Table of Contents

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

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For the fiscal year ended December 31 , 2023

OR

TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934 FOR THE TRANSITION PERIOD FROM TO

☐

Commission File Number 001-40475

Janux Therapeutics, Inc.

(Exact name of Registrant as specified in its Charter)

Delaware	**82-2289112**
(State or other jurisdiction of incorporation or organization)	**(I.R.S. Employer Identification No.)**
10955 Vista Sorrento Parkway, Suite 200 , San Diego , California	**92130**
(Address of principal executive offices)	**(Zip Code)**

Registrant's telephone number, including area code: (858) 751-4493

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, $0.001 par value per share	JANX	The Nasdaq Global Market

Securities registered pursuant to Section 12(g) of the Act: **None**

Indicate by check mark if the Registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act. YES ☐ N O ☒

Indicate by check mark if the Registrant is not required to file reports pursuant to Section 13 or 15(d) of the Act. YES ☐ N O ☒

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. Y ES ☒ 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). Y ES ☒ 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	☐
	☒	Smaller reporting company	
Non-accelerated filer			☒

Emerging growth company

☒

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

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

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

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

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

The aggregate market value of the voting and non-voting common stock held by non-affiliates of the Registrant, as of June 30, 2023, the last business day of the Registrant's most recently completed second fiscal quarter, was approximately $

279.6

million based on the closing price of $11.87 as reported on The Nasdaq Global Market on such date. Solely for the purposes of this disclosure, shares of common stock held by executive officers, directors and certain stockholders of the Registrant as of such date have been excluded because such holders may be deemed to be affiliates.

The number of shares of Registrant's Common Stock outstanding as of March 6, 2024 was

51,660,060

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Table of Contents

DOCUMENTS INCORPORATED BY REFERENCE

Portions of the Registrant's definitive proxy statement for its 2024 Annual Meeting of Stockholders, which the Registrant intends to file pursuant to Regulation 14A with the Securities and Exchange Commission not later than 120 days after the Registrant's fiscal year ended December 31, 2023, are incorporated by reference into Part III of this Annual Report on Form 10-K.

Table of Contents

JANUX THERAPEUTICS, INC.
Annual Report on Form 10-K
For the Fiscal Year Ended December 31, 2023

Table of Contents

Special Note Regarding Forward-Looking Statements

This Annual Report on Form 10-K and the information incorporated herein by reference contain forward-looking statements that involve a number of risks and uncertainties, many of which are beyond our control. Although our forward-looking statements reflect the good faith judgment of our management, these statements can only be based on facts and factors currently known by us. Consequently, these forward-looking statements are inherently subject to risks and uncertainties, and actual results and outcomes may differ materially from results and outcomes discussed in the forward-looking statements as a result of various factors, including those set forth below under the caption "Risk Factors."

Forward-looking statements include, but are not limited to, statements regarding:

- our plans to research, develop and commercialize any product candidates;
- our ability to obtain and maintain regulatory approval of product candidates arising from our proprietary Tumor Activated T Cell Engager (TRACTr) and Tumor Activated Immunomodulator (TRACIr) platform technologies in any of the indications for which we plan to develop them;
- our ability to obtain funding for our operations, including funding necessary to commence and complete the clinical trials, conduct additional manufacturing and conduct preclinical studies of any of our product candidates;
- the success, cost and timing of our research and development activities, including our ongoing and planned preclinical studies and clinical trials;
- the size of the markets for our product candidates, and our ability to serve those markets;
- our ability to successfully commercialize our product candidates;
- the rate and degree of market acceptance of our product candidates;
- our ability to develop and maintain sales and marketing capabilities, whether alone or with potential future collaborators;
- regulatory developments in the United States and foreign countries;
- the performance of our third-party service providers, including our CROs, suppliers and manufacturers;
- the safety, efficacy and market success of competing therapies that are or become available;
- our ability to attract and retain key scientific and management personnel;
- our ability to attract and retain collaborators with development, regulatory and commercialization expertise;
- our expectations regarding the period during which we qualify as an emerging growth company under the JOBS Act;
- the accuracy of our estimates regarding expenses, future revenues, capital requirements and needs for additional financing;
- our expectations regarding our ability to obtain and maintain intellectual property protection for our product candidates and our ability to operate our business without infringing on the intellectual property rights of others; and
- the impact of COVID-19 or other health epidemics or pandemics on our business and operations.

In some cases, you can identify forward-looking statements by terminology such as "aim," "anticipate," "assume," "believe," "contemplate," "continue," "could," "design," "due," "estimate," "expect," "goal," "intend," "may," "objective," "plan," "positioned," "potential," "predict," "seek," "should," "target," "will," "would" and other similar expressions that are predictions of or indicate future events and future trends, or the negative of these terms or other comparable terminology. In addition, statements that "we believe" and similar statements reflect our beliefs and opinions on the relevant subject. These forward-looking statements are subject to a number of known and unknown risks, uncertainties and assumptions described in the sections of this Annual Report on Form 10-K titled "Risk Factors" and "Management's Discussion and Analysis of Financial Condition and Results of Operations" and elsewhere in this report. We discuss many of the risks associated with the forward-looking

statements in this Annual Report on Form 10-K in greater detail under the heading “Risk Factors.” Moreover, we operate in a very competitive and rapidly changing environment. New risks emerge from time to time. It is not possible for our management to predict all risks, nor can we assess the impact of all factors on our business or the extent to which any factor, or combination of factors, may cause actual results to differ materially from those contained in any forward-looking statements we may make. You should be aware that the occurrence of any of the events discussed under the caption “Risk Factors” and elsewhere in this report could substantially harm our business, results of operations and financial condition and that if any of these events occurs, the trading price of our common stock could decline and you could lose all or a part of the value of your shares of our common stock.

