regimen-finding clinical trial of WTX-330 in the first quarter of 2025 in patients with selected advanced or metastatic solid tumors. We presented updated interim safety and efficacy data from the Phase 1 clinical trial at the Society for Immunotherapy of Cancer Annual Meeting in November 2024.

We continue to further the development of our preclinical product candidates, WTX-518, a systemically delivered, conditionally activated Interleukin-18 INDUKINE molecule in development for the treatment of cancer designed to promote activation of immune cells in the TME, resulting in antitumor immunity, WTX-712, a systemically delivered, conditionally activated Interleukin-21, or IL-21, INDUKINE molecule that is being developed to minimize the severe toxicities that have been observed with recombinant IL-21 therapy and maximize clinical benefit when administered as monotherapy or in combination with checkpoint inhibitors in refractory and/or immunologically unresponsive tumors, and WTX-921, a novel Interleukin-10 INDUKINE molecule in development for the treatment of inflammatory bowel disease and potentially other inflammatory diseases. In April 2024, we presented preclinical data for both WTX-518 and WTX-712 at the American Association for Cancer Research Annual Meeting. Our preclinical models demonstrate that WTX-518 exhibits remarkable tumor-selective activation, resistance to IL-18BP and robust immune activation, while WTX-712 acts through a unique mechanism that robustly activates tumor-specific T lymphocytes with an expanded therapeutic window through its selective release of wild-type IL-21 in the TME.

In April 2022, we entered into a global collaboration and license agreement, or the Collaboration Agreement, with Jazz Pharmaceuticals Ireland Limited, or Jazz, under which Jazz acquired exclusive global development and commercialization rights related to Interferon alpha, or IFNα, INDUKINE molecule, JZP898 (formerly WTX-613), as well as products containing certain isolated recombinant polypeptides comprising IFNα that meet specified criteria (each such product, a Licensed Product). Pursuant to the terms of the Collaboration Agreement, we were responsible for certain preclinical development activities with respect to JZP898 and other development activities specified in mutually agreed upon development plans. Jazz generally

reimbursed us for the cost of such activities. Jazz is responsible for all other development and commercialization activities conducted to exploit the Licensed Products.

In June 2024, we executed a transfer agreement, or the Transfer Agreement, to assign our rights in a development agreement with a contract manufacturer of JZP898 to Jazz. The execution of this Transfer Agreement was the last material performance obligation required of us under the Collaboration Agreement.

Financial Operations Overview

Revenue

All of our revenue has been generated from the Collaboration Agreement with Jazz. For the years ended December 31, 2024 and 2023, we recognized $1.9 million and $19.9 million of revenue, respectively. Revenue from the transaction price for the Collaboration Agreement is recognized based on a cost-to-cost input method for both periods and includes upfront, milestone, and cost reimbursement payments. The Collaboration Agreement includes multiple development and regulatory and sales-based milestones, which were excluded from the transaction price at inception of the Collaboration Agreement based on our assessment that there was a high level of uncertainty of achieving the milestones. During the year ended December 31, 2024, we re-evaluated this assessment for any milestones that continue to be excluded from the transaction price, and concluded not to recognize any adjustment to the transaction price associated with variable consideration previously excluded from the transaction price. As of the execution of the Transfer Agreement, we no longer have any material performance obligations under the Collaboration Agreement, and all deferred revenue related to the Collaboration Agreement has been recognized as of December 31, 2024.

In the future, our ability to generate revenue from the Collaboration Agreement will depend on successfully achieving the various development and regulatory and sales-based milestones. We may also generate revenue from product sales or other collaboration agreements, strategic alliances and licensing arrangements. We expect that potential future revenue, if any, will fluctuate from quarter-to-quarter and year-to-year based upon our pattern of performance under the Collaboration Agreement and as a result of the timing and amount of milestones, and other payments and product sales, to the extent any are successfully commercialized. If we fail to complete the development of our product candidates in a timely manner or obtain regulatory approval for them, our ability to generate future revenue, and our results of operations and financial position, would be materially adversely affected.

Operating Expenses

Research and Development Expenses

Research and development expenses consist primarily of costs incurred for our research activities, including our discovery efforts and the development of our product candidates, and include:

- salaries, benefits and other related costs, including stock-based compensation expense, for personnel engaged in research and development functions;
- expenses incurred under agreements with third parties that conduct research, preclinical and clinical activities on our behalf;
- costs of outside consultants, including their fees, stock-based compensation and related travel expenses;
- costs of laboratory supplies and acquiring, developing and manufacturing preclinical study and clinical trial materials; and
- facility-related expenses, which include direct depreciation costs and allocated expenses for rent and maintenance of facilities and other operating costs.

We expense research and development costs as incurred. Costs for external development activities are recognized based on an evaluation of the progress to completion of specific tasks using information provided to us by our vendors. Payments for these activities are based on the terms of the individual agreements, which may differ from the pattern of performance of the individual arrangements, which may differ from the pattern of billings incurred, and are reflected in our consolidated financial statements as prepaid or accrued research and development expenses.

We typically use our employee and infrastructure resources across our development programs. We track external development costs by product candidate or development program, but generally we do not allocate personnel costs, license payments made under our licensing arrangements or other internal costs to specific development programs or product candidates.

Our external development costs were as follows:

	Year Ended December 31,	
	2024	2023
	(in thousands)	
WTX-124	$ 15,481	$ 2,867
WTX-330	13,269	4,698
WTX-712	1,389	1,040
JZP898	545	7,380
WTX-518	294	149
WTX-921	4	—
Pre-development candidates	1,793	2,360
Total external development costs	$ 32,775	$ 18,494

Research and development activities are central to our business model. We expect that our research and development expenses will continue to increase substantially for the foreseeable future as we progress our clinical trials of WTX-124 and WTX-330, continue preclinical development of WTX-712, WTX-518 and WTX-921, and continue to discover and develop additional product candidates. As a result of our entry into the Collaboration Agreement, which commenced in April 2022, our external preclinical development costs for JZP898 were generally reimbursed by Jazz until we completed all material performance obligations in June 2024.

The process of conducting the necessary clinical research to obtain regulatory approval is costly and time-consuming. We cannot reasonably estimate or know the nature, timing and estimated costs of the efforts that will be necessary to complete development of our current or future product candidates. The actual probability of success for our product candidates will depend on a variety of factors, including:

- the scope, rate of progress and expenses of our ongoing research activities as well as any preclinical studies and clinical trials, including our ongoing Phase 1/1b clinical trial for WTX-124 and Phase 1 clinical trial for WTX-330, and other research and development activities;
- establishing an appropriate safety profile;
- successful enrollment in and completion of clinical trials;
- whether our product candidates show safety and efficacy in our clinical trials;
- receipt of marketing approvals from applicable regulatory authorities;
- establishing commercial manufacturing capabilities or making arrangements with third-party manufacturers;
- obtaining and maintaining patent and trade secret protection and regulatory exclusivity for our product candidates;
- commercializing product candidates, if and when approved, whether alone or in collaboration with others; and
- continued acceptable safety profile of the products following any regulatory approval.

A change in the outcome of any of these variables with respect to the development of our current and future product candidates would significantly change the costs and timing associated with the development of those product candidates and we may never succeed in achieving regulatory approval for any of our product candidates. As a result of the uncertainties discussed above, we are unable to determine the duration and completion costs of our research and development activities.

General and Administrative Expenses

General and administrative expenses consist primarily of salaries, benefits and other related costs, including stock-based compensation, for personnel in our executive, finance, people operations, business development, legal, information technology and administrative functions. General and administrative expenses also include legal fees relating to intellectual property and corporate matters; professional fees for accounting, audit, tax and consulting services; insurance costs; travel expenses; and facility-related expenses, which include direct depreciation costs and allocated expenses for rent and maintenance of facilities and other operating costs.

We expect that our general and administrative expenses will increase in the future as we increase our personnel headcount to support the increasing size and complexity of our research, development and manufacturing activities.

Other Income

Interest Income

Interest income consists of interest earned from cash and cash equivalents and restricted cash and cash equivalents invested in money market funds.

Interest Expense

Interest expense represents interest incurred from our loan agreement, or the PWB Loan Agreement, with Pacific Western Bank, or PWB, until the extinguishment of the PWB term loan in May 2024, interest incurred from our loan and security agreement, or the K2HV Loan Agreement, with K2 HealthVentures LLC, or K2HV, and non-cash interest expense related to the amortization of debt issuance costs.

Loss on Extinguishment of Debt

Loss on extinguishment of debt consists of any residual financial impact from the repayment of term loans with lenders, specifically the extinguishment of the PWB term loan in May 2024.

Other Income (Expense), Net

Other income (expense), net consists primarily of remeasurement gains or losses attributable to changes in the fair value of the conversion option derivative liability associated with the K2HV Loan Agreement and the gain or loss recognized on the change in the fair value of the success payment liability that was associated with our debt agreement with PWB.

Critical Accounting Policies and 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 generally accepted accounting principles in the United States. The preparation of these consolidated financial statements and related disclosures requires us to make estimates and assumptions that affect the reported amounts of assets and liabilities, costs and expenses and the disclosure of contingent assets and liabilities in our financial statements and accompanying notes. On an ongoing basis, we evaluate our estimates which include, but are not limited to those related to revenue recognition, accrued expenses, assumptions used in the valuation of stock-based compensation expense and the fair value of the derivative liability and income taxes. We base our estimates on historical experience, known trends and events and various other factors that we believe to be reasonable under the circumstances. Actual results could differ from those estimates under different assumptions and conditions.

While our significant accounting policies are described in more detail in Note 2, *"Basis of Presentation and Summary of Significant Accounting Policies"* to our consolidated financial statements included within Part IV, Item 15 in this Annual Report, we believe the following accounting policies to be most critical to the judgments and estimates used in the preparation of our consolidated financial statements.

Revenue Recognition

We analyze our collaborations to assess whether such arrangements involve joint operating activities performed by parties that are both active participants in the activities and exposed to significant risks and rewards dependent on the commercial success of such activities and therefore within the scope of Accounting Standards Codification, or ASC, Topic 808, *Collaborative Arrangements*, or ASC 808. This assessment is performed throughout the life of the arrangement based on changes in the responsibilities of all parties in the arrangement. For arrangements within the scope of ASC 808 that contain multiple elements, we first determine which elements of the collaboration are deemed to be within the scope of ASC 808 and which elements of the collaboration are more reflective of a vendor-customer relationship and therefore within the scope of ASC Topic 606, *Revenue from Contracts with Customers*, or ASC 606. For elements of collaboration arrangements that are accounted for pursuant to ASC 808, an appropriate recognition method is determined and applied consistently, either by analogy to authoritative accounting literature or by applying a reasonable and rational policy election.

For those elements of the arrangement that are accounted for pursuant to ASC 606, we recognize revenue when our customer obtains control of promised goods or services, in an amount that reflects the consideration that the entity expects to receive in exchange for those goods or services. In applying ASC 606, we perform the following five steps: (i) identify the contract(s) with a customer; (ii) identify the promises and performance obligations in the contract; (iii) determine the transaction price; (iv) allocate the transaction price to the performance obligations in the contract; and (v) recognize revenue when (or as) we satisfy the performance obligations. We only apply the five-step model to contracts when it is probable that we will collect the consideration to which we are entitled in exchange for the goods or services we provide to the customer. At contract inception, once the contract is determined to be within the scope of ASC 606, we assess the goods or services promised within each contract, determine those that are performance obligations and assess whether each promised good or service is distinct. We then recognize as revenue the amount of the transaction price that is allocated to the respective performance obligation when (or

as) the performance obligation is satisfied. As part of the assessment, we must develop assumptions that require judgment to determine the standalone selling price for each performance obligation identified in the contract. We use key assumptions to determine the standalone selling price, which may include reimbursement rates for personnel costs, development timelines and probabilities of regulatory success. We do not assess whether a contract has a significant financing component if the expectation at contract inception is that the period between payment by the customer and the transfer of promised goods or services to the customer will be one year or less.

Arrangements that include upfront payments may require deferral of revenue recognition to a future period until obligations under these arrangements are fulfilled. Event-based milestone payments represent variable consideration, and we use the "most likely amount" method to estimate this variable consideration. Given the high degree of uncertainty around the occurrence of these events, we consider the milestones and other contingent amounts to be fully constrained until the uncertainty associated with these payments is resolved. Revenue will be recognized from sales-based royalty payments when or as the sales occur. We will re-evaluate the transaction price in each reporting period as uncertain events are resolved and other changes in circumstances occur.

Accrued Research and Development Expenses

As part of the process of preparing our consolidated financial statements, we are required to estimate our accrued research and development expenses as of each balance sheet date. In accruing service fees, we estimate the time period over which services will be performed and the level of effort to be expended in each period. This process involves reviewing open contracts and purchase orders, communicating with internal personnel to identify services that have been performed on our behalf and estimating the level of service performed and the associated cost incurred for the service when we have not yet been invoiced or otherwise notified of the actual cost. We periodically confirm the accuracy of our estimates with our service providers and make adjustments if necessary. The majority of our service providers invoice us monthly in arrears for services performed or when contractual milestones are met. The financial terms of agreements with these service providers are subject to negotiation, vary from contract to contract and may result in uneven payment flows. In circumstances where amounts have been paid in excess of costs incurred, we record a prepaid expense.

Although we do not expect our estimates to be materially different from amounts actually incurred, if our estimates of the status and timing of services performed differ from the actual status and timing of services performed, it could result in us reporting amounts that are too high or too low in any particular period.

Stock-based Compensation

We issue stock-based awards to employees and directors, generally in the form of stock options, restricted stock units, or RSUs, restricted stock awards, or RSAs, or as awards under the 2021 Employee Stock Purchase Plan, or the 2021 ESPP. Stock-based compensation is measured at the grant date based on the estimated fair value of the award and recognized as expense over the requisite service period of the award on a straight-line basis. For awards with performance conditions, we estimate the likelihood of satisfaction of the performance condition, which affects the period over which the expense is recognized. When the likelihood of satisfying the performance conditions related to an award is determined to be probable, the expense is recognized over the requisite service period. We have not granted any awards with market conditions. We recognize forfeitures of stock-based awards as they occur.

The grant date fair value of stock options, and awards granted under the 2021 ESPP are measured using the Black-Scholes valuation model, which requires us to make assumptions about the fair value of the underlying common stock on the date of grant. The grant date fair value of RSUs and RSAs is estimated to be equal to the closing price of our common stock on the date of grant. In the event that stock-based awards are granted in contemplation of or shortly before a planned release of material non-public information, and such information is expected to result in a material increase in the share price of our common stock, we may consider whether an adjustment to the observable market price is required when estimating the grant date fair value.

Recent Accounting Pronouncements

See Note 2, *"Basis of Presentation and Summary of Significant Accounting Policies,"* to our consolidated financial statements included within Part IV, Item 15 of this Annual Report for a description of recent accounting pronouncements applicable to our business.

JOBS Act Accounting Election and Smaller Reporting Company Implications

We are an emerging growth company, as defined in the Jumpstart Our Business Startups Act of 2012, as amended, or JOBS Act. For as long as we continue to be an emerging growth company, we may take advantage of exemptions from various reporting requirements that are applicable to other public companies that are not emerging growth companies, including not being required to comply with the auditor attestation requirements of Section 404 of the Sarbanes-Oxley Act of 2002, as amended, or Sarbanes-Oxley Act. Under the JOBS Act, emerging growth companies can also delay adopting new or revised

accounting standards until such time as those standards apply to private companies. We have irrevocably elected not to avail ourselves of this extended transition period, and, as a result, we will adopt new or revised accounting standards on the relevant dates on which adoption of such standards is required for other public companies.

Even after we no longer qualify as an emerging growth company, we may still qualify as a "smaller reporting company," which would allow us to continue to take advantage of reduced disclosure requirements, including not being required to comply with the auditor attestation requirements of Section 404 of the Sarbanes-Oxley Act if we are a smaller reporting company with less than $100.0 million in annual revenue.

Results of Operations

Comparison of the years ended December 31, 2024 and 2023

The following table summarizes our results of operations:

	Year Ended December 31,		
	2024	**2023**	**$ Change**
		(in thousands)	
Revenue:			
Collaboration revenue	$ 1,885	$ 19,943	$ (18,058)
Operating expenses:			
Research and development	56,434	41,776	14,658
General and administrative	19,045	18,670	375
Total operating expenses	75,479	60,446	15,033
Operating loss	(73,594)	(40,503)	(33,091)
Other income:			
Interest income	6,673	7,416	(743)
Interest expense	(4,656)	(3,139)	(1,517)
Loss on extinguishment of debt	(553)	—	(553)
Other income (expense), net	1,615	(1,142)	2,757
Total other income	3,079	3,135	(56)
Net loss	$ (70,515)	$ (37,368)	$ (33,147)

Revenue

Revenue was $1.9 million for the year ended December 31, 2024, which is comprised of partial recognition of the $15.0 million upfront payment received in April 2022 upon the execution of the Collaboration Agreement with Jazz and costs incurred for research services which were reimbursed by Jazz, and revenue related to the achievement of certain variable consideration components. As a result of the execution of the Transfer Agreement, we no longer have any material performance obligations under the Collaboration Agreement, and all deferred revenue related to the Collaboration Agreement has been recognized as of December 31, 2024. Comparatively, we recognized $19.9 million in collaboration revenue during the year ended December 31, 2023 driven by elevated research and development activities related to and in preparation for the IND submission of JZP898 and a cumulative catch-up of revenue related to achieving a variable consideration component included in the Collaboration Agreement, which led to an additional $4.7 million in revenue recognized during the year ended December 31, 2023.

Research and Development Expenses

The following table summarizes our research and development expenses:

	Year Ended December 31,		
	2024	2023	$ Change
	(in thousands)		
Manufacturing	$ 17,458	$ 8,328	$ 9,130
Personnel	16,192	15,242	950
Clinical trial costs	11,710	6,020	5,690
Contract research organization	3,607	4,146	(539)
Lab consumables	3,400	4,430	(1,030)
Facilities	3,346	2,870	476
Other	721	740	(19)
Total research and development expenses	$ 56,434	$ 41,776	$ 14,658

Research and development expenses for the year ended December 31, 2024 were $56.4 million, compared to $41.8 million for the year ended December 31, 2023. The increase of $14.7 million was primarily due to:

- $14.8 million of combined increases in manufacturing costs of $9.1 million and clinical trial costs of $5.7 million. The increases in both our clinical trial and manufacturing costs are driven by an increase of $20.2 million in costs associated with our continued development efforts of WTX-124 and WTX-330, which continue to progress through their respective clinical trials, including manufacturing to support those clinical trials. This increase was partially offset by a decrease of $6.3 million in manufacturing costs associated with JZP898 leading up to and following the execution of the Transfer Agreement with Jazz;
- $1.0 million of increased personnel costs, driven primarily by the timing and valuation of stock-based awards granted to employees, as well as the increased use of external consultants to help further the development of our product candidates; and
- $0.5 million of increased facility costs due to higher costs associated with maintaining our leased office and laboratory space, including higher real estate taxes, utilities, and maintenance costs.

These increases were partially offset by:

- $1.0 million of decreased lab consumables costs and $0.5 million of decreased contract research costs, primarily due to a shift in focus from discovery efforts to furthering the development of existing product candidates in comparison to the prior period.

General and Administrative Expenses

The following table summarizes our general and administrative expenses:

	Year Ended December 31,		
	2024	2023	$ Change
	(in thousands)		
Personnel	$ 9,645	$ 9,187	$ 458
Professional services	5,151	4,710	441
Facility costs	1,446	1,260	186
Corporate insurance	1,151	1,780	(629)
IT costs	757	655	102
Other	895	1,078	(183)
Total general and administrative expenses	$ 19,045	$ 18,670	$ 375

General and administrative expenses were $19.0 million for the year ended December 31, 2024 compared to $18.7 million for the year ended December 31, 2023. The increase of $0.4 million was primarily due to:

- $0.5 million of increased personnel costs, driven by annual cost of living adjustments; and

- $0.4 million of increased professional services costs, driven by costs incurred to protect our intellectual property and general corporate matters.

These increases were partially offset by:

- $0.6 million of decreased corporate insurance costs, driven by a reduction in associated premiums.

Interest Income

Interest income was $6.7 million for the year ended December 31, 2024, compared to $7.4 million for the year ended December 31, 2023. This decrease in interest income was primarily a result of less cash equivalents being held in money market accounts combined with lower interest rates during the year ended December 31, 2024 compared to the year ended December 31, 2023.

Interest Expense

Interest expense was $4.7 million for the year ended December 31, 2024, compared to $3.2 million for the year ended December 31, 2023. This increase is in part due to the fact that our effective interest rate under the K2HV Loan Agreement is higher than the effective interest rate associated with our previous term loan with PWB. Additionally, we did not draw down the PWB term loan until March 2023, resulting in interest expense being recognized for only a portion of the year ended December 31, 2023.

Loss on the Extinguishment of Debt

The extinguishment of the PWB term loan resulted in a one-time loss of $0.6 million for the year ended December 31, 2024. As no corresponding finance activity occurred for the year ended December 31, 2023, we did not incur any gain or loss on a debt extinguishment during the prior period.

Other Income (Expense), Net

Other income (expense), net for the year ended December 31, 2024 primarily consisted of $1.6 million of gains recognized for the change in fair value of the conversion option derivative liability associated with the K2HV Loan Agreement. Other income (expense), net for the year ended December 31, 2023 consisted of $1.0 million in losses recognized for the change in the fair value of the success payment liability during the period, which was settled during the second quarter of 2023, such that we incurred no such losses associated with the success liability in the PWB Loan Agreement during the year ended December 31, 2024.

Liquidity and Capital Resources

Sources of Liquidity

Since our inception in 2017, we have devoted substantially all of our efforts and financial resources to organizing and staffing our company; business planning; raising capital; developing and optimizing our platform technology; identifying potential product candidates; enhancing our intellectual property portfolio; undertaking research, preclinical studies, and clinical trials; and enabling manufacturing for our development programs. Our net loss was $70.5 million and $37.4 million for the years ended December 31, 2024 and 2023, respectively. As of December 31, 2024, we had an accumulated deficit of $414.6 million. As we have no products that are approved for sale, we have not generated any revenue from product sales to date, and we do not expect to generate any such revenue for the foreseeable future, if at all. Instead, we have financed our operations primarily through aggregate cash proceeds from convertible promissory notes, private placements of our convertible preferred stock, our initial public offering, payments from Jazz under the Collaboration Agreement, sales of common stock through our at-the-market program, and the drawdown of our term loans. Because our product candidates are in clinical development and the outcome of our efforts is uncertain, we cannot estimate the actual costs necessary to successfully complete the development and commercialization of our product candidates, or when we may achieve profitability, if at all.

We expect to continue to incur substantial and increasing expenses and net losses for the foreseeable future, as we continue to advance our current and future product candidates through preclinical and clinical development, manufacture drug product and drug supply, seek regulatory approval for our current and future product candidates, maintain and expand our intellectual property portfolio, hire additional research and development and business personnel and operate as a public company. As a result, we expect that our accumulated deficit will also increase significantly.

As a result, we will need substantial additional funding to support our continuing operations and pursue our growth strategy. Until we can generate significant revenue from product sales, if ever, we expect to finance our operations through a combination of public or private equity offerings and debt financings or other sources, such as potential collaboration agreements, strategic alliances and licensing arrangements. We may be unable to raise additional funds or enter into such other agreements or arrangements when needed on acceptable terms, or at all. Additionally, the extent to which we use our at-the-market program as a source of future funding will depend on a number of factors, including the prevailing market price of our common stock, general market conditions, the extent to which we are able to secure funds from other sources, and whether we

are then subject to limitations on our ability to use Form S-3 to sell more than one-third of the aggregate market value of our public float in the trailing 12-month period, which limitations will remain in place until such time as our public float exceeds $75 million. Our failure to raise capital or enter into such agreements as and when needed could have a material adverse effect on our business, results of operations and financial condition.

Term Loan Facilities

PWB Loan Agreement

In April 2022, we entered into the PWB Loan Agreement with PWB and subsequently drew down an aggregate of $40.0 million in term loans. The term loans accrued interest on the outstanding daily balance at a floating annual rate equal to greater of: (i) 0.5% above the prime rate then in effect or (ii) 4.5%. If the prime rate changed throughout the term, the interest rate would have been adjusted effective on the date of the prime rate change. All interest chargeable under the PWB Loan Agreement was computed on a 360-day year for the actual number of days elapsed, with interest payable monthly. We recognized interest expense related to the PWB Loan Agreement of $1.3 million during the year ended December 31, 2024.

In May 2024, we repaid all amounts outstanding under the PWB Loan Agreement, using $29.5 million in net loan proceeds received under the K2HV Loan Agreement, as described below, together with $10.5 million in existing cash. We recognized a total loss on extinguishment of debt in the amount of $0.6 million during the second quarter of 2024 primarily due to the write off of unamortized debt issuance costs.

K2HV Loan Agreement

In May 2024, we, as borrower, entered into the K2HV Loan Agreement with K2HV (which we refer to, together with any other lender from time to time, as the Lenders); K2HV, as administrative agent for the Lenders; and Ankura Trust Company, LLC, as collateral trustee for the Lenders. The K2HV Loan Agreement provides up to $60.0 million principal in term loans. We received $30.0 million in gross loan proceeds at closing; $25.0 million from the first tranche commitment and $5.0 million from the second tranche commitment. A third tranche commitment of up to $10.0 million is available to be drawn at our option between January 1, 2025 and June 30, 2025, subject to the achievement, as determined by the administrative agent in its discretion, of certain time-based, clinical and regulatory milestones and receipt of not less than $60.0 million in net cash proceeds from certain financing activities, with at least $50.0 million from a single offering of common stock. A fourth tranche commitment of up to $20.0 million is available to be drawn down at our option through May 1, 2026 or if the third tranche is funded, May 1, 2027, subject to Lender's review of our clinical, financial and operating plan and subject to the Lender's consent in its sole and absolute discretion.

The term loan matures on May 1, 2028, and we are obligated to make interest only payments for the first 24 months, or 36 months if the third tranche is funded, and then interest and equal principal payments each month thereafter through the maturity date. The term loan bears a variable interest rate equal to the greater of (i) 10.3%, and (ii) the sum of (A) the prime rate last quoted in The Wall Street Journal (or a comparable replacement rate if The Wall Street Journal ceases to quote such rate) and (B) 1.8%. We may prepay, at our option, all, but not less than all, of the outstanding principal balance and all accrued and unpaid interest with respect to the principal balance being prepaid of the term loans, subject to a prepayment premium to which the Lenders are entitled and certain notice requirements. We are obligated to pay a final fee equal to 6.95% of the aggregate amount of the term loans funded, or the Final Fee, to occur upon the earliest of (i) the maturity date, (ii) the acceleration of the term loans, and (iii) the prepayment of the term loans. The Final Fee is being accreted to interest expense using the effective interest method over the life of the debt.

Pursuant to the terms of the K2HV Loan Agreement, the lenders thereto may elect, prior to the full repayment of the term loans, to convert up to $5.0 million of the outstanding principal of the term loans into shares of our common stock at a conversion price of the lesser of $6.3182 per share, or the Fixed Price Conversion, and the lowest effective price per share of our first equity financing following the closing of the K2HV Loan Agreement, or the Variable Price Conversion, subject to customary adjustments and 9.99% and 19.99% beneficial ownership limitations. There will be no prepayment penalty for any principal amount converted into common stock. We determined that the Fixed Price Conversion and the Variable Price Conversion within the K2HV Loan Agreement are required to be bifurcated as an embedded derivative under ASC Topic 815 at fair value, and recorded as a discount on the debt on the date of issuance, with subsequent changes in fair value recognized in the accompanying consolidated statements of operations.

As security for our obligations under the K2HV Loan Agreement, we granted the Lenders a first priority security interest on substantially all of our assets (other than intellectual property), subject to certain exceptions. The K2HV Loan Agreement contains customary representations and warranties, events of default and affirmative and negative covenants, including covenants that limit or restrict our ability to, among other things, dispose of assets, make changes to our business, management, ownership or business locations, merge or consolidate, incur additional indebtedness, incur additional liens, pay dividends or other distributions or repurchase equity, make investments, and enter into certain transactions with affiliates, in each case subject to certain exceptions. Upon the occurrence of an event of default, a default interest rate of an additional 5.0% per annum

may be applied to the outstanding loan balances, and the Lenders may declare all outstanding obligations immediately due and payable and exercise all of its rights and remedies as set forth in the K2HV Loan Agreement and under applicable law. As of December 31, 2024, we are in compliance with all covenants.

Subject to certain conditions, we granted the Lenders the right, prior to repayment of the term loans, to invest up to $5.0 million in the aggregate in future offerings of capital stock, at market terms, subject to certain exceptions and conditions.

We incurred debt issuance costs of $0.7 million in connection with the term loans, composed of the facility fee of $0.4 million and other expenses paid to the Lenders of $0.2 million and external legal fees of $0.1 million. These debt issuance costs, together with fair value of the embedded derivative of $4.5 million, resulted in a debt discount of $5.1 million which is being amortized to interest expense over the term of the K2HV Loan Agreement using the effective interest method.

ATM Offering

On May 10, 2022, we entered into a sales agreement, or the Sales Agreement, with Leerink Partners LLC, or Leerink Partners, pursuant to which, from time to time, we may offer and sell shares of our common stock, which we refer to as the ATM Offering. The Sales Agreement provides that Leerink Partners is entitled to a sales commission equal to 3.0% of the gross sales price per share of all shares sold under the ATM Offering. We were initially entitled to offer and sell shares of our common stock having an aggregate offering price of up to $50.0 million in the ATM Offering. On February 9, 2024, we filed a prospectus supplement, or the Prospectus Supplement, under our shelf registration statement for the offer and sale of shares of our common stock having an offering price of up to an additional $25.0 million in the ATM Offering. Following our filing of the Prospectus Supplement, we are entitled to offer and sell shares of our common stock with an aggregate offering price of up to $75.0 million pursuant to the Sales Agreement. During the year ended December 31, 2024, we had sold an aggregate of 5,272,538 shares under the ATM Offering at an average price of $4.71 per share for net proceeds of $23.5 million after deducting sales commissions and offering expenses.

Jazz Collaboration

As of December 31, 2024, we have received $20.0 million in payments from Jazz, excluding payments for reimbursed costs, under the terms of the Collaboration Agreement. We are eligible to receive up to an additional $515.0 million in development and regulatory milestones, and up to $740.0 million in sales-based milestones for all Licensed Products. In addition, we are eligible to receive tiered mid-single digit royalties based on Jazz's, and any of its affiliates' and sublicensees', annual net sales of Licensed Products, subject to reduction in specified circumstances. As a result of the execution of the Transfer Agreement, we no longer have any material performance obligations under the Collaboration Agreement, and all deferred revenue related to the Collaboration Agreement has been recognized as of December 31, 2024.

Plan of Operation and Future Funding Requirements

As of December 31, 2024, we had cash and cash equivalents of $111.0 million. We expect that our existing cash and cash equivalents at December 31, 2024, will be sufficient to fund our operational expenses and capital expenditure requirements through at least the second quarter of 2026. We have based this estimate on assumptions that may prove to be wrong, however, and we could use our capital resources sooner than we expect. Our need to raise additional funds may be accelerated if our research and development expenses exceed our current expectations, if we acquire a third party, or if we acquire or license rights to additional product candidates or new technologies from one or more third parties.

The timing and amount of our operating expenditures will depend largely on:

- the scope, progress, timing, costs and results of researching and developing our current product candidates or any future product candidates, including with respect to our clinical trials of WTX-124 and WTX-330 and the costs associated with attracting, hiring and retaining skilled personnel and consultants as our preclinical and clinical activities increase;
- the cost of manufacturing our product candidates WTX-124, WTX-330, and any future product candidates for clinical trials and, if we are able to obtain marketing approval, for commercial sale;
- the costs of any third-party products used in our combination clinical trials that are not covered by such third parties or other sources;
- the success of our collaboration with Jazz;
- the timing of, and the cost involved in, obtaining marketing approval for WTX-124 and WTX-330 or any future product candidates, and our ability to obtain marketing approval and generate revenue from any potential commercial sales of such product candidates;

- the cost of building a sales force in anticipation of product commercialization and the cost of commercialization activities for WTX-124, WTX-330 or any future product candidates if we receive marketing approval, including marketing, sales and distribution costs;
- the potential emergence of competing therapies and other adverse market developments;
- the amount and timing of any payments we may be required to make pursuant to our license agreement with Harpoon Therapeutics, Inc., or Harpoon, or other future license agreements or collaboration agreements;
- our ability to establish future collaborations, licensing or other arrangements and the financial terms of any such agreements, including the timing and amount of any future milestone, royalty or other payments due under any such agreement;
- the costs involved in preparing, filing, prosecuting, maintaining, expanding, defending and enforcing patent claims, including litigation costs and the outcome of such litigation;
- any product liability or other lawsuits related to our product candidates;
- the extent to which we in-license or acquire other products and technologies; and
- the costs of operating as a public company.

Our cash and cash equivalents will not be sufficient to complete development of WTX-124, WTX-330 or any other product candidates. Accordingly, we will be required to obtain further funding to achieve our business objectives.

Until such time, if ever, as we can generate substantial revenue from product sales, we expect to fund our operations and capital funding needs through equity and/or debt financing. We may also consider entering into collaboration arrangements or selectively partnering for clinical development and commercialization. The sale of additional equity may result in additional dilution to our stockholders. The incurrence of debt financing would result in debt service obligations and the instruments governing such debt could provide for operating and financing covenants that would restrict our operations or our ability to incur additional indebtedness or pay dividends, among other items. If we raise additional funds through governmental funding, collaborations, strategic partnerships and alliances or marketing, distribution or licensing arrangements with third parties, we may have to relinquish valuable rights to our technologies, future revenue streams, research programs or product candidates or grant licenses on terms that may not be favorable to us. If we are not able to secure adequate additional funding, we may be forced to make reductions in spending, extend payment terms with suppliers, liquidate assets where possible, and/or suspend or curtail planned programs. Any of these actions could materially and adversely affect our business, financial condition, results of operations, cash flows and prospects.

Cash Flows

The following table provides information regarding our cash flows:

	Year Ended December 31,	
	2024	2023
	(in thousands)	
Net cash (used in) provided by:		
Operating activities	$ (56,188)	$ (32,612)
Investing activities	(254)	(769)
Financing activities	13,080	58,429
Net (decrease) increase in cash, cash equivalents and restricted cash and cash equivalents	$ (43,362)	$ 25,048

Operating Activities

Net cash used in operating activities for the year ended December 31, 2024 was $56.2 million, compared to $32.6 million for the year ended December 31, 2023. This increase of approximately $23.6 million was primarily attributable to a decrease in revenue from our Collaboration Agreement of $18.1 million, combined with an increase in research and development expenses of $14.7 million, primarily driven by our continued development efforts of our product candidates. The change in net loss outlined above is partially offset by a net increase of $9.6 million in non-cash charges and changes in operating assets and liabilities.

Investing Activities

Net cash used in investing activities for the year ended December 31, 2024 was $0.3 million, compared to $0.8 million for the year ended December 31, 2023. The activity for both periods represents capital expenditures of property and equipment used in our operations.

Financing Activities

Net cash provided by financing activities for the year ended December 31, 2024 was $13.1 million, compared to $58.4 million for the year ended December 31, 2023. Cash provided by financing activities for the year ended December 31, 2024 primarily consisted of net proceeds from our ATM Offering during the period of $23.6 million, as well as the drawdown of the new term loan under the K2HV Loan Agreement of $30.0 million offset by the repayment of the previous PWB term loan of $40.0 million. Comparatively, cash provided by financing activities for the year ended December 31, 2023 consisted of proceeds from the $40.0 million drawdown of the PWB term loan combined with $18.3 million in net proceeds from our ATM Offering during the period.

Inflation

Inflation generally affects us by increasing our cost of labor and certain services; however, we do not believe that inflation has had a material impact on our results of operations since inception.

Contractual Obligations

Overview

In the normal course of business, we enter into agreements with CROs, contact manufacturers, vendors and other third parties for preclinical studies and clinical trials, manufacturing services and other services and products for operating purposes. These contracts do not contain minimum purchase commitments and are cancellable by us upon prior written notice. Payments due upon cancellation consist only of payments for services provided or expenses incurred, including noncancelable obligations of our service providers, up to the date of cancellation.

Term Loan Facilities

See *"Liquidity and Capital Resources – Sources of Liquidity – Term Loan Facilities"* for a descriptions of the PWB Loan Agreement and the K2HV Loan Agreement.

Lease Agreements

In April 2019, we entered into a lease for office and laboratory space. In May 2022, we entered into a sublease agreement with Crossbow Therapeutics, Inc., or Crossbow, a related party, to sublease the entirety of this space. Both our lease and the sublease with Crossbow expired in March 2024.

The lease for office and laboratory space that we entered into in June 2021 commenced in May 2022 and expires in May 2030. Total estimated base rent payments over the remaining term of the lease are approximately $13.5 million.

Item 7A. Quantitative and Qualitative Disclosures about Market Risk

We are a smaller reporting company as defined by Rule 12b-2 of the Securities Exchange Act of 1934, or the Exchange Act, and are not required to provide the information under this item.

Item 8. Financial Statements and Supplementary Data

The financial statements required to be filed pursuant to this Item 8 are appended to this Annual Report. An index of those financial statements is found in Part IV, Item 15.

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

Our management, with the participation of our principal executive officer and our principal financial officer, evaluated the effectiveness of our disclosure controls and procedures as of December 31, 2024. 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, or the Exchange Act, means controls and other procedures of a company that are designed to ensure that information required to be disclosed by the 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. Based on the evaluation of our disclosure controls and procedures as of December 31, 2024, our principal executive officer and principal financial officer concluded that, as of such date, our disclosure controls and procedures were effective at the reasonable assurance level.

Management's Annual Report on Internal Control over Financial Reporting

Our management is responsible for establishing and maintaining adequate internal control over financial reporting. Internal control over financial reporting is defined in Rules 13a-15(f) and 15d-15(f) under the Exchange Act as a process designed by, or under the supervision of, a company's principal executive officer and principal financial officer, or persons performing similar functions, and effected by a company's 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 in reasonable detail accurately and fairly reflect the transactions and dispositions of a company's assets;
- provide reasonable assurance that transactions are recorded as necessary to permit preparation of financial statements in accordance with generally accepted accounting principles, and that a company's receipts and expenditures are being made only in accordance with authorizations of the company's management and directors; and
- provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use or disposition of a company's assets that could have a material effect on the financial statements.

Because of its inherent limitations, internal control over financial reporting may not prevent or detect misstatements. Projections of any evaluation of effectiveness to future periods are subject to the risk that controls may become inadequate because of changes in conditions, or that the degree of compliance with the policies or procedures may deteriorate.

Under the supervision of and with the participation of our principal executive officer and principal financial officer, our management assessed the effectiveness of our internal control over financial reporting as of December 31, 2024 based on the criteria set forth by the Committee of Sponsoring Organizations of the Treadway Commission in Internal Control – Integrated Framework (2013). Based on this assessment as of December 31, 2024, management concluded that our internal control over financial reporting was effective at the reasonable assurance level.

This Annual Report does not include an attestation report of our independent registered public accounting firm, as it is not required for as long as we remain an emerging growth company or a smaller reporting company with less than $100.0 million in annual revenue.

Changes in Internal Control over Financial Reporting

There have been no changes in our internal control over financial reporting (as defined in Rules 13a-15(f) and 15d-15(f) under the Exchange Act) that occurred during the fourth quarter of the year 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

None of our directors or officers adopted or terminated a Rule 10b5-1 trading arrangement or a non-Rule 10b5-1 trading arrangement (as defined in Item 408(c) of Regulation S-K) during the fourth quarter of 2024.

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 10 will be included in the sections captioned "Corporate Governance" and "Proposal No. 1" in our definitive proxy statement to be filed with the Securities and Exchange Commission, or the SEC, with respect to our 2025 Annual Meeting of Stockholders within 120 days of December 31, 2024, which information is incorporated herein by reference.