The cautionary statements made in this report are intended to be applicable to all related forward-looking statements wherever they may appear in this Annual Report on Form 10-K. We urge you not to place undue reliance on these forward-looking statements, which speak only as of the date of this Annual Report on Form 10-K. For all forward-looking statements, we claim the protection of the safe harbor for forward-looking statements contained in the Private Securities Litigation Reform Act of 1995. Except as required by law, we assume no obligation to update our forward-looking statements publicly, or to update the reasons actual results could differ materially from those anticipated in any forward-looking statements, whether as a result of new information, future events or otherwise.

This Annual Report on Form 10-K also contains estimates, projections and other information concerning our industry, our business, and the markets for our product candidates, including data regarding the estimated size of markets for oncology therapeutics and the incidence of certain medical conditions, statements that certain drugs, classes of drugs, or dosages are widely prescribed in the United States or other markets, statements regarding the perceptions and preferences of patients and physicians regarding certain therapies and other prescription, prescriber and patient data, as well as data regarding market research, estimates and forecasts prepared by our management. Information that is based on estimates, forecasts, projections, market research or similar methodologies is inherently subject to uncertainties, and actual events or circumstances may differ materially from events and circumstances reflected in this information. Unless otherwise expressly stated, we obtained this industry, business, market and other data from reports, research surveys, studies and similar data prepared by market research firms and other third parties, industry, medical and general publications, government data and similar sources.

You should read the following together with the more detailed information regarding our company, our common stock and our financial statements and notes to those statements appearing elsewhere in this report or incorporated by reference. The Securities and Exchange Commission (SEC) allows us to “incorporate by reference” information that we file with the SEC, which means that we can disclose important information to you by referring you to those documents. The information incorporated by reference is considered to be part of this report.

Risk Factors Summary

Below is a summary of the material factors that make an investment in our common stock speculative or risky. This summary does not address all of the risks that we face. Additional discussion of the risks summarized in this risk factor summary, and other risks that we face, can be found below under the heading “Risk Factors” under Part I, Item 1A of this Annual Report and should be carefully considered, together with other information in this Annual Report before making investment decisions regarding our common stock.

- We have a limited operating history, have incurred net losses since our inception, and anticipate that we will continue to incur significant losses for the foreseeable future. We may never generate any revenue or become profitable or, if we achieve profitability, may not be able to sustain it.
- If we are unable to raise additional capital when needed, we may be forced to delay, reduce or eliminate our product development programs or other operations.
- Raising additional capital may cause dilution to our stockholders, restrict our operations or require us to relinquish rights to our technologies or product candidates.
- We are early in our development efforts and all of our product candidates and research programs other than JANX007 and JANX008 are in the preclinical development or discovery stage. We have a very limited history of conducting clinical trials to test our product candidates in humans.
- Preclinical and clinical development is a lengthy, expensive and uncertain process. The results of preclinical studies and early clinical trials are not always predictive of future results. JANX007, JANX008 and any other product candidate that we advance into clinical trials may not achieve favorable results in later clinical trials, if any, or receive marketing approval.

• Our product candidates are based on novel technologies, which make it difficult to predict the timing, results and cost of product candidate development and likelihood of obtaining regulatory approval.

• We may rely on third parties to conduct, supervise, and monitor our ongoing and planned clinical trials and perform some of our research and preclinical studies. If these third parties do not satisfactorily carry out their contractual duties or fail to meet expected deadlines, our development programs may be delayed or subject to increased costs, each of which may have an adverse effect on our business and prospects.

• The market opportunity for our product candidates may be relatively small as it will be limited to those patients who are ineligible for or have failed prior treatments and our estimates of the prevalence of our target patient populations may be inaccurate.

• We are highly dependent on our key personnel, and if we are not successful in attracting and retaining highly qualified personnel, we may not be able to successfully implement our business strategy.

• If we are unable to obtain and maintain sufficient intellectual property protection for our platform technologies and product candidates, or if the scope of the intellectual property protection is not sufficiently broad, our competitors could develop and commercialize products similar or identical to ours, and our ability to successfully commercialize our products may be adversely affected.

• We are subject to stringent and evolving U.S. and foreign laws, regulations, rules, contractual obligations, industry standards, policies and other obligations related to data privacy and security. Our actual or perceived failure to comply with current or future federal, state and foreign laws, regulations, contracts, self-regulatory schemes, industry standards and other obligations relating to privacy and security could lead to regulatory investigations or actions (which could include civil or criminal penalties), private litigation (including class claims) and mass arbitration demands, adverse publicity, disruptions of our business operations and other adverse business consequences.