Code of Ethics

We have adopted a written code of business conduct and ethics that applies to our directors, officers, and employees, including our principal executive officer, principal financial officer, principal accounting officer or controller, or persons performing similar functions. A copy of the code is posted on the Corporate Governance section of our website, which is located at www.werewolftx.com. If we make any substantive amendments to, or grant any waivers from, the code of business conduct and ethics for any officer or director, we will disclose the nature of such amendment or waiver on our website or in a current report on Form 8-K. We will provide any person, without charge, a copy of such Code of Business Conduct and Ethics upon written request, which may be mailed to 200 Talcott Ave, 2nd Floor, Watertown, MA 02472, Attn: Corporate Secretary.

Item 11. Executive Compensation

The information required by this Item 11 will be included in the section captioned "Executive Compensation" in our definitive Proxy Statement for our 2025 Annual Meeting of Stockholders to be filed with the SEC within 120 days of December 31, 2024, which information, other than the information required by Item 402(v) of Regulation S-K, is incorporated herein by reference.

Item 12. Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters

Except to the extent provided below, the information required by this Item 12 will be included in the section captioned "Principal Stockholders" in our definitive Proxy Statement for our 2025 Annual Meeting of Stockholders to be filed with the SEC within 120 days of December 31, 2024, which information is incorporated herein by reference.

Equity Compensation Plan Information

The following table contains information about our 2017 Stock Incentive Plan, or the 2017 Plan, our 2021 Stock Incentive Plan, or the 2021 Plan, and our 2021 Employee Stock Purchase Plan, or 2021 ESPP, as of December 31, 2024:

Plan Category	Number of Securities to be Issued upon Exercise of Outstanding Options, Warrants and Rights	Weighted Average Exercise Price of Outstanding Options, Warrants and Rights	Number of Securities Remaining Available for Future Issuance under Equity Compensation Plans (Excluding Securities Reflected in Column (a))
	(a)	(b)	(c)
Equity compensation plans approved by security holders [1]	7,693,841	$ 6.19	2,353,185
Equity compensation plans not approved by security holders	—	—	—
Total	7,693,841	$ 6.19	2,353,185

(1) Includes the 2017 Plan, the 2021 Plan and the 2021 ESPP. As of December 31, 2024, 1,919,921 shares of our common stock were available for issuance under the 2021 Plan. The number of shares reserved for issuance under the 2021 Plan will be increased on each January 1 through January 1, 2031 by the lesser of (i) 5% of the number of shares of our common stock outstanding on the first day of such year and (ii) an amount determined by our board of directors. The shares of common stock underlying any awards that are expired, forfeited, canceled, held back upon exercise or settlement of an award to satisfy the exercise price or tax withholding, repurchased or are otherwise terminated by us under the 2021 Plan or the 2017 Plan are added back to the shares of common stock available for issuance under the 2021 Plan. On January 1, 2025, the shares under the 2021 Plan were increased by 2,241,357 shares pursuant to the annual increase described above. As of December 31, 2024, 433,264 shares of our common stock were reserved for issuance under the 2021 ESPP. The number of shares reserved for issuance under the 2021 ESPP will be increased on each January 1 through January 1, 2032 by the least of (i) 488,000 shares, (ii) 1% of the number of shares of our common stock outstanding on the first day of such year and (iii) an amount determined by our board of directors. On January 1, 2025, the shares under the 2021 ESPP were increased by 224,135, representing a 0.5% increase in the number of shares of our common stock available for issuance pursuant to the 2021 ESPP as determined by our board of directors.

Item 13. Certain Relationships and Related Transactions, and Director Independence

The information required by this Item 13 will be included in the sections captioned "Corporate Governance" and "Transactions with Related Persons" in our definitive Proxy Statement for our 2025 Annual Meeting of Stockholders to be filed with the SEC within 120 days of December 31, 2024, which information is incorporated herein by reference.

Item 14. Principal Accountant Fees and Services

The information required by this Item 14 will be included in the section captioned "Ratification of the Appointment of Ernst & Young, LLP As Our Independent Registered Public Accounting Firm For The Fiscal Year Ending December 31, 2025" in our definitive Proxy Statement for our 2025 Annual Meeting of Stockholders to be filed with the SEC within 120 days of December 31, 2024, which information is incorporated herein by reference.

PART IV

Item 15. Exhibit and Financial Statement Schedules

(1) Financial Statements

The following documents are attached hereto and are filed as part of this Annual Report.

(2) Financial Statement Schedules

Schedules have been omitted since they are either not required or not applicable or the information is otherwise included herein.

(3) Exhibits

The exhibits filed or furnished as part of this Annual Report are listed in the Exhibit Index immediately preceding the signatures, which Exhibit Index is incorporated herein by reference.

Item 16. Form 10-K Summary

None.

Report of Independent Registered Public Accounting Firm

To the Stockholders and the Board of Directors of Werewolf Therapeutics, Inc.

Opinion on the Financial Statements

We have audited the accompanying consolidated balance sheets of Werewolf Therapeutics, Inc. (the Company) as of December 31, 2024 and 2023, the related consolidated statements of operations**,** stockholders' equity and cash flows for each of the two years in the period ended December 31, 2024, and 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 at December 31, 2024 and 2023, and the results of its operations and its cash flows for each of the two years in the period ended December 31, 2024, in conformity with U.S. generally accepted accounting principles.

Basis for Opinion

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

/s/ Ernst & Young LLP

We have served as the Company's auditor since 2022.
Boston, Massachusetts
March 11, 2025

Werewolf Therapeutics, Inc.
Consolidated Balance Sheets
(amounts in thousands, except share and per share amounts)

	December 31,	
	2024	**2023**
Assets		
Current assets:		
Cash and cash equivalents	$ 110,995	$ 134,343
Prepaid expenses and other current assets	2,071	2,677
Other receivables	—	1,350
Total current assets	113,066	138,370
Property and equipment, net	6,322	7,958
Restricted cash and cash equivalents, net of current portion	1,220	21,023
Operating lease right of use asset	6,001	6,888
Other assets	320	594
Total assets	$ 126,929	$ 174,833
Liabilities and stockholders' equity:		
Current liabilities:		
Accounts payable	$ 3,035	$ 1,336
Accrued expenses and other current liabilities	10,588	8,860
Operating lease liability, current	1,557	1,608
Deferred revenue, current	—	907
Note payable, current	—	6,667
Total current liabilities	15,180	19,378
Operating lease liability, net of current portion	9,435	10,992
Deferred revenue, net of current portion	—	433
Note payable, net of discount, issuance costs, and current portion	26,095	32,656
Derivative liability	2,829	—
Total liabilities	53,539	63,459
Commitments and contingencies		
Stockholders' equity:		
Preferred stock, $0.0001 par value, 5,000,000 shares authorized as of December 31, 2024 and 2023; no shares issued or outstanding as of December 31, 2024 and 2023	—	—
Common stock, $0.0001 par value, 200,000,000 shares authorized as of December 31, 2024 and 2023; 44,827,159 and 39,107,048 shares issued as of December 31, 2024 and 2023, respectively; 44,827,159 and 39,107,048 shares outstanding as of December 31, 2024 and 2023, respectively	5	4
Additional paid-in capital	487,973	455,443
Accumulated deficit	(414,588)	(344,073)
Total stockholders' equity	73,390	111,374
Total liabilities and stockholders' equity	$ 126,929	$ 174,833

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

Werewolf Therapeutics, Inc.
Consolidated Statements of Operations
(amounts in thousands, except share and per share amounts)

	Year Ended December 31,	
	2024	**2023**
Revenue:		
Collaboration revenue	$ 1,885	$ 19,943
Operating expenses:		
Research and development	56,434	41,776
General and administrative	19,045	18,670
Total operating expenses	75,479	60,446
Operating loss	(73,594)	(40,503)
Other income:		
Interest income	6,673	7,416
Interest expense	(4,656)	(3,139)
Loss on extinguishment of debt	(553)	—
Other income (expense), net	1,615	(1,142)
Total other income	3,079	3,135
Net loss	$ (70,515)	$ (37,368)
Net loss per share, basic	$ (1.63)	$ (1.05)
Net loss per share, diluted	$ (1.63)	$ (1.05)
Weighted-average common shares outstanding, basic	43,332,088	35,646,572
Weighted-average common shares outstanding, diluted	43,859,664	35,646,572

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

Werewolf Therapeutics, Inc.
Consolidated Statements of Stockholders' Equity
(amounts in thousands, except share amounts)

	Common Stock		Additional Paid-in Capital	Accumulated Deficit	Total Stockholders' Equity
	Shares	Amount			
Balance at December 31, 2022	31,515,074	$ 3	$ 429,039	$ (306,705)	$ 122,337
Issuance of common stock from at the market offering, net of issuance costs of $762	7,431,981	1	18,296	—	18,297
Issuance of common stock, net	157,037	—	93	—	93
Stock-based compensation expense	—	—	8,008	—	8,008
Stock option exercises	2,956	—	7	—	7
Net loss	—	—	—	(37,368)	(37,368)
Balance at December 31, 2023	39,107,048	4	455,443	(344,073)	111,374
Issuance of common stock from at the market offering, net of issuance costs of $1,283	5,272,538	1	23,527	—	23,528
Issuance of common stock, net	430,349	—	142	—	142
Stock-based compensation expense	—	—	8,826	—	8,826
Stock option exercises	17,224	—	35	—	35
Net loss	—	—	—	(70,515)	(70,515)
Balance at December 31, 2024	44,827,159	$ 5	$ 487,973	$ (414,588)	$ 73,390

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

Werewolf Therapeutics, Inc.
Consolidated Statements of Cash Flows
(amounts in thousands)

	Year Ended December 31,	
	2024	**2023**
Operating activities:		
Net loss	$ (70,515)	$ (37,368)
Adjustments to reconcile net loss to net cash used in operating activities:		
Stock-based compensation expense	8,826	8,008
Depreciation expense	1,814	1,764
Non-cash interest expense	1,342	273
Non-cash lease expense	887	1,575
Loss on extinguishment of debt	553	—
Change in fair value of derivative liability	(1,621)	—
Change in fair value of success payment liability	—	(1,030)
Amortization of debt issuance costs	—	60
Changes in operating assets and liabilities:		
Prepaid expenses and other assets	669	1,267
Other receivables	1,350	5,578
Accounts payable, accrued expenses and other liabilities	3,455	(4,335)
Deferred revenue	(1,340)	(6,320)
Operating lease liability	(1,608)	(2,084)
Net cash used in operating activities	(56,188)	(32,612)
Investing activities:		
Purchases of property and equipment	(254)	(769)
Net cash used in investing activities	(254)	(769)
Financing activities:		
Proceeds from at the market offering of common stock, net of issuance costs	23,576	18,329
Proceeds from drawdown of term loans	30,000	40,000
Payment of debt issuance costs	(673)	—
Repayment of term loan	(40,000)	—
Proceeds from issuances under Employee Stock Purchase Plan	142	93
Proceeds from stock option exercises	35	7
Net cash provided by financing activities	13,080	58,429
Net (decrease) increase in cash, cash equivalents and restricted cash and cash equivalents	(43,362)	25,048
Cash, cash equivalents and restricted cash and cash equivalents—beginning of period	155,577	130,529
Cash, cash equivalents and restricted cash and cash equivalents—end of period	$ 112,215	$ 155,577
Supplemental disclosure of cash flow information:		
Cash paid for interest	$ 3,358	$ 2,556
Supplemental disclosure of non-cash investing and financing activities:		
Purchases of property and equipment in accounts payable and accrued expenses	$ —	$ 76
Issuance costs in accounts payable and accrued expenses	$ 84	$ 36
Fair value of derivative liability issued with term loan	$ 4,450	$ —

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

Werewolf Therapeutics, Inc.
Notes to Consolidated Financial Statements

1. Nature of Business

Werewolf Therapeutics, Inc. was incorporated in the state of Delaware in October 2017. As used throughout these consolidated financial statements, the terms "Werewolf," "we," "us," and "our" refer to the business of Werewolf Therapeutics, Inc., and its wholly owned subsidiary. We are an innovative biopharmaceutical company pioneering the development of therapeutics engineered to stimulate the body's immune system for the treatment of cancer. Our headquarters are located in Watertown, Massachusetts.

Since inception, we have devoted substantially all of our efforts and financial resources to organizing and staffing the company; business planning; raising capital; developing and optimizing our platform technology; identifying potential product candidates; enhancing our intellectual property portfolio; undertaking research, preclinical studies, and clinical trials; and enabling manufacturing for our development programs. We are subject to risks and uncertainties common to early-stage companies in the biotechnology industry including, but not limited to, technical risks associated with the successful research, development and manufacturing of product candidates, development by competitors of new technological innovations, dependence on key personnel, protection of proprietary technology, compliance with government regulations and the ability to secure additional capital to fund operations. Current and future programs will require significant research and development efforts, including extensive preclinical and clinical testing and regulatory approval prior to commercialization. These efforts require significant amounts of additional capital, adequate personnel and infrastructure. Even if our product development efforts are successful, it is uncertain when, if ever, we will realize significant revenue from product sales.

We had cash and cash equivalents of $111.0 million at December 31, 2024. We expect that our cash and cash equivalents will enable us to fund our operating expenses and capital expenditure requirements for at least twelve months from the date of issuance of the consolidated financial statements included in this Annual Report on Form 10-K. However, additional funding will be necessary beyond this point to fund future preclinical and clinical activities. We expect to finance our future cash needs through a combination of equity or debt financings, collaboration agreements, strategic alliances and licensing arrangements. There is no guarantee that additional financing will be available to us on acceptable terms, or at all. If we fail to raise capital as and when needed, we may be forced to delay, reduce or eliminate our research and development programs or future commercialization efforts, or seek to merge with or be acquired by another company.

2. Basis of Presentation and Summary of Significant Accounting Policies

Basis of Presentation and Consolidation

The accompanying consolidated financial statements have been prepared in accordance with the rules and regulations of the Securities and Exchange Commission (the "SEC") and generally accepted accounting principles in the United States of America ("GAAP") as found in the Accounting Standards Codification ("ASC") and Accounting Standards Updates ("ASU") of the Financial Accounting Standards Board ("FASB"). The accompanying consolidated financial statements include the accounts of Werewolf Therapeutics, Inc. and its wholly owned subsidiary, Werewolf Therapeutics Mass Securities, Inc. All intercompany transactions and balances have been eliminated in consolidation.

Segment Information

We operate in one business segment, which focuses on the discovery and development of cancer therapeutics. Our chief operating decision maker ("CODM"), our Chief Executive Officer, makes operating decisions based upon the performance of the enterprise as a whole and utilizes our consolidated financial statements for decision making.

Use of Estimates

The preparation of financial statements in conformity with GAAP requires management to make estimates and assumptions that affect the amounts reported in the financial statements and accompanying notes. Significant estimates and assumptions reflected in these consolidated financial statements include, but are not limited to, those related to revenue recognition, accrued expenses, assumptions used in the valuation of stock-based compensation expense and the fair value of the derivative liability, and income taxes. Actual results could differ from those estimates.

Fair Value of Financial Instruments

ASC Topic 820, *Fair Value Measurement* ("ASC 820"), establishes a fair value hierarchy for instruments measured at fair value that distinguishes between assumptions based on market data (observable inputs) and our own assumptions (unobservable inputs). Observable inputs are inputs that market participants would use in pricing the asset or liability based on market data obtained from sources independent from us. Unobservable inputs are inputs that reflect our assumptions about the inputs that market participants would use in pricing the asset or liability and are developed based on the best information available in the circumstances.

ASC 820 defines fair value as the exchange price, or exit price, representing the amount that would be received to sell an asset or paid to transfer a liability in an orderly transaction between market participants. As a basis for considering market participant assumptions in fair value measurements, ASC 820 establishes a three-tiered fair value hierarchy that distinguishes between the following:

- Level 1 - Observable inputs such as quoted prices (unadjusted) 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, including quoted prices for similar assets or liabilities in active markets; quoted prices for identical or similar assets or liabilities in markets that are not active; inputs other than quoted prices that are observable for the asset or liability (e.g., interest rates); and inputs that are derived principally from or corroborated by observable market data by correlation or other means.
- Level 3 - Unobservable inputs for which little or no market data exists and that are significant to the fair value measurement, such as our own assumptions used to measure assets and liabilities at fair value.

To the extent that the valuation is based on models or inputs that are less observable or unobservable in the market, the determination of fair value requires more judgment. Accordingly, the degree of judgment exercised by us in determining fair value is greatest for instruments categorized in Level 3. The classification of a financial asset or liability within the fair value hierarchy is based on the lowest level of any input that is significant to the fair value measurement.

Cash and Cash Equivalents and Restricted Cash and Cash Equivalents

Our cash and cash equivalents consist of cash maintained within standard checking accounts. We also maintain cash sweep accounts in which cash from our main operating cash accounts are invested overnight in highly liquid, short-term investments. We consider all highly liquid investments with a maturity date of 90 days or less at the date of purchase to be cash equivalents.

We maintained restricted cash and cash equivalents of $1.2 million and $21.2 million at December 31, 2024 and December 31, 2023, respectively. The restricted cash and cash equivalents balance as of December 31, 2024 are comprised solely of a letter of credit required pursuant to our leased office spaces (see Note 10, *Commitments and Contingencies*). At December 31, 2023, $20.0 million of the restricted cash and cash equivalents balance represents an obligation under the term loan facility to maintain a minimum cash balance in our accounts with Pacific Western Bank (“PWB”). This obligation became effective upon imminent achievement of the funding goal as required by the terms of an amended and restated loan and security agreement (the “PWB Loan Agreement”) with PWB (see Note 7, *Term Loan*). The remaining restricted cash and cash equivalents balance as of December 31, 2023 are comprised solely of letters of credit required pursuant to our leased office spaces (see Note 10, *Commitments and Contingencies*). Restricted cash and cash equivalents are presented as current or non-current assets based on when the restrictions are expected to expire. The current portion of restricted cash and cash equivalents is included in prepaid expenses and other current assets in the accompanying consolidated balance sheets.

The following table provides a reconciliation of cash, cash equivalents, and restricted cash and cash equivalents reported within the consolidated balance sheets that sum to the total of the same amounts shown in the consolidated statements of cash flows:

	December 31,	
	2024	2023
	(in thousands)	
Cash and cash equivalents	$ 110,995	$ 134,343
Prepaid expenses and other current assets	—	211
Restricted cash and cash equivalents, net of current portion	1,220	21,023
Total cash, cash equivalents and restricted cash and cash equivalents	$ 112,215	$ 155,577

Property and Equipment

Property and equipment are stated at cost. Depreciation is recorded using the straight-line method over the estimated useful lives of the applicable assets. Upon the sale or retirement of an asset, the cost and related accumulated depreciation are eliminated from the respective account, and the resulting gain or loss, if any, is included in current operations. Amortization of leasehold improvements is recorded as depreciation expense using the straight-line method over the shorter of the remaining lease term or the estimated useful life of the related asset. We capitalize property and equipment that are acquired for research and development activities and that have an alternate future use. Expenditures for maintenance and repairs are recorded to

expense as incurred, whereas major betterments are capitalized as additions to property and equipment. Property and equipment are depreciated over the following periods:

Laboratory equipment	5 years
Furniture and office equipment	5 years
Computer equipment	3 years
Leasehold improvements	Shorter of lease term or useful life of asset

Costs for property and equipment not yet placed into service are classified as construction in progress and depreciated in accordance with the above guidelines once placed into service.

Impairment of Long-lived Assets

Long-lived assets consist of property and equipment. We review our property and equipment whenever events or changes in circumstances indicate that the carrying value of certain assets might not be recoverable. If such events or changes in circumstances arise, we compare the carrying amount of the long-lived assets to the estimated future undiscounted cash flows expected to be generated by the long-lived assets. If the estimated aggregate undiscounted cash flows are less than the carrying amount of the long-lived assets, an impairment charge, calculated as the amount by which the carrying amount of the assets exceeds the fair value of the assets, is recorded. The fair value of long-lived assets is determined based on the estimated discounted cash flows expected to be generated from the long-lived assets. We have not recorded any material impairment charges during the years ended December 31, 2024 or 2023.