PART I

Item 1. Business.

Unless the context otherwise requires, the terms “Janux Therapeutics,” “Janux,” “we,” “us,” “our” and similar references in this Annual Report on Form 10-K refer to Janux Therapeutics, Inc.

Overview

We are an innovative clinical-stage biopharmaceutical company developing tumor-activated immunotherapies for cancer. Our proprietary technology has enabled the development of two distinct bispecific platforms: Tumor Activated T Cell Engagers (TRACTr) and Tumor Activated Immunomodulators (TRACIr). The TRACTr platform produces T cell engagers (TCEs) with a tumor antigen-binding domain and a CD3 T cell binding domain, while the TRACIr platform produces bispecifics with a tumor antigen-binding domain and a costimulatory CD28 binding domain. The goal of both platforms is to provide cancer patients with safe and effective therapeutics that direct and guide their immune system to eradicate tumors while minimizing safety concerns. Our initial focus is on developing a novel class of TRACTr therapeutics designed to target clinically validated TCE drug targets, but overcome liabilities associated with prior generations of TCEs. While TCE therapeutics have displayed potent anti-tumor activity in hematological cancers, developing TCEs to treat solid tumors has faced challenges due to the limitations of prior TCE technologies, namely (i) on-target healthy tissue immune activation that contributes to cytokine release syndrome (CRS) and healthy tissue toxicity and (ii) poor pharmacokinetics (PK) leading to short half-life. Our first clinical candidate, JANX007, is a prostate-specific membrane antigen or PSMA-TRACTr and is being investigated in a Phase 1 clinical trial in adult subjects with metastatic castration-resistant prostate cancer (mCRPC). In February 2024 we announced updated interim clinical data for JANX007 which displayed meaningful PSA drops, and a favorable safety profile, low-grade CRS, and PK, consistent with the TRACTr mechanism-of-action. Our second clinical candidate, JANX008, is an epidermal growth factor receptor or EGFR-TRACTr and is being studied in a Phase 1 clinical trial for the treatment of multiple solid cancers including colorectal cancer, squamous cell carcinoma of the head and neck, non-small cell lung cancer, and renal cell carcinoma. The first patient for this trial was dosed in April 2023 and in February 2024 we announced positive early data JANX008 that displayed anti-tumor activity in multiple tumor types with low-grade CRS and predominantly low-grade TRAEs. We are also generating a

number of unnamed TRACTr and TRACIr programs for potential future development, some of which are at development candidate stage or later. We are currently assessing priorities in our preclinical pipeline.

The promise of TCE technologies and their current limitations

TCEs are an emerging class of immunotherapies that bridge a tumor cell and a T cell to activate and redirect T cells to attack and eliminate tumors. TCEs have demonstrated promising anti-tumor activity in early clinical trials and in multiple animal models that rivals that of chimeric antigen receptor T cell (CAR T cell) therapies, with the distinct advantage that they are not cell therapies and have the potential to be offered as readily available, off-the-shelf therapies, which would avoid the lengthy, complicated, and expensive manufacturing process required for approved autologous CAR T cell therapies. One TCE, blinatumomab, marketed by Amgen as BLINCYTO, has been approved by the FDA and, like the FDA-approved CAR T cell therapies, has been limited to hematological malignancies.

Three properties of existing TCEs have limited their potential to treat solid tumors:

- **Cytokine release syndrome (CRS).** CRS arises from the systemic activation of T cells and can result in life-threatening elevations in inflammatory cytokines such as interleukin-6 (IL-6). Severe and acute CRS leading to dose-limiting toxicities and deaths has been observed upon the dosing of TCEs developed using other platforms to treat cancer patients in prior clinical studies. This toxicity severely restricts the maximum blood levels of TCEs that can be safely dosed.
- **On-target, healthy tissue toxicity.** On-target, healthy tissue toxicity, arising from expression of the tumor target in healthy tissue and scarcity of highly tumor-selective antigens, is another limitation hindering the development of TCEs to treat solid tumor cancers. TCEs developed using other platforms not designed for tumor-specific activation have resulted in clinical holds and dose-limiting toxicities resulting from target expression in healthy tissues.
- **Short half-lives.** TCEs quickly reach sub-therapeutic levels after being administered as they are quickly eliminated from the body due to their short exposure half-lives. For this reason, TCEs such as blinatumomab (BLINCYTO) are typically administered by a low-dose, continuous infusion pump over a period of weeks to overcome the challenge of a short half-life and maintain therapeutic levels of the drug in the body. This continuous infusion dosing regimen represents a significant burden for patients.

Our TRACTr and TRACIr platforms

We believe our proprietary TRACTr and TRACIr platforms offer the potential to expand the breadth of patients that can be treated with TCEs and non-TCE based immunomodulators while reducing the risk of life-threatening toxicities. Each of our proprietary TRACTrs and TRACIrs are comprised of an antigen-binding domain, a T cell-binding domain, domain-optimized peptide masks, an albumin-binding domain, and cleavable peptide linkers. The mask is a peptide designed to bind to the tumor or T cell-binding domain. It inhibits the binding domain's interaction with its target, thereby inhibiting the activation of T cells. The antigen and T cell-binding domains in our TRACTr and TRACIr product candidates may be covalently attached to peptide masks that block binding and activity until they are removed. We use proprietary peptide linker sequences composed of tumor protease recognition sites to attach these masks to the antigen-binding domains in a way designed to make the masks highly sensitive to removal by tumor proteases but highly stable in the absence of these proteases. In addition, we attach an albumin-binding domain to one mask, which is designed to extend the half-life of our TRACTr and TRACIr product candidates until they become activated inside a tumor.

While our TRACTr and TRACIr platforms are novel and unproven and our product candidates remain in the early clinical, preclinical or discovery stage, our technology is designed to offer the following features for the discovery and development of novel therapies for the treatment of solid tumors:

- **Potential to reduce CRS and on-target, healthy tissue toxicity risk.** By engineering our TRACTrs and TRACIrs with novel peptide masks that are designed (i) to be selectively activated in the tumor microenvironment and (ii) for any activated TCEs or non-TCE based immunomodulators to be rapidly cleared from healthy tissue upon escaping from the tumor, our product candidates have the potential to

overcome the toxicity challenges of TCEs, non-TCE based immunomodulators and systemic immunotherapies in general.

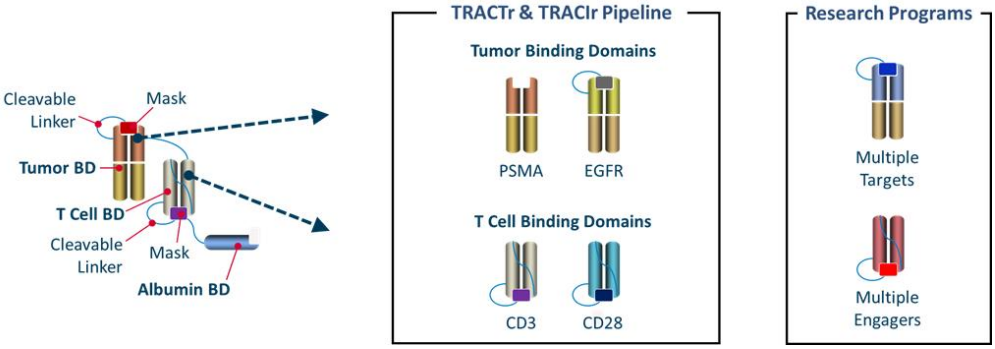
• **Potential for extended half-life of our TRACTrs and TRACIrs.** We designed our TRACTrs and TRACIrs with an albumin-binding domain to be stable in the bloodstream and to have an extended serum half-life before activation. Our TRACTrs and TRACIrs have demonstrated long half-lives in NHPs. This contrasts to first-generation TCEs and non-TCE based immunomodulators that are rapidly cleared and require high frequency or continuous dosing.

• **Potential for activity at low levels of target expression.** Our TRACTrs and TRACIrs are designed to be active at low levels of tumor target expression where other treatment modalities lose efficacy. In preclinical studies, our TRACTrs and TRACIrs did not require high levels of tumor target expression to activate T cells to kill cancer cells.

• **Modularity.** Our TRACTr and TRACIr platforms' modular characteristics enable us to leverage the learnings from the development of our product candidates to progress the discovery process of new TRACTr and TRACIr candidates against a wide variety of targets.

• **Manufacturability.** The development, manufacturing and control processes of our TRACTr and TRACIr molecules closely resemble those used for monoclonal antibodies (mAbs) with the expectation for a relatively lower cost of goods.

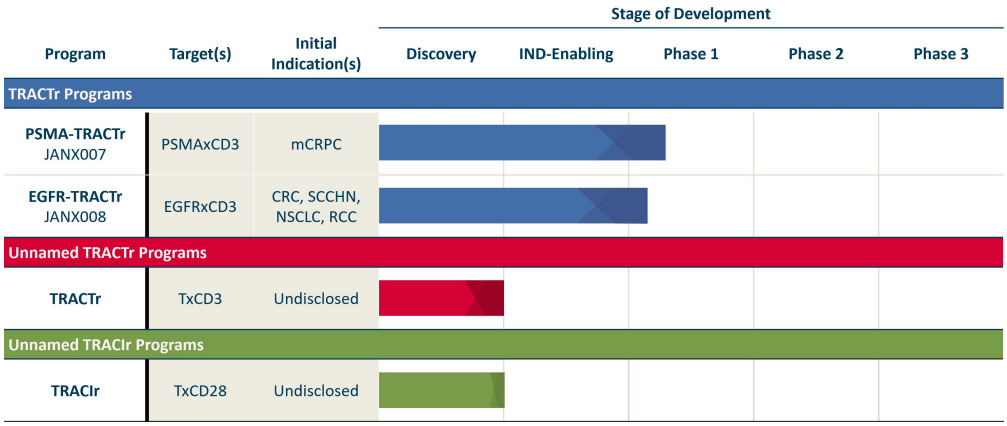
A schematic of our proprietary TRACTrs and TRACIrs in development and their modular components is depicted below.