Leases

At the inception of an arrangement, we determine whether the arrangement is or contains a lease based on the unique facts and circumstances present in the arrangement. Leases with a term greater than twelve months are recognized on the balance sheet as right-of-use assets and current or non-current lease liabilities, as applicable. We do not recognize leases with terms of twelve months or less on the balance sheet. The lease term is determined at lease commencement, and includes the noncancellable period during which we have the right to use the underlying asset. Any period covered by an option to extend or terminate a lease is included in the lease term if we are reasonably certain that the option to extend will be exercised or the option to terminate will not be exercised. We monitor our plans to renew material leases on a quarterly basis.

We combine lease and non-lease components for our leases. Lease payments included in determining the right-of-use asset and lease liability recognized include fixed payments to be paid over the term of the lease, less any lease incentives to be paid or payable to us by the lessor. Variable lease payments are included if they are based on an index or rate. Variable lease payments that are not based on an index or rate are recognized as expense in the period incurred.

The interest rate implicit in lease contracts is typically not readily determinable. As a result, we utilize our incremental borrowing rate (“IBR”), which reflects the fixed rate at which we could borrow on a collateralized basis the amount of the lease payments in the same currency, for a similar term, and in a similar economic environment. The lease liability is measured as the value of the remaining lease payments, discounted to present value using the IBR for the lease.

All of our leases are classified as operating leases. Operating lease expense is recognized over the lease term using the straight-line method.

Revenue Recognition

We analyze our collaborations to assess whether such arrangements involve joint operating activities performed by parties that are both active participants in the activities and exposed to significant risks and rewards dependent on the commercial success of such activities and therefore within the scope of ASC Topic 808, *Collaborative Arrangements* (“ASC 808”). This assessment is performed throughout the life of the arrangement based on changes in the responsibilities of all parties in the arrangement. For arrangements within the scope of ASC 808 that contain multiple elements, we first determine which elements of the collaboration are deemed to be within the scope of ASC 808 and which elements of the collaboration are more reflective of a vendor-customer relationship and therefore within the scope of ASC Topic 606, *Revenue from Contracts with Customers* (“ASC 606”). For elements of collaboration arrangements that are accounted for pursuant to ASC 808, an appropriate recognition method is determined and applied consistently, either by analogy to authoritative accounting literature or by applying a reasonable and rational policy election.

For those elements of the arrangement that are accounted for pursuant to ASC 606, we recognize revenue when our customer obtains control of promised goods or services, in an amount that reflects the consideration that the entity expects to receive in exchange for those goods or services. In applying ASC 606, we perform the following five steps: (i) identify the contract(s) with a customer; (ii) identify the promises and performance obligations in the contract; (iii) determine the transaction price; (iv) allocate the transaction price to the performance obligations in the contract; and (v) recognize revenue when (or as) we satisfy the performance obligations. We only apply the five-step model to contracts when it is probable that we will collect the

consideration to which we are entitled in exchange for the goods or services we provide to the customer. At contract inception, once the contract is determined to be within the scope of ASC 606, we assess the goods or services promised within each contract, determine those that are performance obligations and assess whether each promised good or service is distinct. We then recognize as revenue the amount of the transaction price that is allocated to the respective performance obligation when (or as) the performance obligation is satisfied. As part of the assessment, we must develop assumptions that require judgment to determine the standalone selling price for each performance obligation identified in the contract. We use key assumptions to determine the standalone selling price, which may include reimbursement rates for personnel costs, development timelines and probabilities of regulatory success. We do not assess whether a contract has a significant financing component if the expectation at contract inception is that the period between payment by the customer and the transfer of promised goods or services to the customer will be one year or less.

Arrangements that include upfront payments may require deferral of revenue recognition to a future period until obligations under these arrangements are fulfilled. Event-based milestone payments represent variable consideration, and we use the "most likely amount" method to estimate this variable consideration. Given the high degree of uncertainty around the occurrence of these events, we consider the milestones and other contingent amounts to be fully constrained until the uncertainty associated with these payments is resolved. Revenue will be recognized from sales-based royalty payments when or as the sales occur. We will re-evaluate the transaction price in each reporting period as uncertain events are resolved and other changes in circumstances occur.

Research and Development Expenses

Expenditures relating to research and development are expensed as incurred. Research and development expenses include external expenses incurred under arrangements with third parties, academic and non-profit institutions and consultants; salaries and personnel-related costs, including non-cash stock-based compensation expense; license fees to acquire in-process technology and other expenses, which include direct and allocated expenses for laboratory, facilities and other costs. Non-refundable advance payments for goods and services that will be used in future research and development activities are expensed when the activity has been performed or when the goods have been received rather than when the payment is made.

Intellectual Property Expenses

We expense costs associated with intellectual property-related matters as incurred and classify such costs as general and administrative expenses within the consolidated statements of operations.

Stock-based Compensation

We issue stock-based awards to employees and directors, generally in the form of stock options, restricted stock units ("RSUs"), restricted stock awards ("RSAs"), or as awards under the 2021 Employee Stock Purchase Plan (the "2021 ESPP"). Stock-based compensation is measured at the grant date based on the estimated fair value of the award and recognized as expense over the requisite service period of the award on a straight-line basis. For awards with performance conditions, we estimate the likelihood of satisfaction of the performance condition, which affects the period over which the expense is recognized. When the likelihood of satisfying the performance conditions related to an award is determined to be probable, the expense is recognized over the requisite service period. We have not granted any awards with market conditions. We recognize forfeitures of stock-based awards as they occur.

The grant date fair value of stock options, and awards granted under the 2021 ESPP are measured using the Black-Scholes valuation model, which requires us to make assumptions about the fair value of the underlying common stock on the date of grant. The grant date fair value of RSUs and RSAs is estimated to be equal to the closing price of our common stock on the date of grant. In the event that stock-based awards are granted in contemplation of or shortly before a planned release of material non-public information, and such information is expected to result in a material increase in the share price of our common stock, we may consider whether an adjustment to the observable market price is required when estimating the grant date fair value.

Debt Issuance Costs

Certain costs associated with the issuance of debt instruments are capitalized and amortized over the term of the respective debt instrument using the effective interest method through the maturity date of the related debt instrument and are recognized as a non-cash component of interest expense. The carrying value of our debt instruments is presented net of debt issuance costs.

Equity Issuance Costs

Equity issuance costs represent costs paid to third parties to secure equity financing and generally consist of sales agent commissions, incremental legal fees and other professional fees. Equity issuance costs are capitalized as other assets until the associated equity financing is consummated. Upon consummation of an equity financing, these costs are recorded as a

reduction of additional paid-in capital. In the event that a planned equity financing is abandoned, any capitalized equity issuance costs are immediately expensed to operating expenses in the consolidated statement of operations.

Income Taxes

Income taxes are recorded in accordance with ASC Topic 740, *Income Taxes* ("ASC 740") which provides for deferred taxes using an asset and liability approach. We recognize deferred tax assets and liabilities for the expected future tax consequences of events that have been included in the consolidated financial statements or tax returns. Deferred tax assets and liabilities are determined based on the difference between the financial statement and tax bases of assets and liabilities using enacted tax rates in effect for the year in which the differences are expected to reverse. A valuation allowance against deferred tax assets is recorded if, based on the weight of the available evidence, it is more likely than not that some or all of the deferred tax assets will not be realized.

We account for uncertain tax positions using a more-likely-than-not threshold for recognizing and resolving uncertain tax positions. The evaluation of uncertain tax positions is based on factors, including, but not limited to, changes in the law, the measurement of tax positions taken or expected to be taken in tax returns, the effective settlement of matters subject to audit, new audit activity and changes in facts or circumstances related to a tax position. We recognize any material interest and penalties related to unrecognized tax benefits in income tax expense.

Comprehensive Loss

We do not have items of other comprehensive loss for the years ended December 31, 2024 and 2023, and therefore do not present a consolidated statement of comprehensive loss. Our comprehensive loss equals our net loss.

Basic and Diluted Net Loss per Common Share

Basic net loss per share is calculated based upon the weighted-average number of common shares outstanding during the period, excluding outstanding stock options and RSUs that have been issued but are not yet vested. Diluted net loss per share is calculated based upon the weighted-average number of common shares outstanding during the period plus the dilutive impact of weighted-average common equivalent shares outstanding during the period. The potentially dilutive shares of common stock resulting from the assumed exercise of outstanding stock options and the assumed vesting of RSUs are determined under the treasury stock method. The potentially dilutive shares of common stock resulting from the assumed conversion of the currently outstanding convertible term loan is determined using the if-converted method.

Concentration of Credit Risk and Off-Balance Sheet Risk

Financial instruments that potentially subject us to significant concentrations of credit risk consist of cash and cash equivalents. Cash and cash equivalents are primarily held with two reputable financial institutions in the United States. At times, such deposits may be in excess of insured limits. We have not experienced any losses on our deposits of cash and cash equivalents. We have no significant off-balance sheet concentrations of credit risk, such as foreign currency exchange contracts, option contracts or other hedging arrangements.

Recently Adopted Accounting Pronouncements

In August 2020, the FASB issued ASU No. 2020-06, *Debt—Debt with Conversion and Other Options (Subtopic 470-20) and Derivatives and Hedging Contracts in Entity's Own Equity (Subtopic 815-40)* ("ASU No. 2020-06"), which reduces the number of accounting models for convertible debt instruments and convertible preferred stock as well as amends the derivatives scope exception for contracts in an entity's own equity. ASU No. 2020-06 also simplifies the diluted earnings per share calculation in certain areas. We adopted ASU No. 2020-06 on January 1, 2024. The adoption did not have a material impact on our consolidated financial statements.

In November 2023, the FASB issued ASU No. 2023-07, *Segment Reporting (Topic 280): Improvements to Reportable Segments Disclosures* ("ASU No. 2023-07"), which improves segment disclosure requirements, primarily through enhanced disclosure requirements for significant segment expenses. The improved disclosure requirements apply to all public entities that are required to report segment information, including those with only one reportable segment. We adopted ASU No. 2023-07 on January 1, 2024. The adoption had no impact on the reportable segment we have identified, and additional required disclosures have been included in Note 15.

Recent Accounting Pronouncements

In December 2023, the FASB issued ASU No. 2023-09, *Income Taxes (Topic 740): Improvements to Income Tax Disclosures* ("ASU No. 2023-09"), which enhances the transparency and decision usefulness of income tax disclosures primarily related to rate reconciliation and income taxes paid. The provisions of ASU No. 2023-09 are effective for fiscal years beginning after December 15, 2024, with early adoption permitted, and are required to be applied on a prospective basis. We are currently evaluating the impact that this standard will have on our consolidated financial statements.

In November 2024, the FASB issued ASU No. 2024-03, *Income Statement—Reporting Comprehensive Income—Expense Disaggregation Disclosures (Subtopic 220-04)* ("ASU No. 2024-03"), which requires the disclosure of additional information about specific expense categories in the notes to the consolidated financial statements at interim and annual reporting periods. The provisions of ASU No. 2024-03 are effective for annual reporting periods beginning after December 31, 2026, with early adoption permitted. We are currently evaluating the impact that this standard will have on our consolidated financial statements.

Other accounting standards that have been issued or proposed by the FASB or other standards-setting bodies that do not require adoption until a future date are not expected to have a material impact on our consolidated financial statements upon adoption.

Subsequent Events

We have evaluated subsequent events and transactions that occurred after the balance sheet date up to the date that the financial statements were issued. Other than as described in these financial statements, we did not identify any subsequent events that would have required adjustment to or disclosure in the financial statements.

3. Jazz Collaboration and License Agreement

In April 2022, we entered into an exclusive global collaboration and license agreement (the "Collaboration Agreement") with Jazz Pharmaceuticals Ireland Limited ("Jazz") pursuant to which we granted Jazz certain licenses to develop and commercialize products containing our Interferon alpha ("IFNα") INDUKINE™ molecule, JZP898 (formerly WTX-613), as well as products containing certain isolated recombinant polypeptides comprising IFNα that meet specified criteria (each such product, a "Licensed Product"). Under the Collaboration Agreement, we were responsible for certain preclinical development activities with respect to JZP898 and other development activities specified in mutually agreed upon development plans. Jazz had generally reimbursed us for the cost of such activities. Jazz is responsible for all other development and commercialization activities conducted to exploit the Licensed Products, including submission of an investigational new drug application ("IND") to the U.S. Food and Drug Administration (the "FDA"). Jazz received IND application clearance for JZP898 in July 2023 and initiated a Phase 1 clinical trial of JZP898 in the fourth quarter of 2023.

In June 2024, we executed a transfer agreement (the "Transfer Agreement") to assign our rights in a development agreement with a contract manufacturer of JZP898 to Jazz. The execution of this Transfer Agreement was the last material performance obligation required of us under the Collaboration Agreement.

Under the terms of the Collaboration Agreement, we received a non-refundable upfront cash payment of $15.0 million in April 2022 and a variable consideration payment of $5.0 million in July 2023, which is included in the overall transaction price as described below.

Milestones and Royalties

As of December 31, 2024, we are eligible to receive up to $515.0 million in development and regulatory milestones, and up to $740.0 million in sales-based milestones for all Licensed Products. In addition, we are eligible to receive tiered mid-single digit royalties based on Jazz's, and any of its affiliates' and sublicensees' annual net sales of Licensed Products, subject to reduction in specified circumstances.

As of December 31, 2024, we have not recognized any revenue related to sales-based milestones.

Accounting Analysis under ASC 606

Identification of the Contract(s)

We assessed the Collaboration Agreement and concluded that it represents a contract with a customer within the scope of ASC 606.

Identification of Promises and Performance Obligations

We have concluded that the exclusive license to our intellectual property, JZP898, and the non-exclusive corresponding "know-how" are not capable of being distinct from the other promises within the contract, and as such, we have determined that the license and "know-how" combined with the other research and development services and supply represent a single combined performance obligation.

Determination of Transaction Price

The overall transaction price as of the inception of the contract was determined to be $32.3 million, which was comprised of the nonrefundable upfront payment of $15.0 million and the estimated costs for research services of $17.3 million. Outside of the estimated costs for research services, there was no other variable consideration included in the transaction price at inception. We used the most likely amount method to estimate variable consideration and estimated that the most likely amount for each potential development and regulatory milestone payment under this agreement was zero at inception of the contract, as achievement of those milestones was uncertain and highly susceptible to factors outside of our control. Accordingly, all such

milestone payments were excluded from the transaction price at inception. We re-evaluate the transaction price at the end of each reporting period and as uncertain events are resolved or other changes in circumstances occur, and adjust the transaction price as necessary. During the year ended December 31, 2024, we did not recognize any adjustment to the transaction price associated with variable consideration previously excluded from the transaction price. During the year ended December 31, 2023, the overall transaction price was adjusted to include $5.0 million in variable consideration that was previously excluded based on our evaluation of the variable constraint associated with the variable payment. Sales based royalties, including milestones based on the level of sales, were also excluded from the transaction price, as the license is deemed to be the predominant item to which the royalties relate. We will recognize such revenue at the later of (i) when the related sales occur, or (ii) when the performance obligation to which some or all of the royalty has been allocated has been satisfied (or partially satisfied).

The upfront payment of $15.0 million was recorded as deferred revenue and, along with payments related to our conduct of research services under the Collaboration Agreement or any development and regulatory milestones, has been recognized as revenue using an input-based measurement of actual costs incurred as a percentage of the estimated total costs expected to be incurred over the expected term of conduct of the research services. We believe this input-based method to recognize revenue best reflects the transfer of value to Jazz. As of the execution of the Transfer Agreement, we no longer have any material performance obligations under the Collaboration Agreement. As a result, all deferred revenue related to the Collaboration Agreement has been recognized as of December 31, 2024.

Recognition of Revenue

We use the cost-to-cost input method, which best depicts the research services performed for the customer, to measure the revenue recognized under the Collaboration Agreement. Significant judgements used in the cost-to-cost method include estimated costs for research services and assumptions about the timing of when those costs are expected to be incurred. Differences in these estimates and assumptions can have a significant impact on the measurement and timing of when revenue under the Collaboration Agreement is recognized. For the years ended December 31, 2024 and 2023, we recognized $1.9 million and $19.9 million of revenue related to the Collaboration Agreement, respectively. The measurement of revenue recognized based on the cost-to-cost input method and the timing of payments received under the Collaboration Agreement directly impact the amounts reported as contract liabilities in our consolidated balance sheets as of December 31, 2024 and 2023. During the year ended December 31, 2023, the total revenue recognized included a cumulative catch-up of revenue of $4.2 million related to a variable payment that was previously excluded from the overall transaction price based on our evaluation of the variable constraint associated with the variable payment. The cumulative catch-up of revenue was recognized based on the cost-to-cost input method discussed above. Revenue from the reimbursement of costs for research activities was recognized during each of the respective periods in amounts equal to the costs incurred.

The following table presents the activity in our contract liabilities during the year ended December 31, 2024:

	Beginning of Period Balance	Additions	Reductions	End of Period Balance
	(in thousands)			
Contract liabilities:				
Deferred revenue	$ 1,340	$ —	$ (1,340)	$ —
Total contract liabilities	$ 1,340	$ —	$ (1,340)	$ —

The following table presents the activity in our contract liabilities during the year ended December 31, 2023:

	Beginning of Period Balance	Additions	Reductions	End of Period Balance
	(in thousands)			
Contract liabilities:				
Deferred revenue	$ 7,660	$ 5,000	$ (11,320)	$ 1,340
Total contract liabilities	$ 7,660	$ 5,000	$ (11,320)	$ 1,340

There are no unbilled receivables or receivables related to the Collaboration Agreement as of December 31, 2024. Unbilled receivables and receivables related to the Collaboration Agreement of $0.4 million and $0.9 million, respectively, were included in other receivables in the accompanying consolidated balance sheets as of December 31, 2023. Revenue recognized during the year ended December 31, 2024 includes $1.3 million of revenue that was included in deferred revenue as of

December 31, 2023. Revenue recognized during the year ended December 31, 2023 includes $6.7 million of revenue that was included in deferred revenue as of December 31, 2022.

As of December 31, 2024, we have not received any royalty payments under the Collaboration Agreement.

4. Financial Instruments and Fair Value Measurements

Our assets that are required to be measured at fair value on a recurring basis consist of money market funds, classified as cash, cash equivalents and restricted cash and cash equivalents on our consolidated balance sheets as of December 31, 2024 and 2023 .

Our liabilities that are required to be measured at fair value on a recurring basis consist of a derivative liability pursuant to a loan and security agreement (the "K2HV Loan Agreement") with K2 HealthVentures LLC ("K2HV") (see Note 7, *Term Loan*) as of December 31, 2024. We did not have any liabilities that are required to be measured at fair value on a recurring basis as of December 31, 2023.

The carrying amounts reflected in the consolidated balance sheets for cash, prepaid expenses and other current assets, accounts payable and accrued expenses approximate their fair values, due to their short-term nature.

Assets and liabilities measured at fair value on a recurring basis as of December 31, 2024 were as follows:

	Level 1	Level 2	Level 3	Total
		(in thousands)		
Assets:				
Money market funds	$ 105,526	$ —	$ —	$ 105,526
Total assets	$ 105,526	$ —	$ —	$ 105,526
Liabilities:				
Derivative liability	$ —	$ —	$ 2,829	$ 2,829
Total liabilities	$ —	$ —	$ 2,829	$ 2,829

Assets measured at fair value on a recurring basis as of December 31, 2023 were as follows:

	Level 1	Level 2	Level 3	Total
		(in thousands)		
Assets:				
Money market funds	$ 149,294	$ —	$ —	$ 149,294
Total assets	$ 149,294	$ —	$ —	$ 149,294

There were no changes in valuation techniques during the year ended December 31, 2024.