Our lead programs

Our lead TRACTr clinical candidates are designed to target PSMA and EGFR. Each of these tumor targets is clinically validated and implicated in solid tumors with high prevalence, including metastatic castrate-resistant prostate cancer (mCRPC), colorectal cancer (CRC), renal cell carcinoma (RCC), squamous cell carcinoma of the head and neck (SCCHN), and non-small cell lung cancer (NSCLC). We are also generating a number of unnamed

TRACTr and TRACIr programs for potential future development, some of which are at development candidate stage or later. Our wholly-owned pipeline is summarized below:



In addition to our wholly-owned pipeline programs, we have a strategic research collaboration with Merck Sharp & Dohme Corp. (Merck) to develop TRACTr product candidates directed against two cancer targets selected by Merck.

Our Clinical TRACTr Programs

We are building a broad portfolio of TRACTr programs led by our PSMA and EGFR targeted TRACTrs.

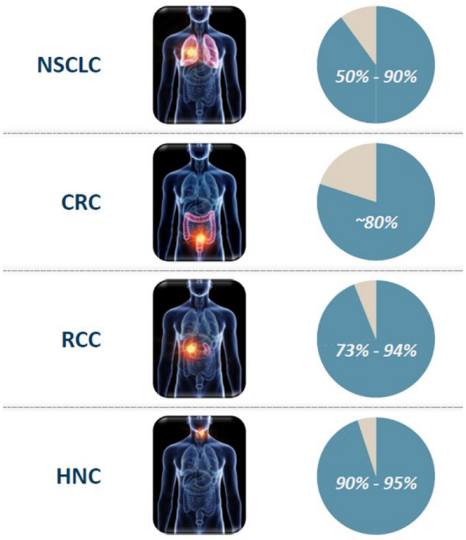
Our PSMA-TRACTr (JANX007)

Our lead clinical candidate is JANX007, our PSMA-TRACTr designed to target PSMA, a protein expressed in prostate cancer tumors and the vasculature of other tumors. Excluding nonmelanoma skin cancer, prostate cancer is the second most common cancer and led to an estimated 34,700 deaths in the United States in 2023. PSMA is highly expressed in prostate cancer which has led to the development of PSMA-targeted biologics, including TCEs. A third-party clinical trial with a continuously infused PSMA-TCE demonstrated clinical benefit, suggesting the potential of a PSMA-TCE approach. Given the challenges of continuous infusion, other companies are developing TCEs that enable less frequent dosing. However, clinical trial results have shown dose-limiting CRS toxicities as single agents, highlighting the limitations of traditional TCEs. Our PSMA-TRACTr is designed to generate potent anti-tumor activity in mCRPC patients by enabling the delivery of higher concentrations of active drugs to tumors than traditional TCEs. We believe that our PSMA-TRACTr product candidate has the potential to deliver therapeutic benefits to patients while minimizing severe adverse events (SAEs), including the prevention of dose-limiting CRS. In February 2024 we announced updated interim clinical data for JANX007 which displayed meaningful PSA drops, and a favorable safety profile, low-grade CRS, and PK, consistent with the TRACTr mechanism-of-action.

Our EGFR-TRACTr (JANX008)

Our second clinical candidate is JANX008, our EGFR-TRACTr designed to target EGFR, a well-validated target that is overexpressed in many cancer types with multiple approved mAbs, including ERBITUX, marketed by Eli Lilly and Merck KGaA, for the treatment of CRC and SCCHN, and VECTIBIX, marketed by Amgen and Takeda, for the treatment of CRC. Beyond CRC and SCCHN, the below figure describes cancers included in our Phase 1 clinical trial.

Figure 1. Cancers included in our Phase 1 clinical trial



CRC represents one tumor type for which EGFR is overexpressed. However, many patients do not respond to anti-EGFR mAbs, and of those that do, resistance often develops. SCCHN and NSCLC cancers also represent tumor types for which EGFR is frequently overexpressed, and anti-EGFR antibodies have received marketing approvals. Frequently genetic mutations in signaling pathways, such as KRAS mutants can lead to de novo resistance to naked antibody therapy. Stronger tumoricidal activity is needed. We believe that EGFR-directed immunotherapies, including TCEs, have the potential to address this high unmet need. Our EGFR-TRACTr is designed to generate potent anti-tumor activity by enabling the delivery of higher concentrations of active drug to tumors than traditional TCEs. We believe that our EGFR-TRACTr product candidate has the potential to deliver therapeutic benefits to patients while minimizing SAEs, including on-target, off-tumor healthy tissue toxicities and dose-limiting CRS. JANX008 is being studied in a Phase 1 clinical trial for the treatment of multiple solid cancers including colorectal cancer, squamous cell carcinoma of the head and neck, non-small cell lung cancer, and renal cell carcinoma. The first patient for this trial was dosed in April 2023 and in February 2024 we announced positive early data JANX008 that displayed anti-tumor activity in multiple tumor types with low-grade CRS and predominantly low-grade TRAEs.

Our Research Collaboration with Merck Sharp & Dohme Corp.

In December 2020, we entered into a research collaboration and exclusive license agreement with Merck to develop TRACTr product candidates distinct from those in our internally developed pipeline. Merck had the right to select up to two collaboration targets related to next-generation TCE immunotherapies for cancer treatment, both of which have been selected. Merck received an exclusive worldwide license for each selected target and intellectual property from the collaboration. In return, we are eligible to receive up to $500.5 million per target in upfront and milestone payments, plus royalties on sales of the products derived from the collaboration. Merck is providing research funding under the collaboration.

We plan to selectively consider other strategic collaboration opportunities in the future.

Our Strategy

Our goal is to unleash the potential of our TRACTr and TRACIr platforms technology to transform the lives of cancer patients. To achieve this goal, critical elements of our strategy include the following:

• **Advance our lead TRACTr programs through clinical development.** In February 2024 we announced updated interim clinical data for JANX007 which displayed meaningful PSA drops, and a favorable safety profile, low-grade CRS, and PK, consistent with the TRACTr mechanism-of-action. In April 2023, the first patient was dosed with our EGFR-TRACTr JANX008 and in February 2024 we announced positive early data that displayed anti-tumor activity in multiple tumor types with low-grade CRS and predominantly low-grade TRAEs. We believe that our programs have the potential to transform the treatment of metastatic diseases such as mCRPC, CRC, NSCLC, RCC, SCCHN, and a wide range of other tumor types that overexpress PSMA or EGFR, which are clinically validated targets.

• **Broaden our portfolio of TRACTr product candidates.** Our TRACTr platform technology's modular characteristics enable us to leverage the learnings from the development of our product candidates to progress the discovery process of new TRACTr candidates against a wide variety of targets. For our first three programs, once an antibody was identified, we developed a masked tumor-binding domain in less than six months to begin evaluating TRACTr development candidates. We are actively pursuing the development of additional TRACTr programs against several other clinically validated targets.

• **Expand our internal pipeline into logical classes of therapeutics beyond TCEs.** Our tumor-activated masking and bispecific molecule design enable more molecular phenotypes than classic CD3 targeted TCEs. For example, our proprietary technology allows the masking and tumor activation of different T cell therapy modalities, including costimulation via CD28 engagement and our TRACIr platform. We believe TRACIr programs could have the potential to be used as a single-agent or in combination with our current TRACTr pipeline and other modalities. We are also applying our proprietary technology to create molecules designed to attract, redirect, or mobilize different types of immune cells to tumor sites that exclude or lack resident immune cells.

• **Selectively evaluate opportunities to maximize the potential of our programs in partnership with leading biopharmaceutical companies.** We plan to selectively evaluate potential opportunities on a program-by-program basis with biopharmaceutical companies whose research, development, and/or geographic capabilities complement our own with the goal to help mitigate clinical and commercial risk and/or maximize global commercial potential.

TCEs as novel therapeutics to overcome the limitations of current immunotherapies

Background

Immunotherapy has ushered in a new era of cancer treatment with unprecedented responses in many tumor types. Unleashing the power of the immune system on cancer cells has been one of the most promising new advancements in a field long dominated by suboptimal approaches such as chemotherapy. One class of immunotherapy, checkpoint inhibitors, has generated encouraging efficacy results and represents the standard of care (SOC) in selected tumor types. However, despite this clinical benefit for a subset of patients, only a fraction of all cancer patients in the United States respond to checkpoint inhibitors. Tumors have evolved to evade and dampen tumor immune surveillance. Consequently, new classes of immunotherapy designed to overcome the various immune-evasion mechanisms that tumors employ have emerged.

TCEs are immunotherapies that bridge tumor-fighting T cells and tumors in a way that overcomes this challenge. TCEs are bivalent biologics; that is, they can bind to two different cell surface targets. By selecting one target on a tumor cell and another on a T cell, the TCE bridges these two cell types to trigger tumor cell killing by the T cell. TCEs can be mass-produced and made available as off-the-shelf therapies. Furthermore, TCEs, as biologics, have pharmacologic properties that allow control of the amount of active drug in the body at any one time. The doses that are delivered can be titrated, and the pharmacokinetics generally follow those of other biologics.

Other approaches to immunotherapy, like cell therapies, such as CAR T cell therapy, are also emerging. We believe the unique characteristics of TCEs render them an attractive immunotherapy alternative to these approaches. While cell therapies have displayed efficacy in treating cancer, these treatments have also led to morbidity and mortality resulting from toxicity. Cell therapies also typically require complex and costly manufacturing strategies, making them unsuitable for several aggressive tumors and advanced disease patients. They are primarily confined to treatment for hematological malignancies, and CAR T cell therapies have not to date been successfully developed for any solid tumor.

While we believe that TCEs hold promise in treating solid tumors, three properties of TCEs derived from other platforms have limited their potential:

- **Cytokine release syndrome (CRS).** CRS arises from the systemic activation of T cells and can result in life-threatening elevations in inflammatory cytokines such as IL-6. Severe and acute CRS leading to dose-limiting toxicities and deaths has been observed upon the dosing of TCEs developed using other platforms to treat cancer patients in prior clinical studies. This toxicity severely restricts the maximum blood levels of TCEs that can be safely dosed.