Derivative Liability

In May 2024, we entered into the K2HV Loan Agreement, as further described in Note 7, which provides up to $60.0 million principal in term loans. Pursuant to the terms of K2HV Loan Agreement, the lenders thereto may elect, prior to the full repayment of the term loans, to convert up to $5.0 million of the outstanding principal of the term loans into shares of our common stock at a conversion price of the lesser of $6.3182 per share (the "Fixed Price Conversion") and the lowest effective price per share of our first equity financing following the closing of the K2HV Loan Agreement (the "Variable Price Conversion"), subject to customary adjustments and 9.99% and 19.99% beneficial ownership limitations. The Fixed Price Conversion and Variable Price Conversion within the K2HV Loan Agreement are required to be bifurcated as a single compound embedded derivative carried at fair value, with subsequent changes in fair value recognized in the consolidated statement of operations.

The following table reconciles the change in fair value of the derivative liability during the year ended December 31, 2024 based on Level 3 inputs (in thousands):

Balance at December 31, 2023	$ —
Fair value of derivative liability at issuance of term loan	4,450
Change in fair value	(1,621)
Balance at December 31, 2024	$ 2,829

The change in fair value of the derivative liability is included in other income (expense), net in the accompanying consolidated statements of operations. We recognized a gain on the change in fair value of the derivative liability of $1.6 million during the year ended December 31, 2024.

The fair value of the conversion option derivative liability in the term loan was estimated using the Monte Carlo model. A summary of the weighted-average significant unobservable inputs (Level 3 inputs) used in measuring the conversion option derivative liability in the term loan as of December 31, 2024 and May 2, 2024 (inception) is as follows:

	December 31, 2024	May 2, 2024
Stock Price	$1.48	$6.08
Volatility	103.0%	101.0%
Risk-free rate (continuous)	4.2%	4.7%
Expected term (in years)	0.58	0.91
Dividend yield (continuous)	—%	—%

Success Payment Liability

In April 2022, we entered into an amended and restated loan and security agreement (the "PWB Loan Agreement") with PWB, as described below in Note 7. In conjunction with the PWB Loan Agreement, we became obligated to pay to PWB a one-time success payment of up to $1.6 million (the "Success Fee") upon achieving certain conditions defined in the PWB Loan Agreement (the "Success Fee Event"). The Success Fee Event occurred during the second quarter of 2023, resulting in the immediate payment in full of the required Success Fee.

Prior to the occurrence of the Success Fee Event, we recognized a success payment liability that was stated at fair value and was considered Level 3 because its fair value measurement was based, in part, on significant inputs not observed in the market. Upon completion of the Success Fee Event, we paid the total $1.6 million success payment and removed the corresponding success payment liability. We remeasured the success payment liability at each reporting date and immediately prior to the Success Fee Event. During the year ended December 31, 2023, we recognized expense of $1.0 million associated with the change in the fair value of the success payment liability which is included in other income (expense), net in the accompanying consolidated statement of operations. We had no outstanding obligation associated with the Success Fee as of December 31, 2024 or December 31, 2023.

5. Property and Equipment, Net

Property and equipment, net was comprised as follows:

	December 31,	
	2024	2023
	(in thousands)	
Leasehold improvements	$ 7,971	$ 7,971
Laboratory equipment	2,485	2,339
Computer equipment	539	512
Furniture and fixtures	311	306
Total property and equipment, gross	11,306	11,128
Less: accumulated depreciation	(4,984)	(3,170)
Total property and equipment, net	$ 6,322	$ 7,958

6. Accrued Expenses and Other Current Liabilities

Accrued expenses and other current liabilities were comprised as follows:

	December 31,	
	2024	2023
	(in thousands)	
Manufacturing	$ 4,783	$ 2,772
Employee compensation and benefits	3,616	3,627
Contract research	820	1,049
Professional fees	747	655
Accrued interest	266	310
Other	356	447
Total accrued expenses and other current liabilities	$ 10,588	$ 8,860

7. Term Loan

PWB Loan Agreement

In April 2022, we entered into the PWB Loan Agreement with PWB and subsequently drew down an aggregate of $40.0 million in term loans. The term loans accrued interest on the outstanding daily balance at a floating annual rate equal to greater of (i) 0.5% above the prime rate then in effect or (ii) 4.5%. If the prime rate changed throughout the term, the interest rate would have been adjusted effective on the date of the prime rate change. All interest chargeable under the PWB Loan Agreement was computed on a 360-day year for the actual number of days elapsed, with interest payable monthly. We recognized interest expense related to the PWB Loan Agreement of $1.3 million and $2.9 million during the years ended December 31, 2024 and 2023, respectively.

In May 2024, we repaid all amounts outstanding under the PWB Loan Agreement, using $29.5 million in net loan proceeds received under the K2HV Loan Agreement, as described below, together with $10.5 million in existing cash. We recognized a total loss on extinguishment of debt in the amount of $0.6 million during the year ended December 31, 2024 primarily due to the write off of unamortized debt issuance costs.

We were obligated to pay PWB a one-time fee in the event of certain corporate transactions equal to either (i) the greater of (a) $0.2 million and (b) 2.0% of the amount drawn under the term loans, for a transaction occurring on or before March 31, 2023, or (ii) for any transaction occurring thereafter, the greater of (a) $0.4 million and (b) 4.0% of the amount drawn under the term loans (the “Success Fee”). We determined that the Success Fee constituted a freestanding financial instrument that was required to be accounted for as a liability in connection with ASC Topic 815, *Derivatives and Hedging* (“ASC 815”). We determined the fair value of the Success Fee upon the closing date of the PWB Loan Agreement and then marked to market the fair value of the Success Fee as of December 31, 2023. The Success Fee Event (as defined in the PWB Loan Agreement) occurred during the second quarter of 2023, resulting in the immediate payment in full of the $1.6 million required Success Fee.

K2HV Loan Agreement

In May 2024, we, as borrower, entered into the K2HV Loan Agreement with K2HV (together with any other lender from time to time, the “Lenders”); K2HV, as administrative agent for the Lenders; and Ankura Trust Company, LLC, as collateral trustee for the Lenders. The K2HV Loan Agreement provides up to $60.0 million principal in term loans. We received $30.0 million in gross loan proceeds at closing; $25.0 million from the first tranche commitment and $5.0 million from the second tranche commitment. A third tranche commitment of up to $10.0 million is available to be drawn at our option between January 1, 2025 and June 30, 2025, subject to the achievement, as determined by the administrative agent in its discretion, of certain time-based, clinical and regulatory milestones and receipt of not less than $60.0 million in net cash proceeds from certain financing activities, with at least $50.0 million from a single offering of common stock. A fourth tranche commitment of up to $20.0 million is available to be drawn down at our option through May 1, 2026 or if the third tranche is funded, May 1, 2027, subject to Lender’s review of our clinical, financial and operating plan and subject to the Lender’s consent in its sole and absolute discretion.

The term loan matures on May 1, 2028, and we are obligated to make interest only payments for the first 24 months, or 36 months if the third tranche is funded, followed by interest and equal principal payments each month thereafter through the maturity date. The term loan bears a variable interest rate equal to the greater of (i) 10.3%, and (ii) the sum of (A) the prime rate last quoted in The Wall Street Journal (or a comparable replacement rate if The Wall Street Journal ceases to quote such rate) and (B) 1.8%. We may prepay, at our option, all, but not less than all, of the outstanding principal balance and all accrued and unpaid interest with respect to the principal balance being prepaid of the term loans, subject to a prepayment premium to which

the Lenders are entitled and certain notice requirements. We are obligated to pay a final fee equal to 6.95% of the aggregate amount of the term loans funded, or the Final Fee, to occur upon the earliest of (i) the maturity date, (ii) the acceleration of the term loans, and (iii) the prepayment of the term loans. The Final Fee is being accreted to interest expense using the effective interest method over the life of the debt.

The Lenders may elect prior to the full repayment of the term loans to convert up to $5.0 million of outstanding principal of the term loans into shares of our common stock, pursuant to the Fixed Price Conversion or the Variable Price Conversion, subject to customary adjustments and 9.99% and 19.99% beneficial ownership limitations. There will be no prepayment penalty for any principal amount converted into common stock. We determined that the Fixed Price Conversion and the Variable Price Conversion within the K2HV Loan Agreement are required to be bifurcated as an embedded derivative under ASC 815 at fair value, and recorded as a discount on the debt on the date of issuance, with subsequent changes in fair value recognized in the accompanying consolidated statements of operations. See Note 4 for further discussion on this derivative instrument.

As security for our obligations under the K2HV Loan Agreement, we granted the Lenders a first priority security interest on substantially all of our assets (other than intellectual property), subject to certain exceptions. The K2HV Loan Agreement contains customary representations and warranties, events of default and affirmative and negative covenants, including covenants that limit or restrict our ability to, among other things, dispose of assets, make changes to our business, management, ownership or business locations, merge or consolidate, incur additional indebtedness, incur additional liens, pay dividends or other distributions or repurchase equity, make investments, and enter into certain transactions with affiliates, in each case subject to certain exceptions. Upon the occurrence of an event of default, a default interest rate of an additional 5.0% per annum may be applied to the outstanding loan balances, and the Lenders may declare all outstanding obligations immediately due and payable and exercise all of their rights and remedies as set forth in the K2HV Loan Agreement and under applicable law. As of December 31, 2024, we are in compliance with all covenants.

Subject to certain conditions, we granted the Lenders the right, prior to repayment of the term loans, to invest up to $5.0 million in the aggregate in future offerings of capital stock, at market terms, subject to certain exceptions and conditions.

We incurred debt issuance costs of $0.7 million in connection with the term loans, composed of the facility fee of $0.4 million and other expenses paid to the Lenders of $0.2 million and external legal fees of $0.1 million. These debt issuance costs, together with the fair value of the embedded derivative of $4.5 million at inception of the K2HV Loan Agreement, resulted in a debt discount of $5.1 million which is being amortized to interest expense over the term of the K2HV Loan Agreement using the effective interest method. As of December 31, 2024, the fair value of the term loan was estimated to be approximately $28.2 million. The fair value was measured using a discounted cash flow analysis, specifically the yield method, which requires the use of Level 3 inputs in the fair value hierarchy.

The outstanding term loans payable consists of the following:

	December 31, 2024
	(in thousands)
Term loans	$ 30,000
Unamortized debt discount	(3,905)
Total debt, long-term	$ 26,095

The following table provides the components of interest expense related to the K2HV Loan Agreement:

	Year Ended December 31, 2024
	(in thousands)
Interest expense based on coupon interest rate (10.3%) of outstanding term loans	$ 2,094
Amortization of debt discount and accretion of Final Fee (8.94%)	1,217
Total interest expense on effective rate (19.24%)	$ 3,311

The following table presents the total principal payments scheduled to become due during each of the years ended December 31 (in thousands):

2025	$ —
2026	9,600
2027	14,400
2028	8,085
Total principal payments and Final Fee	$ 32,085

8. Common and Preferred Stock

Common Stock

We are authorized to issue 200,000,000 shares of common stock. Common stockholders are entitled to dividends if and when declared by our board of directors. As of December 31, 2024, no dividends on common stock had been declared by us.

On May 10, 2022, we entered into a Sales Agreement (the "Sales Agreement") with Leerink Partners, LLC ("Leerink Partners"), pursuant to which we are entitled to offer and sell shares of our common stock (the "ATM Offering"). The Sales Agreement provides that Leerink Partners will be entitled to a sales commission equal to 3.0% of the gross sales price per share of all shares sold under the ATM Offering. We were initially entitled to offer and sell shares of our common stock having an aggregate offering price of up to $50.0 million in the ATM Offering. On February 9, 2024, we filed a prospectus supplement (the "Prospectus Supplement") under our shelf registration statement for the offer and sale of shares of our common stock having an offering price of up to an additional $25.0 million in the ATM Offering. Following our filing of the Prospectus Supplement, we are now entitled to offer and sell shares of our common stock with an aggregate offering price of up to $75.0 million pursuant to the Sales Agreement. During the year ended December 31, 2024, we sold an aggregate of 5,272,538 shares under the ATM Offering at an average price of $4.71 per share for net proceeds of $23.5 million after deducting sales commissions and offering expenses. During the year ended December 31, 2023, we sold an aggregate of 7,431,981 shares under the ATM Offering at an average price of $2.56 per share for net proceeds of $18.3 million after deducting sales commissions and offering expenses.

We have reserved shares of common stock for issuance as follows:

	As of December 31,	
	2024	**2023**
Shares reserved for exercises of outstanding stock options	7,634,937	5,700,070
Shares reserved for vesting of restricted stock units	—	361,500
Shares reserved for exercises of warrants	58,904	58,904
Shares reserved for issuance under the 2021 Employee Stock Purchase Plan	433,264	507,113
Shares reserved for future issuance under the 2021 Stock Incentive Plan	1,919,921	1,911,660
Shares reserved for future issuance as part of the K2HV Loan Agreement conversion feature	791,364	—
Total shares reserved for future issuance	10,838,390	8,539,247

Preferred Stock

We are authorized to issue 5,000,000 shares of undesignated preferred stock in one or more series. As of December 31, 2024, no shares of preferred stock were issued or outstanding.

9. Stock-based Compensation

2017 Stock Incentive Plan

In December 2017, we adopted the 2017 Stock Incentive Plan (the "2017 Plan"), as amended and restated, under which it could grant incentive stock options ("ISOs"), non-qualified stock options, RSAs, RSUs, stock appreciation rights and other stock-based awards to eligible employees, officers, directors and consultants. The terms of stock options and RSAs, including vesting requirements, are determined by our board of directors, subject to the provisions of the 2017 Plan.

2021 Stock Incentive Plan

In April 2021, our board of directors adopted and our stockholders approved the 2021 Stock Incentive Plan (the "2021 Plan"), which became effective immediately prior to the effectiveness of our initial public offering (the "IPO"). As a result of the adoption of the 2021 Plan, no further awards will be made under the 2017 Plan.

The 2021 Plan provides for the grant of ISOs, non-qualified stock options, RSAs, RSUs, stock appreciation rights and other stock-based awards. Our employees, officers, directors, consultants and advisors are eligible to receive awards under the 2021 Plan. The terms of awards, including vesting requirements, are determined by our board of directors, subject to the provisions of the 2021 Plan.

We initially registered 3,352,725 shares of common stock under the 2021 Plan, pursuant to a Registration Statement on Form S-8 filed with the SEC on April 30, 2021, which was comprised of (i) 2,843,116 shares of common stock reserved for issuance under the 2021 Plan, (ii) 31,884 shares of common stock originally reserved for issuance under the 2017 Plan that became available for issuance under the 2021 Plan upon the completion of the IPO, and (iii) 477,725 shares of unvested restricted stock subject to repurchase by us that may become issuable under the 2021 Stock Incentive Plan following such repurchase. The 2021 Plan also provides that an additional number of shares will be added annually to the shares authorized for issuance under the 2021 Plan on the first day of each fiscal year, beginning with the fiscal year ending December 31, 2022 and continuing until, and including, the fiscal year ended December 31, 2031. The number of shares added each year will be equal to the lesser of (i) 5% of the number of outstanding common stock on such date and (ii) such amount as determined by the board of directors. As of December 31, 2024, a total of 4,911,502 additional shares have been added to the total shares authorized for issuance under the 2021 Plan in accordance with these terms.

As of December 31, 2024, there were 1,919,921 shares available for future issuance under the 2021 Plan. Effective January 1, 2025, 2,241,357 additional shares were added to the shares authorized for future issuance under the 2021 Plan pursuant to the terms of the annual increase described above.

2021 Employee Stock Purchase Plan

The 2021 ESPP permits eligible employees to purchase shares of our common stock at a discount and consists of consecutive six-month offering periods, each containing a single six-month purchase period. On the first day of each offering period, each employee who is enrolled in the 2021 ESPP will automatically receive an option to purchase up to a whole number of shares of our common stock. The purchase price of each of the shares purchased, in a given purchase period, will be equal to 85% of the lesser of the closing price of a share of our common stock on (i) the first day of the offering period, or (ii) the last day of the offering period. During the year ended December 31, 2024, 73,849 shares of our common stock were purchased by participants of the 2021 ESPP for total proceeds of $0.1 million. During the year ended December 31, 2023, 52,037 shares of our common stock were purchased by participants of the 2021 ESPP for total proceeds of $0.1 million.

Stock-Based Compensation Expense

Total stock-based compensation expense recognized in the consolidated statements of operations was as follows:

	Year Ended December 31,	
	2024	2023
	(in thousands)	
Research and development	$ 4,606	$ 4,003
General and administrative	4,220	4,005
Total stock-based compensation	$ 8,826	$ 8,008

RSA Activity

We may, at our discretion, repurchase unvested shares of restricted stock issued pursuant to the 2017 Plan at the initial purchase price if the employees or non-employees terminate their service relationship with us. The shares are recorded in stockholders' deficit as they vest.

As of December 31, 2023, all RSAs granted to employees or non-employees had become fully vested or had been previously forfeited. No RSAs were granted during the year ended December 31, 2024. Accordingly, we had no unrecognized stock-based compensation expense related to unvested RSAs as of December 31, 2024.

The aggregate fair value of RSAs that vested during the year ended December 31, 2023, based upon the fair value of the stock underlying the RSAs on the day of vesting, was $0.2 million.

RSU Activity

We have granted RSUs to our employees under the 2021 Plan. The following table summarizes RSU activity during the year ended December 31, 2024:

	Shares/Units	Weighted-Average Grant Date Fair Value Per Share
Unvested at December 31, 2023	361,500	$ 3.92
Granted	—	$ —
Vested	(356,500)	$ 3.95
Forfeited	(5,000)	$ 2.45
Unvested at December 31, 2024	—	$ —

As of December 31, 2024, there were no unvested RSUs. Accordingly, we had no unrecognized stock-based compensation expense related to unvested RSUs as of December 31, 2024.

The aggregate fair value of RSUs that vested during the year ended December 31, 2024, based upon the fair value of the stock underlying the RSUs on the day of vesting was $1.0 million. The aggregate fair value of RSUs that vested during the year ended December 31, 2023, based upon the fair value of the stock underlying the RSUs on the day of vesting was $0.2 million.

Stock Option Activity

During the year ended December 31, 2022, we granted performance-based stock options to certain executive officers for the purchase of an aggregate of 883,352 shares of common stock with a grant date fair value of $3.36 per share. These stock options would have vested only upon achievement of specified performance targets related to certain business objectives prior to December 31, 2023. These performance targets were not achieved, and accordingly these awards expired without vesting on December 31, 2023. No stock-based compensation expense was recognized during the year ended December 31, 2023 based on our assessment about the probability that the performance targets would be achieved prior to expiration.

The fair value of stock options granted during the years ended December 31, 2024 and 2023 was calculated on the date of grant using the following weighted-average assumptions:

	Year Ended December 31,	
	2024	2023
Risk-free interest rate	4.0 %	3.9 %
Expected term (in years)	6.0	6.0
Expected annual dividend yield	— %	— %
Expected volatility	92.7 %	82.7 %

The valuation assumptions were determined as follows:

- *Risk-free interest rate:* The yield on zero-coupon U.S. Treasury securities for a period that was commensurate with the expected term of the awards.
- *Expected term (in years):* The expected term of the awards represents the period of time that the awards were expected to be outstanding. We use the simplified method to estimate the expected term due to a lack of sufficient historical exercise data to provide a reasonable basis on which to estimate the expected term. Under this method, the expected term equals the average of the vesting term and the original contractual term of the option.
- *Expected annual dividend yield:* The estimated dividend yield was zero because we have no history of paying dividends, and do not intend to do so in the foreseeable future.
- *Expected volatility:* The expected term of stock options granted by us is generally longer than the trading history of our common stock since the IPO on April 30, 2021. Accordingly, we estimated the expected volatility based on the historical volatility of a group of publicly-traded companies with similar characteristics to us, including stage of product development and therapeutic focus within the life sciences industry. The historical volatility of these companies was calculated over a period of time commensurate with the expected term of the stock option.

Using the Black-Scholes option pricing model, the weighted-average grant date fair value of stock options granted during the years ended December 31, 2024 and 2023 was $3.43 and $1.56 per share, respectively.