- **On-target, healthy tissue toxicity.** On-target, healthy tissue toxicity, arising from the expression of the tumor target in healthy tissue and scarcity of highly tumor-selective antigens, is another limitation hindering the development of TCEs to treat solid tumor cancers. TCEs developed using other platforms not designed for tumor-specific activation have resulted in clinical holds and dose-limiting toxicities resulting from target expression in healthy tissues.

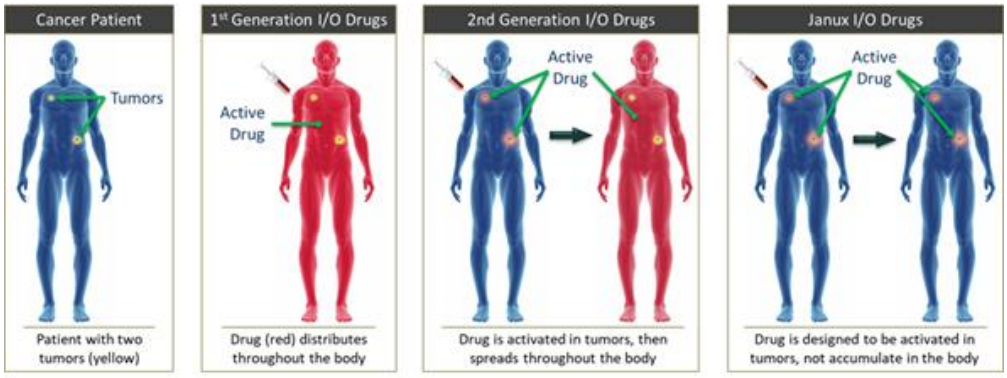
- **Short half-lives.** TCEs quickly reach sub-therapeutic levels after being administered as they are quickly eliminated from the body due to their short exposure half-lives. For this reason, TCEs such as blinatumomab (BLINCYTO) are typically administered by a low-dose, continuous infusion pump over a period of weeks to overcome the challenge of a short half-life and to maintain therapeutic levels of the drug in the body. This continuous infusion dosing regimen represents a significant burden for patients.

Next generation approaches to overcome the challenges of conventional TCEs

First-generation immuno-oncology drugs have an increased risk of systemic toxicity due to the active drug circulating throughout the body. Second generation immuno oncology drugs, such as protease-activated antibodies, have attempted to limit systemic toxicities by being administered in an inactive form and only activated upon exposure to tumor proteases within the tumor microenvironment. However, once these activated drugs leave the tumor, they circulate throughout the body and accumulate over time, leading to on-target, healthy tissue toxicity in target-expressing tissues. Several product candidates have been developed that take advantage of tumor-associated proteases to activate potent drugs in tumors. These include prodrugs such as leucine-doxorubicin and masked antibodies such as Probodies developed by CytomX. In initial clinical trials, CytomX has demonstrated clinical benefit in patients and a mechanistic proof-of-concept for this masked antibody approach. However, an unwanted consequence of CytomX's approach is that the relatively long half-lives of its drugs in active form led to their accumulation in healthy tissue throughout treatment.

We are developing our TRACTr and TRACIr platforms to address the limitations of previous generations of immuno-oncology drugs and to restrict activity to tumors. Our TRACTrs and TRACIrs are designed to be activated by tumor-specific proteases but, upon activation, be converted to a form that has a short half-life to eliminate them from the body rapidly should they re-enter the circulatory system. A representation of the pharmacokinetic design of first and second-generation TCEs and our TRACTrs / TRACIrs is shown in the figure below.

Figure 2. Our TRACTr and TRACIr platforms are designed to limit the activity of our therapies to tumor sites, reducing the risk of on-target, healthy tissue toxicity



Our TRACTr and TRACIr Platforms

Our TRACTr and TRACIr platforms are designed to offer the following features for the discovery and development of novel therapies for the treatment of solid tumors:

- **Potential to reduce CRS and on-target, healthy tissue toxicity risk.** By engineering our TRACTrs and TRACIrs with novel peptide masks that are designed to be selectively activated in the tumor microenvironment and designed for any activated TCEs or non-TCE based immunomodulators to be rapidly cleared from healthy tissue upon escaping from the tumor, our product candidates have the potential to overcome the toxicity challenges of TCEs, non-TCE based immunomodulators and systemic immunotherapies in general.
- **Potential for the extended half-life of our TRACTrs and TRACIrs.** We designed our TRACTrs and TRACIrs with an albumin-binding domain to be stable in the bloodstream and to have an extended serum half-life before activation. Our TRACTrs and TRACIrs have demonstrated long half-lives in NHPs. This contrasts with first-generation TCEs or non-TCE based immunomodulators that are rapidly cleared and require high frequency or continuous dosing.
- **Potential for activity at low levels of target expression.** Our TRACTrs and TRACIrs are designed to be active at low levels of tumor target expression where other treatment modalities lose efficacy. In preclinical studies, our TRACTrs and TRACIrs did not require high levels of tumor target expression to activate T cells to kill cancer cells.
- **Modularity.** Our TRACTr and TRACIr platforms' modular characteristics enable us to leverage the learnings from the development of our product candidates to progress the discovery process of new TRACTr and TRACIr candidates against a wide variety of targets.
- **Manufacturability.** The development, manufacturing and control processes of our TRACTr and TRACIr molecules closely resemble those used for monoclonal antibodies with the expectation for a relatively lower cost of goods.