The following table summarizes stock option activity during the year ended December 31, 2024:

	Options Outstanding			
	Number of Options	Weighted-Average Exercise Price per Share	Weighted-Average Remaining Contractual Life (in years)	Aggregate Intrinsic Value (in millions)
Outstanding at December 31, 2023	5,700,070	$ 6.89		
Granted	2,381,112	$ 4.44		
Exercised	(17,224)	$ 2.05		
Cancelled	(429,021)	$ 4.98		
Outstanding, December 31, 2024	7,634,937	$ 6.24	7.44	$ —
Exercisable at December 31, 2024	4,866,277	$ 7.13	6.79	$ —

The aggregate intrinsic fair value of stock options exercised during the years ended December 31, 2024 and 2023 were nominal for each year.

As of December 31, 2024, there was unrecognized stock-based compensation expense related to unvested stock options of $8.9 million, which we expect to recognize over a weighted-average period of approximately 2.2 years.

10. Commitments and Contingencies

Leases

Our leases are as follows:

- An April 2019 operating lease for approximately 9,949 square feet of office and laboratory space which commenced in April 2019 and terminated in March 2024. The lease was subject to fixed-rate rent escalations and provided for a term extension option, which was not reasonably certain of exercise. In May 2022, we entered into a sublease agreement with Crossbow Therapeutics, Inc. (“Crossbow”), to sublease the entirety of this space. The total rent due to us for the subleased premises over the term of the sublease was approximately $2.1 million, which is greater than the annual rent paid by us to the landlord for the leased premises over the same term. Rent expense associated with the April 2019 operating lease was recognized net of the lease income generated from the sublease agreement. Lease income was allocated to either research and development expense or general and administrative expense in the same manner as the associated rent expense was allocated. Crossbow was obligated to pay all real estate taxes and costs related to the subleased premises, including cost of operations, maintenance, repair, replacement, and property management. The sublease with Crossbow terminated in March 2024 concurrently with the termination of the lease.
- A June 2021 operating lease for approximately 25,778 square feet of office and laboratory space, which commenced in May 2022 and terminates in May 2030. The lease is subject to fixed-rate rent escalations and provided for $5.7 million in tenant improvements, which we fully utilized, and a term extension option, which was not reasonably certain of exercise. We provided the landlord with a security deposit in the form of a letter of credit in the amount of $1.0 million upon signing, which is included in restricted cash and cash equivalents, net of current portion as of December 31, 2024 and 2023.

The following table summarizes operating lease costs:

	Year Ended December 31,	
	2024	2023
	(in thousands)	
Operating lease costs	$ 1,918	$ 2,442
Variable lease costs	1,280	1,210
Sublease income	(398)	(1,562)
Total	$ 2,800	$ 2,090

Cash paid for amounts included in the measurement of lease liabilities were $2.5 million and $3.0 million for the years ended December 31, 2024 and 2023, respectively.

The following table summarizes the lease term and discount rate for operating leases:

	As of December 31,	
	2024	2023
Weighted-average remaining lease term (years)	5.4	6.3
Weighted-average discount rate	8.0 %	8.0 %

As of December 31, 2024, the future minimum lease payments due under our lease for each of the next five years ended December 31, and thereafter are as follows (in thousands):

2025	$ 2,337
2026	2,403
2027	2,471
2028	2,542
2029	2,614
Thereafter	1,102
Total future minimum lease payments	13,469
Less: imputed interest	(2,477)
Total lease liability	$ 10,992

License Agreements

Harpoon License

In March 2018, we entered into a Patent Assignment and License Agreement (the "Harpoon Agreement") with Harpoon Therapeutics, Inc. ("Harpoon"), a clinical-stage immune-oncology company developing a novel class of T-cell engagers to fight cancer and other diseases. Under the terms of the Harpoon Agreement, Harpoon granted us a license to use its intellectual property, solely to make, have made, use, sell, offer for sale and import covered products in the licensed field and Harpoon sold, assigned and transferred other specific patents to us (the "Harpoon License").

On October 19, 2018, we entered into the First Amended and Restated Assignment and License Agreement with Harpoon, which amended certain terms of the original agreement, but did not change the terms of the license to us, patent assignments between the parties or payments due to Harpoon. Further, on December 20, 2019, the companies entered into the Second Amended and Restated Assignment and License Agreement, which also amended certain terms of the original agreement to expand the licenses and assignments for specific patents granted to us or by us to Harpoon. In exchange for these additional terms, Harpoon agreed to reimburse up to $75,000 of our legal costs. Additionally, we agreed to pay to Harpoon royalties on future net sales and pay minimum annual royalties of $250,000 upon achievement of our first commercial sale.

Under the terms of the Harpoon License, we paid an upfront fee of $500,000 in 2018 and are obligated to reimburse Harpoon for certain legal costs incurred by Harpoon. In addition, we are obligated to pay Harpoon royalties based on future net sales and have agreed to pay a minimum annual royalty payment at an amount in the low hundreds of thousands of dollars upon achievement of our first commercial sale. In 2018, we recorded the upfront fee as research and development expense upon payment as the intellectual property was acquired prior to regulatory approval and does not have an alternative future use. The royalty payments are contingent upon sales and, as such, the royalty payments made to Harpoon will be considered probable and estimable and treated as cost of sales when incurred. Accordingly, at the commencement of sales, we will account for the royalty payments as cost of sales equal to the greater of a percentage in the low-single digits of the net sales of the patent-covered products or a minimum annual royalty payment at an amount in the low hundreds of thousands of dollars. Any legal fees incurred in connection with the Harpoon Agreement will be expensed as incurred.

The Harpoon License will expire on a country-by-country basis upon the expiration of the last to expire patent or patent application included in the licensed patents within the applicable country. We have the right to terminate the Harpoon License upon 30 days prior written notice to Harpoon, and either party may terminate for a material breach if such breach is not cured within a specified number of days.

Adimab 2018 License

In March 2018, we entered into a Development and Option Agreement (the "Adimab Agreement") with Adimab LLC ("Adimab"), a company specializing in antibody discovery, humanization and optimization. Under the terms of the Adimab

Agreement, Adimab granted us the rights to initiate certain research initiatives on a specified number of targets. Adimab also granted us a license to certain Adimab core technologies, antibodies and products applicable to certain targets ("Adimab License").

In August 2020, we entered into Amendment One to the Development and Option Agreement with Adimab, which extended the period of time for us to evaluate candidate antibodies in advance of electing to exercise the option to acquire exclusive rights to licensed antibodies (the "Evaluation Term"), but did not otherwise change the terms of the Adimab License. The Evaluation Term was then further extended in December 2020 by entering into Amendment Two to the Development and Option Agreement, through delivery of a non-refundable payment of $100,000 by us to Adimab, which was creditable toward the option fee. The non-refundable payment was recorded immediately as research and development expense in the consolidated statements of operations. In July 2021, we entered into the First Amended and Restated Development and Option Agreement with Adimab to extend the target selection time period and to allow for us to add additional antibody discovery programs to be covered under the agreement, but otherwise retaining all other material provisions of the Adimab License.

Under the terms of the Adimab License, we must pay both an upfront fee and final fee of $200,000 for all research programs. We must also pay Adimab milestone fees with respect to each research program ranging from $150,000 to $200,000 based on the achievement of technical milestones by Adimab for the applicable research program. In order to exercise any options in the Adimab Agreement, we must pay a $500,000 fee for each target option exercised.

For each target option exercised, we are also obligated to pay certain milestones ranging from $1.0 million to $4.0 million for certain clinical and commercialization achievements. Additionally, for licensed products sold during the applicable royalty term, we must pay Adimab royalties at percentages in the low-to-mid single digits.

The Adimab Agreement will expire upon the expiration of any options or if an option is exercised, on a country-by-country and licensed product-by-licensed product basis on the expiration of the last royalty term for a licensed product in the particular country. As of December 31, 2024, we have exercised the target option for one target covered under the Adimab Agreement. As of December 31, 2024, we have not made any payments for clinical or sales-based milestones or royalties pursuant to the Adimab Agreement.

Adimab 2022 Collaboration

In November 2022, we entered into a Collaboration Agreement (the "Adimab Collaboration Agreement") with Adimab. Under the terms of the Adimab Collaboration Agreement, Adimab has agreed to provide us with services to help discover, generate, optimize and/or engineer specified proteins. In addition, Adimab will provide us with a license to certain Adimab core technologies, patents and products applicable to certain targets ("Adimab Collaboration License"), separate from those provided in the 2018 Adimab Agreement.

Under the terms of the Adimab Collaboration Agreement, we must pay Adimab milestone fees with respect to each research program ranging from $500,000 to $1.5 million based on the achievement of certain clinical milestones by us. The Adimab Collaboration Agreement provides us with an option to obtain any development and commercialization licenses from Adimab used in products. To exercise an option, we must pay a $500,000 fee for each product option exercised.

For each product sold, we are also obligated to pay certain milestones ranging from $1.0 million to $2.0 million based on the achievement of the first commercial sale in certain countries. Additionally, for licensed products sold during the applicable royalty term, we must pay Adimab royalties at percentages in the low-to-mid single digits.

The Adimab Collaboration Agreement will expire upon the expiration of any options or if an option is exercised, on a country-by-country and licensed product-by-licensed product basis on the expiration of the last royalty term for a licensed product in the particular country. As of December 31, 2024, we have not exercised any options and have not made any payments for clinical or sales-based milestones or royalties pursuant to the Adimab Collaboration Agreement.

11. Income Taxes

During the years ended December 31, 2024 and 2023, we recorded no current or deferred income tax expenses or benefits as we have incurred losses since inception and have provided a full valuation allowance against our deferred tax assets.

A reconciliation of the expected income tax expense (benefit) computed using the federal statutory income tax rate to our effective income tax rate is as follows:

	Year Ended December 31,	
	2024	2023
Income tax computed at federal statutory rate	21.0 %	21.0 %
State taxes	6.5	9.4
Change in valuation allowance	(29.4)	(12.4)
R&D credit carryovers	3.7	4.5
Stock-based compensation	(2.4)	(3.0)
Permanent differences	0.5	(0.6)
Section 382 net operating loss adjustments	0.0	(20.2)
Other	0.1	1.3
Effective income tax rate	0.0 %	0.0 %

Our deferred tax assets and liabilities consist of the following:

	As of December 31,	
	2024	2023
	(in thousands)	
Deferred tax assets:		
Net operating losses	$ 32,781	$ 23,873
Tax credit carryforwards	6,141	3,168
Lease liability	3,069	3,645
Other capitalized costs—net of amortization	219	95
Reserves and accruals	983	1,295
Stock-based compensation	1,921	2,021
Capitalized research and experimental expenditures—net of amortization	25,214	16,162
Deferred tax assets	70,328	50,259
Valuation allowance	(67,756)	(47,058)
Deferred tax assets	2,572	3,201
Deferred tax liabilities:		
Right of use asset	(1,676)	(1,993)
Fixed assets and depreciation	(896)	(1,208)
Deferred tax liabilities	(2,572)	(3,201)
Net deferred taxes	$ —	$ —

The Tax Cuts and Jobs Act ("TCJA") requires taxpayers to capitalize and amortize research and experimental ("R&E") expenditures under Section 174 for tax years beginning after December 31, 2021. This rule became effective for us during 2022 and resulted in the capitalization of R&E expenditures of $50.2 million and $27.9 million during the years ended December 31, 2024 and 2023, respectively. We amortize these costs for tax purposes over 5 years for research and development ("R&D") performed in the U.S. and over 15 years for R&D performed outside the U.S.

We evaluated the positive and negative evidence bearing upon our ability to realize the deferred tax assets as of December 31, 2024 and 2023. We considered our cumulative net losses and concluded as of December 31, 2024 and 2023, that it was more likely than not that we would not realize the benefits of the deferred tax assets. Accordingly, a full valuation allowance was established against the net deferred tax assets as of December 31, 2024 and 2023. The valuation allowance increased by $20.7 million during the year ended December 31, 2024 primarily due to an increase in deferred tax assets related to capitalized R&E expenditures, and as the result of operating losses generated with no corresponding financial statement benefit. The valuation allowance increased by $4.6 million during the year ended December 31, 2023 primarily due to an increase in deferred tax assets related to capitalized R&E expenditures, and as the result of operating losses generated with no corresponding financial statement benefit. These increases were offset by a decrease in deferred tax assets as the result of our Section 382 study that was completed for the period of January 22, 2018, through December 31, 2022, which resulted in limitations being identified on historical net operating losses and research and development tax credits.

We have incurred net operating losses since inception. As of December 31, 2024 and 2023, we had federal net operating loss carryforwards of $126.8 million and $96.6 million, respectively, available to reduce future federal taxable income. The carryforwards generated from losses incurred prior to January 1, 2018 will expire in 2037. The carryforwards generated from losses incurred after December 31, 2017 do not expire. As of December 31, 2024, federal net operating loss carryforwards includes $126.7 million of carryforwards that do not expire. The TCJA enacted on December 22, 2017 limits a taxpayer's ability to utilize a net operating loss deduction in a year to 80% taxable income for federal net operating losses arising in tax years beginning after December 31, 2017. As of December 31, 2024 and 2023, we had state net operating loss carryforwards of $76.8 million and $44.9 million, respectively, available to reduce future state taxable income, which expire at various dates beginning in 2037.

As of December 31, 2024 and 2023, we had federal research and development tax credit carryforwards of $4.9 million and $2.3 million, respectively, available to reduce future federal tax liabilities, which expire at various dates beginning in 2042. We had state research and development tax credit carryforwards as of December 31, 2024 and 2023 of $1.3 million and $0.9 million, respectively, available to reduce future state tax liabilities, which expire at various dates beginning in 2037.

Utilization of our net operating loss carryforwards and research and development tax credit carryforwards may be subject to a substantial annual limitation under Section 382 of the Internal Revenue Code of 1986 due to ownership changes that have occurred previously or that could occur in the future. These ownership changes may limit the amount of carryforwards that can be utilized annually to offset future taxable income. In general, an ownership change, as defined by Section 382, results from transactions increasing the ownership of certain stockholders or public groups in the stock of a corporation by more than 50% over a three-year period.

We completed a Section 382 study for the period of January 22, 2018, through December 31, 2022 and identified three ownership changes that occurred on June 10, 2019, August 2, 2019, and August 31, 2022 for Section 382 purposes. As we experienced these ownership changes, all pre-change net operating loss and research and development tax credit carryforwards are subject to limitation. Due to the unlimited carryover period for net operating losses generated after December 31, 2017, none of our federal net operating losses will expire unused. A portion of our state net operating losses, and federal and state research and development tax credits are expected to expire unused. We have analyzed the impact of these limitations on our attributes and included the impact of these limitations in our deferred tax assets as of December 31, 2024 and 2023.

We have not recorded any reserves for uncertain tax positions as of December 31, 2024 and 2023. We have conducted a study of research and development tax credit for tax years 2018 through 2020. The amounts of federal and state research and development tax credit carryforwards presented above have reflected the results from the study. A full valuation allowance has been provided against our research and development credits.

We file tax returns as prescribed by the tax laws of the jurisdictions in which we operate. In the normal course of business, we are subject to examination by federal and state jurisdictions, where applicable. There are currently no pending tax examinations. The statute of limitations for assessment by the Internal Revenue Service, or IRS, and state tax authorities is closed for tax years prior to 2021, although carryforward attributes that were generated prior to 2021 may still be adjusted upon examination by the IRS or state tax authorities if they either have been or will be used in a future period.

12. Related Parties

In May 2022, we entered into a sublease agreement with Crossbow, for which entities affiliated with MPM Capital ("MPM Capital") are also beneficial owners, to sublease the entirety of our office and laboratory space in Cambridge, Massachusetts. Luke Evnin, Ph.D., the chair of our board of directors, co-founded MPM Capital and serves as Managing Director of MPM Capital. Briggs Morrison, who serves on our board of directors, serves as Executive Partner of MPM Capital and Chief Executive Officer of Crossbow. The term of the sublease agreement commenced in June 2022 and ended in March 2024, with no option to extend (see Note 10, *Commitments and Contingencies*). We received cash payments under our sublease of $0.4 million and $1.6 million during the years ended December 31, 2024 and 2023, respectively. In addition, we received $0.2 million from Crossbow in June 2022 as a security deposit, which was remitted to Crossbow following the termination of the sublease. The security deposit was included within accrued expenses and other current liabilities in the accompanying consolidated balance sheet as of December 31, 2023.

13. Defined Contribution Benefit Plan

We sponsor a defined contribution benefit plan under Section 401(k) of the Internal Revenue Code (the "401(k) Plan"). The 401(k) Plan covers all employees who meet defined minimum age and service requirements, and allows participants to contribute a portion of their annual compensation, subject to statutory limitations. We match 50% of each participant's contribution up to a maximum of 6% of such participant's eligible compensation paid in a calendar year. During the years ended December 31, 2024 and 2023, we recognized expense of $0.3 million and $0.2 million related to matching contributions, respectively.

14. Net Loss Attributable to Common Stockholders per Share

For purposes of the diluted net loss attributable to common stockholders per share calculation, outstanding stock options, unvested RSAs, unvested RSUs, the conversion option derivative under the K2HV Loan Agreement, and warrants to purchase common stock are considered to be potentially dilutive securities, however the following weighted-average amounts were excluded from the calculation of diluted net loss attributable to common stockholders per share because their effect would be anti-dilutive:

	December 31,	
	2024	2023
Outstanding stock options	7,634,937	5,700,070
Unvested RSUs	—	361,500
Warrants to purchase common stock	58,904	58,904
Common stock to be issued under the 2021 ESPP	67,445	22,611
Total	7,761,286	6,143,085

Basic net loss per share is computed by dividing net loss by the weighted-average number of shares of common stock outstanding during the applicable period. In computing diluted net loss per share, only potential shares of common stock equivalents that are dilutive are included. We considered each issue or series of issues of potential shares of common stock separately when determining whether potential shares of common stock equivalents are dilutive or anti-dilutive. We made such determination in sequence from the most dilutive to the least dilutive and concluded that the conversion option derivative under the K2HV Loan Agreement is dilutive to net loss per share for the year ended December 31, 2024. Pursuant to ASC Topic 260, *Earnings Per Share*, we applied the if-converted method to determine the effect of the conversion option derivative under the K2HV Loan Agreement on the diluted earnings per share calculations. Pursuant to such method, we adjusted the numerator for the gain recognized during the period in net loss due to the change in the fair value of the conversion option derivative liability under the K2HV Loan Agreement and the interest expense recognized during the period that is attributable to the portion of the term loan that is subject to the conversion option. We also increased the denominator to include the weighted-average number of additional shares of common stock that would have been outstanding if the conversion option derivative under the K2HV Loan Agreement were converted at the inception of the K2HV Loan Agreement. The following table summarizes the computations of basic and diluted net loss per share as presented in our consolidated statements of operations:

	Year Ended December 31,	
	2024	2023
	(in thousands, except share and per share amounts)	
Numerator		
Net loss	$ (70,515)	$ (37,368)
Less: change in fair value of derivative liability	(1,621)	—
Plus: interest expense on converted term loan	493	—
Adjusted net loss	$ (71,643)	$ (37,368)
Denominator		
Weighted-average common stock outstanding, basic	43,332,088	35,646,572
Dilutive effect of common stock issuable from assumed conversion of convertible term loan	527,576	—
Weighted-average common stock outstanding, diluted	43,859,664	35,646,572
Net loss per share		
Basic	$ (1.63)	$ (1.05)
Diluted	$ (1.63)	$ (1.05)

15. Segment Information

We have one reportable segment which focuses on the discovery and development of cancer therapeutics. The segment derives its revenues from the Collaboration Agreement with Jazz (see Note 3, *Jazz Collaboration and License Agreement*).

Our CODM manages our operations on an integrated basis for the purpose of allocating resources. When evaluating our financial performance, our CODM regularly reviews total expenses and expenses by function and makes decisions using this information based on the performance of the enterprise as a whole. Our CODM primarily evaluates the performance of the

enterprise based on results that have a direct impact on our available cash and cash equivalents and accordingly places less significance on non-cash expenses such as stock-based compensation and depreciation expenses in determining how to allocate resources.

Segment assets regularly reviewed by our CODM include measures of liquidity, primarily available cash and cash equivalents, and are consistent with the presentation of cash and cash equivalents reported in our consolidated balance sheets.

The following is a summary of our segment and consolidated net loss, including significant segment expenses:

	Year Ended December 31,	
	2024	2023
	(in thousands)	
Collaboration revenue	$ 1,885	$ 19,943
Less:		
Manufacturing	19,759	10,521
Clinical development	16,361	9,335
Research and discovery	14,389	16,673
General and administrative support	14,330	14,145
Other segment expenses[(a)]	10,640	9,772
Interest income	6,673	7,416
Interest expense	(4,656)	(3,139)
Loss on extinguishment of debt	(553)	—
Other income (expense), net	1,615	(1,142)
Segment and consolidated net loss	$ (70,515)	$ (37,368)

(a) Other segment expenses includes non-cash expenses for stock-based compensation and depreciation expenses.

EXHIBIT INDEX

Exhibit No.	Description of Exhibit
3.1	Restated Certificate of Incorporation of the Registrant (incorporated by reference to Exhibit 3.1 to the Registrant's Current Report on Form 8-K, filed with the Securities and Exchange Commission on May 5, 2021, File No. 001-40366).
3.2	Second Amended and Restated Bylaws of the Registrant (incorporated by reference to Exhibit 3.1 to the Registrant's Current Report on Form 8-K, filed with the Securities and Exchange Commission on June 27, 2023).
4.1	Specimen Stock Certificate evidencing the shares of common stock of the Registrant (incorporated by reference to Exhibit 4.1 to Amendment No. 1 to the Registrant's Registration Statement on Form S-1, filed with the Securities and Exchange Commission on April 26, 2021, File No. 333-255132).
4.2	Description of securities registered under Section 12 of the Securities Exchange Act of 1934, as amended (incorporated by reference to Exhibit 4.3 to the Registrant's Annual Report on Form 10-K, filed with the Securities and Exchange Commission on March 24, 2022).
4.3	Form of Common Stock Purchase Warrant (incorporated by reference to Exhibit 4.1 to the Registrant's Quarterly Report on Form 10-Q, filed with the Securities and Exchange Commission on August 8, 2024).
10.1	2017 Stock Incentive Plan (incorporated by reference to Exhibit 10.1 to Amendment No. 1 to the Registrant's Registration Statement on Form S-1, filed with the Securities and Exchange Commission on April 26, 2021, File No. 333-255132).
10.2	Form of Stock Option Agreement under 2017 Stock Incentive Plan (incorporated by reference to Exhibit 10.2 to Amendment No. 1 to the Registrant's Registration Statement on Form S-1, filed with the Securities and Exchange Commission on April 26, 2021, File No. 333-255132).
10.3	Form of Restricted Stock Agreement under 2017 Stock Incentive Plan (incorporated by reference to Exhibit 10.3 to Amendment No. 1 to the Registrant's Registration Statement on Form S-1, filed with the Securities and Exchange Commission on April 26, 2021, File No. 333-255132).
10.4	2021 Stock Incentive Plan (incorporated by reference to Exhibit 10.4 to Amendment No. 1 to the Registrant's Registration Statement on Form S-1, filed with the Securities and Exchange Commission on April 26, 2021, File No. 333-255132).
10.5	Form of Stock Option Agreement under 2021 Stock Incentive Plan (incorporated by reference to Exhibit 10.5 to Amendment No. 1 to the Registrant's Registration Statement on Form S-1, filed with the Securities and Exchange Commission on April 26, 2021, File No. 333-255132).
10.6	Form of Restricted Stock Agreement under 2021 Stock Incentive Plan (incorporated by reference to Exhibit 10.6 to Amendment No. 1 to the Registrant's Registration Statement on Form S-1, filed with the Securities and Exchange Commission on April 26, 2021, File No. 333-255132).
10.7	Form of Restricted Stock Unit Agreement under 2021 Stock Incentive Plan (incorporated by reference to Exhibit 10.7 to Amendment No. 1 to the Registrant's Registration Statement on Form S-1, filed with the Securities and Exchange Commission on April 26, 2021, File No. 333-255132).
10.8	2021 Employee Stock Purchase Plan (incorporated by reference to Exhibit 10.8 to Amendment No. 1 to the Registrant's Registration Statement on Form S-1, filed with the Securities and Exchange Commission on April 26, 2021, File No. 333-255132).
10.9	Form of Indemnification Agreement between the Registrant and each of its Executive Officers and Directors (incorporated by reference to Exhibit 10.10 to the Registrant's Registration Statement on Form S-1, filed with the Securities and Exchange Commission on April 8, 2021, File No. 333-255132).
10.10#	Second Amended and Restated Assignment and License Agreement dated as of December 20, 2019, by and between the Registrant and Harpoon Therapeutics, Inc (incorporated by reference to Exhibit 10.11 to the Registrant's Registration Statement on Form S-1, filed with the Securities and Exchange Commission on April 8, 2021, File No. 333-255132).
10.11	Amended and Restated Royalty Transfer Agreement dated as of August 2, 2019, by and among MPM Oncology Impact Fund Charitable Foundation, Inc. and UBS Optimus Foundation (incorporated by reference to Exhibit 10.12 to the Registrant's Registration Statement on Form S-1, filed with the Securities and Exchange Commission on April 8, 2021, File No. 333-255132).
10.12	Lease Agreement dated as of June 1, 2021, by and between the Registrant and ARE-MA Region No. 75, LLC. (incorporated by reference to Exhibit 10.1 to the Registrant's Current Report on Form 8-K, filed with the Securities and Exchange Commission on June 2, 2021, File No. 001-40366).
10.13+	Employment Agreement dated as of April 23, 2021, by and between the Registrant and Daniel J. Hicklin, Ph.D. (incorporated by reference to Exhibit 10.15 to Amendment No. 1 to the Registrant's Registration Statement on Form S-1, filed with the Securities and Exchange Commission on April 26, 2021, File No. 333-255132).

10.14+	Employment Agreement dated as of April 23, 2021, by and between the Registrant and Randi Isaacs M.D. (incorporated by reference to Exhibit 10.16 to Amendment No. 1 to the Registrant's Registration Statement on Form S-1, filed with the Securities and Exchange Commission on April 26, 2021, File No. 333-255132).
10.15+	Employment Agreement dated as of April 23, 2021, by and between the Registrant and Ellen Lubman, M.B.A. (incorporated by reference to Exhibit 10.19 to Amendment No. 1 to the Registrant's Registration Statement on Form S-1, filed with the Securities and Exchange Commission on April 26, 2021, File No. 333-255132).
10.16+	Employment Agreement dated as of April 23, 2021, by and between the Registrant and Timothy W. Trost (incorporated by reference to Exhibit 10.20 to Amendment No. 1 to the Registrant's Registration Statement on Form S-1, filed with the Securities and Exchange Commission on April 26, 2021, File No. 333-255132).
10.17+	Employment Agreement dated as of April 30, 2021 by and between the Registrant and Chulani Karunatilake (incorporated by reference to Exhibit 10.1 to the Registrant's Quarterly Report on Form 10-Q, filed with the Securities and Exchange Commission on November 10, 2021, File No. 001-40366).
10.18#	Collaboration and License Agreement, dated as of April 6, 2022, by and between the Registrant and Jazz Pharmaceuticals Ireland Limited (incorporated by reference to Exhibit 10.1 to the Registrant's Quarterly Report on Form 10-Q, filed with the Securities and Exchange Commission on May 10, 2022).
10.19	Form of Restricted Stock Unit Agreement under 2021 Stock Incentive Plan (incorporated by reference to Exhibit 10.22 to the Registrant's Annual Report on Form 10-K filed with the Securities and Exchange Commission on March 7, 2024).
10.20	Loan and Security Agreement, dated as of May 2, 2024, by and among the Registrant, each other person party thereto as a borrower from time to time, each person party thereto as a guarantor from time to time, the lenders from time to time party thereto, K2 HealthVentures LLC, as administrative agent for the lenders, and Ankura Trust Company LLC, as administrative agent (incorporated by reference to Exhibit 10.1 to the Registrant's Quarterly Report on Form 10-Q, filed with the Securities and Exchange Commission on August 8, 2024).
10.21*	First Amendment to Lease dated as of December 31, 2024 by and between the Registrant and ARE-MA Region No. 75, LLC.
10.22*	Non-Employee Director Compensation Policy.
19*	Insider Trading Policy
21.1	Subsidiaries of the Registrant (incorporated by reference to Exhibit 21.1 to Amendment No. 1 to the Registrant's Registration Statement on Form S-1, filed with the Securities and Exchange Commission on April 26, 2021, Registration No. 333-255132).
23.1*	Consent of Ernst & Young LLP, Independent Registered Accounting Firm.
31.1*	Certification of Principal Executive Officer Pursuant to Rules 13a-14(a) and 15d-14(a) under the Securities Exchange Act of 1934, as Adopted Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
31.2*	Certification of Principal Financial Officer Pursuant to Rules 13a-14(a) and 15d-14(a) under the Securities Exchange Act of 1934, as Adopted Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
32.1†	Certifications of Principal Executive Officer and Principal Financial Officer Pursuant to 18 U.S.C. Section 1350, as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
97	Dodd-Frank Compensation Recovery Policy (incorporated by reference to Exhibit 97 to the Registrant's Annual Report on Form 10-K, filed with the Securities and Exchange Commission on March 7, 2024).
101.INS*	Inline XBRL Instance Document – the instance document does not appear in the Interactive Data File because XBRL tags are embedded within the Inline XBRL document.
101.SCH*	Inline XBRL Taxonomy Extension Schema Document
101.CAL*	Inline XBRL Taxonomy Extension Calculation Linkbase Document
101.DEF*	Inline XBRL Taxonomy Extension Definition Linkbase Document
101.LAB*	Inline XBRL Taxonomy Extension Label Linkbase Document
101.PRE*	Inline XBRL Taxonomy Extension Presentation Linkbase Document
104*	Cover Page Interactive Data File (formatted as Inline XBRL with applicable taxonomy extension information contained in Exhibits 101)

*	Filed herewith.
†	The certifications attached as Exhibit 32.1 that accompany this Annual Report, are deemed furnished and not filed with the Securities and Exchange Commission and are not to be incorporated by reference into any filing of Werewolf Therapeutics, 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, irrespective of any general incorporation language contained in such filing.
+	Indicates management contract.
#	Portions of this exhibit have been omitted pursuant to Item 601(b)(10)(iv) of Regulation S-K because such information is not material and is the type of information that the registrant treats as private or confidential.

SIGNATURES

Pursuant to the requirements of Section 13 or 15(d) 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.

WEREWOLF THERAPEUTICS, INC.

Date: March 11, 2025

By: /s/ Daniel J. Hicklin
Daniel J. Hicklin, Ph.D.
President and Chief Executive Officer

SIGNATURES

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.

SIGNATURE	TITLE	DATE
/s/ Daniel J. Hicklin Daniel J. Hicklin, Ph.D.	President, Chief Executive Officer and Director (Principal Executive Officer)	March 11, 2025
/s/ Timothy W. Trost Timothy W. Trost	Chief Financial Officer and Treasurer (Principal Financial and Accounting Officer)	March 11, 2025
/s/ Luke Evnin Luke Evnin, Ph.D.	Chair of the Board of Directors	March 11, 2025
/s/ Michael B. Atkins Michael B. Atkins, M.D.	Director	March 11, 2025
/s/ Meeta Chatterjee Meeta Chatterjee, Ph.D.	Director	March 11, 2025
/s/ Derek DiRocco Derek DiRocco, Ph.D.	Director	March 11, 2025
/s/ Alon Lazarus Alon Lazarus, Ph.D.	Director	March 11, 2025
/s/ Briggs W. Morrison Briggs W. Morrison, M.D.	Director	March 11, 2025
/s/ Michael A. Sherman Michael A. Sherman, M.B.A.	Director	March 11, 2025
/s/ Anil K. Singhal Anil K. Singhal	Director	March 11, 2025

FIRST AMENDMENT TO LEASE

THIS FIRST AMENDMENT TO LEASE (this "**First Amendment**") is made as of December 31, 2024, by and between **ARE-MA REGION NO. 75, LLC**, a Delaware limited liability company ("**Landlord**"), and **WEREWOLF THERAPEUTICS, INC.,** a Delaware corporation ("**Tenant**").

RECITALS

WHEREAS, Landlord and Tenant are parties to that certain Lease Agreement dated as of June 1, 2021, as affected by that certain letter agreement dated as of November 14, 2022 (as affected, collectively, the "**Lease**"). Pursuant to the Lease, Tenant leases certain premises containing approximately 25,778 rentable square feet (the "**Premises**"), in the building commonly known as "Building 37" located at 200 Talcott Avenue, Watertown, Massachusetts (the "**Building**"), within the complex commonly known as The Arsenal on the Charles, as more particularly described in the Lease. Capitalized terms used herein without definition shall have the meanings defined for such terms in the Lease.

WHEREAS, Landlord and Tenant mutually desire that the Lease be amended on and subject to the terms and conditions contained herein.

AGREEMENT

NOW, THEREFORE, in consideration of the foregoing Recitals, which are incorporated herein by this reference, the mutual promises and conditions contained herein, and for other good and valuable consideration, the receipt and sufficiency of which are hereby acknowledged, Landlord and Tenant hereby agree as follows:

1. **Amendment to Rentable Area of Project and Building's Share of Project**. In connection with new buildings at the Project becoming operational at various points during 2024, Landlord has caused the Project to be re-measured in accordance with Section 5 of the Lease. Notwithstanding anything to the contrary contained in the Lease, and without derogating from Landlord's right to remeasure the Project from time to time as provided in the Lease (and to make corresponding updates to the Rentable Area of Building, the Rentable Area of Project, the Building's Share of Project, and the Tenant's Share of Operating Expenses resulting therefrom, as applicable), the parties acknowledge and agree that the "**Rentable Area of Project**" shall be (x) 980,119 square feet for the period commencing on February 1, 2024 and ending on June 30, 2024, (y) 1,006,979 square feet for the period commencing on July 1, 2024 and ending on August 31, 2024, and (z) 1,134,543 square feet for the period from and after September 1, 2024. Accordingly, the "**Building's Share of Project**" shall be (i) 5.17% for the period commencing on February 1, 2024 and ending on June 30, 2024, (ii) 5.03% for the period commencing on July 1, 2024 and ending on August 31, 2024, and (iii) 4.47% for the period from and after September 1, 2024.

2. **OFAC**. Tenant and all beneficial owners of Tenant are currently (a) in compliance with and shall at all times during the Term of the Lease remain in compliance with the regulations of the Office of Foreign Assets Control ("**OFAC**") of the U.S. Department of Treasury and any statute, executive order, or regulation relating thereto (collectively, the "**OFAC Rules**"), (b) not listed on, and shall not during the term of the Lease be listed on, the Specially Designated Nationals and Blocked Persons List, Foreign Sanctions Evaders List, or the Sectoral Sanctions Identification List, which are all maintained by OFAC and/or on any other similar list maintained by OFAC or other governmental authority pursuant to any authorizing statute, executive order, or regulation, and (c) not a person or entity with whom a U.S. person is prohibited from conducting business under the OFAC Rules.

3. **Brokers**. Landlord and Tenant each represents and warrants that it has not dealt with any broker, agent or other person (collectively, "**Broker**") in connection with the transaction reflected in this First Amendment and that no Broker brought about this transaction. Landlord and Tenant each hereby agrees to indemnify and hold the other harmless from and against any claims by any Broker claiming a commission or other form of compensation by virtue of having dealt with Tenant or Landlord, as applicable, with regard to this First Amendment.

4. **Miscellaneous**.

a. This First Amendment is the entire agreement between the parties with respect to the subject matter hereof and supersedes all prior and contemporaneous oral and written agreements and discussions. This First Amendment may be amended only by an agreement in writing, signed by the parties hereto.

b. This First Amendment is binding upon and shall inure to the benefit of the parties hereto, and their respective successors and assigns.

c. This First Amendment may be executed in 2 or more counterparts, each of which shall be deemed an original, but all of which together shall constitute one and the same instrument. Counterparts may be delivered via electronic mail (including pdf or any electronic signature process complying with the U.S. federal ESIGN Act of 2000) or other transmission method and any counterpart so delivered shall be deemed to have been duly and validly delivered and be valid and effective for all purposes. Electronic signatures shall be deemed original signatures for purposes of this First Amendment and all matters related thereto, with such electronic signatures having the same legal effect as original signatures.

d. Except as amended and/or modified by this First Amendment, the Lease is hereby ratified and confirmed and all other terms of the Lease shall remain in full force and effect, unaltered and unchanged by this First Amendment. In the event of any conflict between the provisions of this First Amendment and the provisions of the Lease, the provisions of this First Amendment shall prevail. Whether or not specifically amended by this First Amendment, all of the terms and provisions of the Lease are hereby amended to the extent necessary to give effect to the purpose and intent of this First Amendment.

[Signatures are on the next page]

IN WITNESS WHEREOF, the parties hereto have executed this First Amendment as of the day and year first above written.

TENANT:

WEREWOLF THERAPEUTICS, INC.,
a Delaware corporation

By: /s/ Michael Urban
Name: Michael Urban
Title: Controller, VP of Finance

X□ I hereby certify that the signature, name, and title above are my signature, name, and title.

LANDLORD:

ARE-MA REGION NO. 75, LLC,
a Delaware limited liability company

By: Alexandria Real Estate Equities, L.P., a Delaware limited partnership, managing member

By: ARE-QRS Corp.,
a Maryland corporation, general partner

By: /s/ Scott Sherwood
Name: Scott Sherwood
Title: VP – Real Estate Legal Affairs

Exhibit 10.22

WEREWOLF THERAPEUTICS, INC.
DIRECTOR COMPENSATION POLICY

The non-employee directors of Werewolf Therapeutics, Inc. (the "Company") shall receive the following compensation for their service as members of the Board of Directors (the "Board") of the Company.

1. Initial Stock Option Grant. Upon initial election to the Board, each non-employee director will be granted, automatically and without the need for any further action by the Board, a stock option under the Company's 2021 Stock Incentive Plan (the "2021 Plan") to purchase 45,000 shares of the Company's common stock, par value $0.0001 per share (the "Common Stock"). Subject to the non-employee director's continued service as a director, the stock option will vest with respect to 1/3 of the total number of shares on the first anniversary of the grant date and thereafter in equal monthly installments until the third anniversary of the grant date and, in the event of a change in control of the Company, the vesting schedule of the stock option will accelerate in full. The exercise price of the stock option will be equal to the fair market value of the Common Stock on the date of grant.

2. Annual Stock Option Grant. Each non-employee director serving on the Board will be granted, automatically and without the need for any further action by the Board, a stock option under the 2021 Plan to purchase 22,500 shares of Common Stock on the date of each annual meeting of stockholders; provided that, if any such director is initially elected to the Board in the twelve months immediately preceding the annual meeting of stockholders, the number of shares of Common Stock subject to such stock option shall be pro-rated on a monthly basis for time in service (including partial months). Unless otherwise provided at the time of grant, subject to the non- employee director's continued service as a director, the stock option will vest in full on the first anniversary of the grant date (or, if earlier, the date of the next annual meeting of stockholders following the date of grant) and, in the event of a change in control of the Company, the vesting schedule of the stock option will accelerate in full. The exercise price of the stock option will be equal to the fair market value of the Common Stock on the date of grant.

3. Annual Fee; Reimbursement of Travel and Other Expenses. Each non-employee director will receive an annual fee relating to such director's service on the Board and any committees thereof as follows:

	Chair	**Other Member**
Board	$70,000	$40,000
Audit Committee	$15,000	$7,500
Compensation Committee	$10,000	$5,000
Nominating and Corporate Governance Committee	$8,000	$4,000

Each annual fee shall be payable in arrears in four equal quarterly installments on the last day of each quarter, provided that the amount of such payment shall be prorated

for any portion of such quarter that the director was not serving on the Board or the applicable committee of the Board. Each non-employee director will also be reimbursed for reasonable travel and other expenses in connection with attending meetings of the Board and any committee on which he or she serves.

Exhibit 19

WEREWOLF THERAPEUTICS, INC.

Insider Trading Policy

1. BACKGROUND AND PURPOSE

1.1 Why Have We Adopted This Policy?

The federal securities laws prohibit any member of the Board of Directors (a "Director"), officer (as defined in Rule 16a-1(f) under the Securities Exchange Act of 1934 (the "Exchange Act"), an "executive officer") or employee of Werewolf Therapeutics, Inc. (together with its subsidiaries, the "Company"), as well as agents of the Company owing duties of confidentiality to the Company, from purchasing or selling Company securities on the basis of material nonpublic information concerning the Company, or from tipping material nonpublic information to others. These laws impose severe sanctions on individuals who violate them. In addition, the
U.S. Securities and Exchange Commission (the "SEC") has the authority to impose large fines on the Company and on the Company's Directors, executive officers and controlling stockholders if the Company's employees or agents engage in insider trading and the Company has failed to take appropriate steps to prevent it (so-called "controlling person" liability).

This insider trading policy is being adopted in light of these legal requirements, and with the goal of helping:

- prevent inadvertent violations of the insider trading laws;
- avoid embarrassing proxy disclosure of reporting violations by persons subject to Section 16 of the Exchange Act;
- promote compliance with the Company's obligation to publicly disclose information related to its insider trading policies and procedures and the use of certain trading arrangements by Company insiders;
- avoid even the appearance of impropriety on the part of those employed by, or associated with, the Company;
- protect the Company from controlling person liability; and
- protect the reputation of the Company, its Directors, its employees and its agents.

As detailed below, this policy applies to family members and certain other persons and entities with whom Directors, employees and agents have relationships. While the provisions in Sections 2 and 3 of this policy are not applicable to transactions by the Company itself, transactions by the Company will only be made in accordance with applicable U.S. federal securities laws, including those relating to insider trading.

1.2 What Type of Information is "Material"?

Information concerning the Company is considered material if there is a substantial likelihood that a reasonable stockholder would consider the information important in making an investment decision with respect to the Company's securities. Stated another way, there must be a substantial likelihood that a reasonable stockholder would view the information as having significantly altered the "total mix" of information available about the Company. Material information can include positive or negative information about the Company. Information concerning any of the following subjects, or the Company's plans with respect to any of these subjects, would often be considered material:

- the Company's liquidity, cash burn rate, revenues, earnings or losses (including forecasts);
- a significant merger or acquisition involving the Company;
- a significant licensing or collaboration agreement, or serious discussions regarding such an agreement;
- a change in control of the Company;
- a significant change in management or the Board of Directors;
- information concerning upcoming U.S. Food and Drug Administration actions or other significant regulatory developments, including significant new clinical trial results or a significant product recall;
- information concerning the Company's ongoing and planned clinical trials and preclinical studies, including the timing of and findings and data from such trials and studies;
- the public or private sale of a significant amount of securities of the Company;
- the Company's decision to commence or terminate the payment of cash dividends;
- the establishment of a program to repurchase securities of the Company;
- a stock split;
- a default on outstanding debt of the Company or a bankruptcy filing;
- a new product release or a significant development, invention or discovery;
- the loss, delay or gain of a significant contract, sale or order or other important development regarding customers, collaborators or suppliers;

- a significant operational issue or investigation of a potential such issue, including cybersecurity incidents and product defects;
- any litigation, dispute or government investigation to which the Company may be a party;
- a conclusion by the Company or a notification from its independent auditor that any of the Company's previously issued financial statements should no longer be relied upon; or
- a change in or disagreement (within the meaning of Item 304 of Regulation S-K) with the Company's independent auditor.

This list is illustrative only and is not intended to provide a comprehensive list of circumstances that could give rise to material information.

1.3 When is Information "Nonpublic"?

Information concerning the Company is considered nonpublic if it has not been disseminated in a manner making it available to investors generally.

Information will generally be considered nonpublic unless (1) the information has been disclosed in a press release, in a public filing made with the SEC (such as a Report on Form 10- K, Form 10-Q or Form 8-K), or through a news wire service or daily newspaper of wide circulation, and (2) a sufficient amount of time has passed so that the information has had an opportunity to be digested by the marketplace.

2. PROHIBITIONS RELATING TO TRANSACTIONS IN THE COMPANY'S SECURITIES

2.1 Covered Persons. This Section 2 applies to the following individuals and entities (collectively, "Covered Persons"):

- all Directors;
- all employees;
- such other agents of the Company as are designated from time to time by the Board of Directors or the Chief Executive Officer as being subject to this Section 2 (the "Designated Agents");
- all family members of Directors, employees or Designated Agents who share the same address as, or are financially dependent on, the Director, employee or Designated Agent and any other person who shares the same address as the Director, employee or Designated Agent (other than (x) an employee or tenant of the Director, employee or Designated Agent or (y) another unrelated person whom the Chief Executive Officer determines should not be covered by this policy); and

- all corporations, limited liability companies, partnerships, trusts or other entities controlled by any of the above Covered Persons, unless the entity has implemented policies or procedures designed to ensure that such Covered Person cannot influence transactions by the entity involving Company securities.

2.2 Prohibition on Trading While Aware of Material Nonpublic Information.

(a) Prohibited Activities. Except as provided in Section 2.2(b), no Covered

Person may:

- purchase, sell or donate any securities of the Company while such Covered Person is aware of any material nonpublic information concerning the Company or recommend to another person that they do so; or

- tip or otherwise disclose to any other person any material nonpublic information concerning the Company if the recipient may use that information to purchase, sell or donate Company securities or tip that information to others.

In addition, no Covered Person who, in the course of service to the Company, learns of material nonpublic information about another company (1) with which the Company does business, such as the Company's distributors, vendors, customers and suppliers, or (2) that is involved in a potential transaction or business relationship with Company, may purchase, sell or donate that other company's securities until the information becomes public or is no longer material, or tip or otherwise disclose to someone else such information if the recipient may use that information to purchase, sell or donate that other company's securities or tip that information to others.

(b) Exceptions. The prohibitions in Sections 2.2(a) and 2.3 on purchases, sales and donations of Company securities do not apply to:

- exercises of stock options or other equity awards or the surrender of shares to the Company in payment of the exercise price or in satisfaction of any tax withholding obligations, in each case in a manner permitted by the applicable equity award agreement; provided, however, that the securities so acquired may not be sold (either outright or in connection with a "cashless" exercise transaction through a broker) while the Covered Person is aware of material nonpublic information or during an applicable blackout period (as defined in Section 2.3(b));

- acquisitions or dispositions of Company common stock under the Company's 401(k) or other individual account plan that are made pursuant to standing instructions, in a form approved by the Company, not entered into or modified while the Covered Person is aware of material nonpublic information or during an applicable blackout period;

- other purchases of securities from the Company (including purchases under the Company's employee stock purchase plan pursuant to standing instructions, in a form approved by the Company) or sales of securities to the Company; provided, however, that if the transaction involves the exercise of stock options or other equity awards, the transaction must be permitted by the first bullet above;

- purchases, sales or donations made pursuant to a binding contract, written plan or specific instruction which satisfies the applicable affirmative defense conditions of Rule 10b5-1(c), including as applicable the requirements applicable to an eligible sell-to-cover transaction as defined in Rule 10b5-1(c)(1)(ii)(D)(3) (a "trading plan"); provided such trading plan: (1) is in writing and (2) was submitted to the Company for review prior to its adoption; and

- purchases, sales or donations made pursuant to a binding contract, written plan or specific instruction which satisfies the definition of a "non-Rule 10b5-1 trading arrangement" as such term is defined in Item 408(c) of Regulation S-K, provided such non-Rule 10b5-1 trading arrangement: (1) is in writing and (2) was submitted to the Company for review prior to its adoption.

(c) Application of Policy After Cessation of Service. If a person or entity ceases to be a Covered Person, at a time when such person or entity is aware of material nonpublic information concerning the Company, the prohibition on purchases, sales or donations of Company securities in Section 2.2(a) shall continue to apply until that information has become public or is no longer material.

2.3 Blackout Periods.

(a) Regular Blackout Periods. Except as provided in Section 2.2(b), no Covered Person may purchase, sell or donate any securities of the Company during the period beginning on the first calendar day following the most recently ended fiscal quarter and ending upon the completion of the second full trading day after the public announcement of earnings for such quarter (a "regular blackout period").

(b) Corporate News Blackout Periods. The Company may from time to time notify Directors, executive officers and other specified employees and Designated Agents that an additional blackout period (a "corporate news blackout period") is in effect in view of significant events or developments involving the Company. In such event, except as provided in Section 2.2(b), no such individual may purchase, sell or donate any securities of the Company during such corporate news blackout period or inform anyone else that a corporate news blackout period is in effect. (In this policy, regular blackout periods and corporate news blackout periods are each referred to as a "blackout period.")

(c) Awareness of Material Non-Public Information when a Blackout Period is Not in Effect. Even if no blackout period is then in effect, if a Covered Person is aware of material nonpublic information the prohibitions contained in Section 2.2(a) apply.

2.4 Prohibition on Pledges. No Covered Person may purchase Company securities on margin, borrow against Company securities held in a margin account, or pledge Company securities as collateral for a loan. However, an exception may be granted in extraordinary situations where a Covered Person wishes to pledge Company securities as collateral for a loan (other than a margin loan) and clearly demonstrates the financial capacity to repay the loan without resort to the pledged securities. Any Covered Person who wishes to pledge Company securities as collateral for a loan must submit a request for approval to the General Counsel, the Chief Executive Officer or the Chief Financial Officer. In addition, any such request by a director or executive officer must also be reviewed and approved by the Audit Committee.

2.5 Prohibition on Short Sales, Derivative Transactions and Hedging Transactions. No Covered Person may engage in any of the following types of transactions with respect to Company securities:

- short sales, including short sales "against the box"; or
- purchases or sales of puts, calls or other derivative securities; or
- purchases of financial instruments (including prepaid variable forward contracts, equity swaps, collars and exchange funds) or other transactions that hedge or offset, or are designed to hedge or offset, any decrease in the market value of Company securities.

2.6 Partnership Distributions. Nothing in this policy is intended to limit the ability of a venture capital partnership or other similar entity with which a Director is affiliated to distribute Company securities to its partners, members or other similar persons. It is the responsibility of each affected Director and the affiliated entity, in consultation with their own counsel (as appropriate), to determine the timing of any distributions, based on all relevant facts and circumstances and applicable securities laws.

2.7 Underwritten Public Offering. Nothing in this policy is intended to limit the ability of any Covered Person to sell Company securities as a selling stockholder in an underwritten public offering pursuant to an effective registration statement in accordance with applicable securities law.

3. ADDITIONAL PROHIBITIONS APPLICABLE TO DIRECTORS, EXECUTIVE OFFICERS AND DESIGNATED EMPLOYEES

3.1 Pre-Clearance Persons. This Section 3 applies to the following Covered Persons, who are subject to certain additional restrictions as set forth herein (collectively, "Pre-Clearance Persons"):

- all Directors;

- all executive officers;
- such other employees as are designated from time to time by the Board of Directors or the Chief Executive Officer as being subject to this Section 3 (the "Designated Employees");
- all family members of Directors, executive officers and Designated Employees who share the same address as, or are financially dependent on, the Director, executive officer or Designated Employee and any other person who shares the same address as the Director, executive officer or Designated Employee (other than (x) an employee or tenant of the Director, executive officer or Designated Employee or (y) another unrelated person whom the Chief Executive Officer determines should not be covered by this policy); and
- all corporations, limited liability companies, partnerships, trusts or other entities controlled by any of the above Pre-Clearance Persons, unless the entity has implemented policies or procedures designed to ensure that such person cannot influence transactions by the entity involving Company securities.

3.2 Notice and Pre-Clearance of Transactions.

(a) Pre-Transaction Clearance. No Pre-Clearance Person may purchase, sell, donate, transfer, or otherwise acquire or dispose of securities of the Company, either directly or indirectly, other than in a transaction permitted under Section 2.2(b), without first obtaining written pre-clearance of the transaction from the General Counsel, the Chief Executive Officer or Chief Financial Officer. A request for pre-clearance may be oral or in writing (including by e- mail), should be made at least two business days in advance of the proposed transaction and should include the identity of the Pre-Clearance Person, the type of proposed transaction (for example, an open market purchase, a privately negotiated sale, an option exercise, etc.), the proposed date of the transaction and the number of shares or options to be involved. In addition, the Pre-Clearance Person must execute a certification (in the form approved by the General Counsel, Chief Executive Officer or Chief Financial Officer) that he, she or it is not aware of material nonpublic information about the Company. The General Counsel, Chief Executive Officer and Chief Financial Officer shall have sole discretion to decide whether to clear any contemplated transaction. (The Chief Executive Officer and General Counsel shall have sole discretion to decide whether to clear transactions by the Chief Financial Officer or Pre-Clearance Persons subject to this policy as a result of their relationship with the Chief Financial Officer; the Chief Financial Officer and General Counsel shall have sole discretion to decide whether to clear transactions by the Chief Executive Officer or Pre-Clearance Persons subject to this policy as a result of their relationship with the Chief Executive Officer; and the Chief Executive Officer and Chief Financial Officer shall have sole discretion to decide whether to clear transactions by the General Counsel or Pre-Clearance Persons subject to this policy as a result of their relationship with the General Counsel.) All transactions that are pre-cleared must be effected within three business days of receipt of the pre-clearance unless a longer or shorter period has been specified by the General Counsel, Chief Executive Officer or Chief Financial Officer. A pre-cleared transaction (or any portion of a pre-cleared transaction) that has not been effected during the three business day period must be pre-cleared again prior to execution. **Notwithstanding**

receipt of pre-clearance, if the Pre-Clearance Person becomes aware of material non-public information or becomes subject to a blackout period before the transaction is effected, the transaction may not be completed.

(b) Post-Transaction Notice. Each Pre-Clearance Person who is subject to reporting obligations under Section 16 of the Exchange Act shall also notify the General Counsel, Chief Executive Officer or Chief Financial Officer (or his or her designee) of the occurrence of any purchase, sale, donation, transfer, or other acquisition or disposition of securities of the Company as soon as possible following the transaction, but in any event within one business day after the transaction. Such notification may be oral or in writing (including by e-mail) and should include the identity of the Pre-Clearance Person, the type of transaction, the date of the transaction, the number of shares involved, the purchase or sale price, and whether the transaction was effected pursuant to a contract, instruction or written plan that is intended either to satisfy the affirmative defense conditions of Rule 10b5-1(c) (and if so, the date of adoption of such contract, instruction or written plan) or to constitute a non-Rule 10b5-1 trading arrangement (as defined in Item 408(c) of Regulation S-K).

(c) Deemed Time of a Transaction. For purposes of this Section 3.2, a purchase, sale, donation, transfer, or other acquisition or disposition shall be deemed to occur at the time the person becomes irrevocably committed to it (for example, in the case of an open market purchase or sale, this occurs when the trade is executed, not when it settles).

4. REGULATION BTR

If the Company is required to impose a "pension fund blackout period" under Regulation BTR, each Director and executive officer shall not, directly or indirectly sell,
purchase or otherwise transfer during such blackout period any equity securities of the Company acquired in connection with his or her service as a director or officer of the Company, except as permitted by Regulation BTR.

5. PENALTIES FOR VIOLATION

Violation of any of the foregoing rules is grounds for disciplinary action by the Company, including termination of employment or other service. In addition to any disciplinary actions the Company may take, insider trading can also result in administrative, civil or criminal proceedings which can result in significant fines and civil penalties, being barred from service as an officer or director of a public company, or imprisonment.

6. COMPANY ASSISTANCE AND EDUCATION

6.1 Education. The Company shall take reasonable steps designed to ensure that all Directors and employees of the Company and all Designated Agents are educated about, and periodically reminded of, the federal securities law restrictions and Company policies regarding insider trading.

6.2 Assistance. The Company shall provide reasonable assistance to all Directors and executive officers, as requested by such Directors and executive officers, in connection with the

filing of Forms 3, 4 and 5 under Section 16 of the Exchange Act. However, the ultimate responsibility, and liability, for timely filing remains with the Directors and executive officers.

6.3 Limitation on Liability. None of the Company, General Counsel, Chief Executive Officer, Chief Financial Officer or the Company's other employees will have any liability for any delay in reviewing, or refusal of, a trading plan submitted pursuant to Section 2.2(b), a request for pre-clearance submitted pursuant to Section 3.2(a) or a request to allow a pledge submitted pursuant to Section 2.4. Notwithstanding any review of a trading plan pursuant to Section 2.2(b) or pre-clearance of a transaction pursuant to Section 3.2(a), none of the Company, General Counsel, Chief Executive Officer or Chief Financial Officer or the Company's other employees assumes any liability for the legality or consequences of such trading plan or transaction to the person engaging in or adopting such trading plan or transaction.

Adopted: February 19, 2025

Exhibit 23.1

Consent of Independent Registered Public Accounting Firm

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

(1) Registration Statement (Form S-3 No. 333-264844) of Werewolf Therapeutics, Inc.,

(2) Registration Statement (Form S-8 No. 333-270764) pertaining to the 2021 Stock Incentive Plan and the 2021 Employee Stock Purchase Plan of Werewolf Therapeutics, Inc., as amended by Post-Effective Amendment No. 1 on Form S-8 filed on August 8, 2024,

(3) Registration Statement (Form S-8 No. 333-277727) pertaining to the 2021 Stock Incentive Plan of Werewolf Therapeutics, Inc.,

(4) Registration Statement (Form S-8 No. 333-263806) pertaining to the 2021 Stock Incentive Plan of Werewolf Therapeutics, Inc., and

(5) Registration Statement (Form S-8 No. 333-255636) pertaining to the 2017 Stock Incentive Plan, the 2021 Stock Incentive Plan, and the 2021 Employee Stock Purchase Plan of Werewolf Therapeutics, Inc.,

of our report dated March 11, 2025, with respect to the consolidated financial statements of Werewolf Therapeutics, Inc. included in this Annual Report (Form 10-K) of Werewolf Therapeutics, Inc. for the year ended December 31, 2024.

/s/ Ernst & Young LLP

Boston, Massachusetts
March 11, 2025

Exhibit 31.1

CERTIFICATION PURSUANT TO
RULES 13a-14(a) AND 15d-14(a) UNDER THE SECURITIES EXCHANGE ACT OF 1934,
AS ADOPTED PURSUANT TO SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002

I, Daniel J. Hicklin, Ph.D., certify that:

1. I have reviewed this Annual Report on Form 10-K of Werewolf Therapeutics, Inc.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

   (a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

   (b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

   (c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

   (d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

   (a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

   (b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: March 11, 2025

By: /s/ Daniel J. Hicklin
Daniel J. Hicklin, Ph.D.
President and Chief Executive Officer
(Principal Executive Officer)

Exhibit 31.2

CERTIFICATION PURSUANT TO
RULES 13a-14(a) AND 15d-14(a) UNDER THE SECURITIES EXCHANGE ACT OF 1934,
AS ADOPTED PURSUANT TO SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002

I, Timothy W. Trost, certify that:

1. I have reviewed this Annual Report on Form 10-K of Werewolf Therapeutics, Inc.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

   (a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

   (b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

   (c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

   (d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

   (a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

   (b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: March 11, 2025

By: /s/ Timothy W. Trost
Timothy W. Trost
Chief Financial Officer and Treasurer
(Principal Financial and Accounting Officer)

Exhibit 32.1

CERTIFICATION PURSUANT TO
18 U.S.C. SECTION 1350, AS ADOPTED PURSUANT TO
SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

In connection with the Annual Report on Form 10-K of Werewolf Therapeutics, Inc. (the "Company") for the period ended December 31, 2024 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), each of the undersigned officers of the Company hereby certifies, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that to his knowledge:

(1) The Report fully complies with the requirements of Section 13(a) or Section 15(d) of the Securities Exchange Act of 1934, as amended; and

(2) The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Date: March 11, 2025 By: /s/ Daniel J. Hicklin

Daniel J. Hicklin, Ph.D.
President and Chief Executive Officer
(Principal Executive Officer)

Date: March 11, 2025 By: /s/ Timothy W. Trost

Timothy W. Trost
Chief Financial Officer and Treasurer
(Principal Financial and Accounting Officer)