TRACTr and TRACIr design and structure

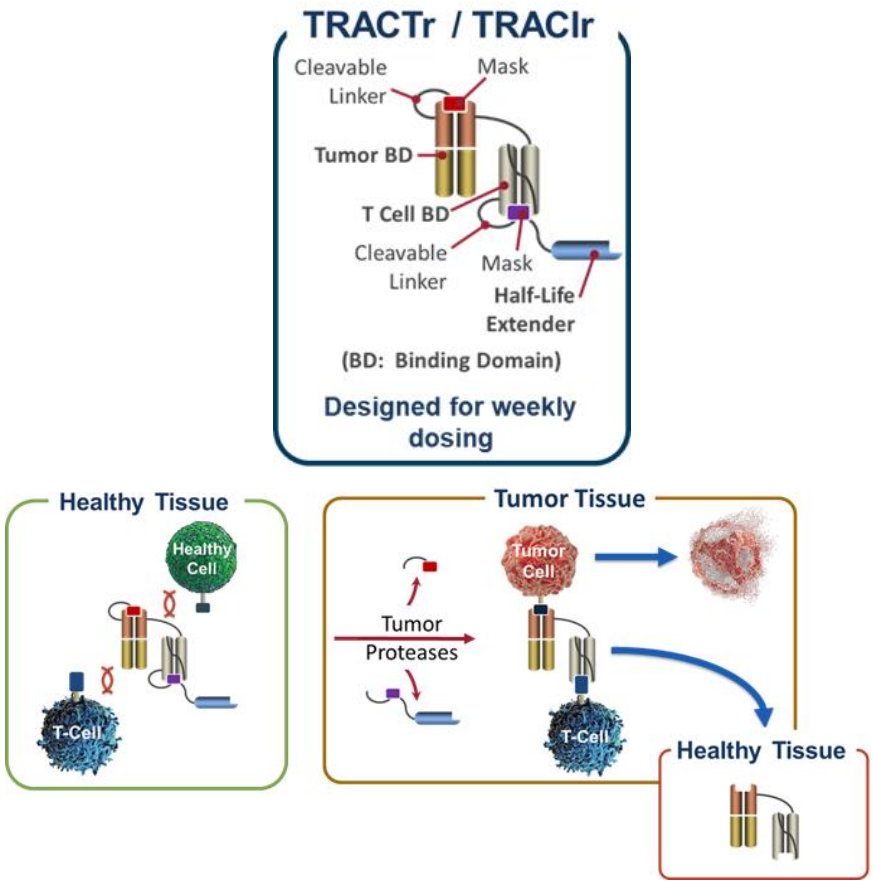
Our TRACTr and TRACIr product candidates are biologics comprised of multiple domains that have been designed to serve specific functions but engineered to function as a single unit. At their core, our TRACTr and TRACIr product candidates are TCEs and non-TCE based immunomodulators, respectively, that couple a tumor antigen binding domain to a T cell-specific antigen binding domain. Masks cover both binding sites and block activity while our TRACTr or TRACIr product candidate are in circulation and exposed to healthy tissues. We use proprietary peptide linker sequences composed of tumor protease recognition sites to attach these masks to the antigen-binding domains in a way that is designed to make the masks highly sensitive to release by tumor proteases.

This release exposes both the tumor-binding domain and the T cell antigen binding domains to generate a fully activated TCE or non-TCE based immunomodulator. This is designed to enable our TRACTr or TRACIr product candidates to bridge the T cells and tumor cells into close proximity and to enable T cell-mediated killing of tumor cells.

Our TRACTr and TRACIr product candidates also have a proprietary albumin-binding domain designed to increase their half-life in serum. This proprietary domain is designed to bind albumin and, by doing so, prevent the rapid degradation and elimination of TRACTr or TRACIr product candidates. In contrast, blinatumomab (BLINCYTO), a TCE that lacks an albumin-binding domain, has a very short half-life in serum and is administered through continuous infusion for 28 days per treatment cycle, with hospitalization recommended for up to the first nine days.

Our TRACTrs and TRACIrs are designed to limit binding to their targets in healthy cells. When our TRACTr or TRACIr product candidates are in the non-activated state, they are designed not to activate T cells before reaching the tumor. Upon exposure to tumor proteases, the linkers are designed to be cleaved, and the masks and albumin-binding domains are designed to be released to generate a fully active TCE or non-TCE based immunomodulator. This is designed to enable tumor-specific T cell activation and tumor cell killing while priming the activated TCE or non-TCE based immunomodulator for rapid elimination should it leave the tumor and re-enter circulation. We believe that our technology's design to restrict T cell activation specifically to tumor sites provides the opportunity to generate TCEs and non-TCE based immunomodulators with broader therapeutic windows. We summarize our

TRACTr and TRACIr structure, activation mechanism in tumor tissue, and rapid elimination from healthy tissue once activated below.

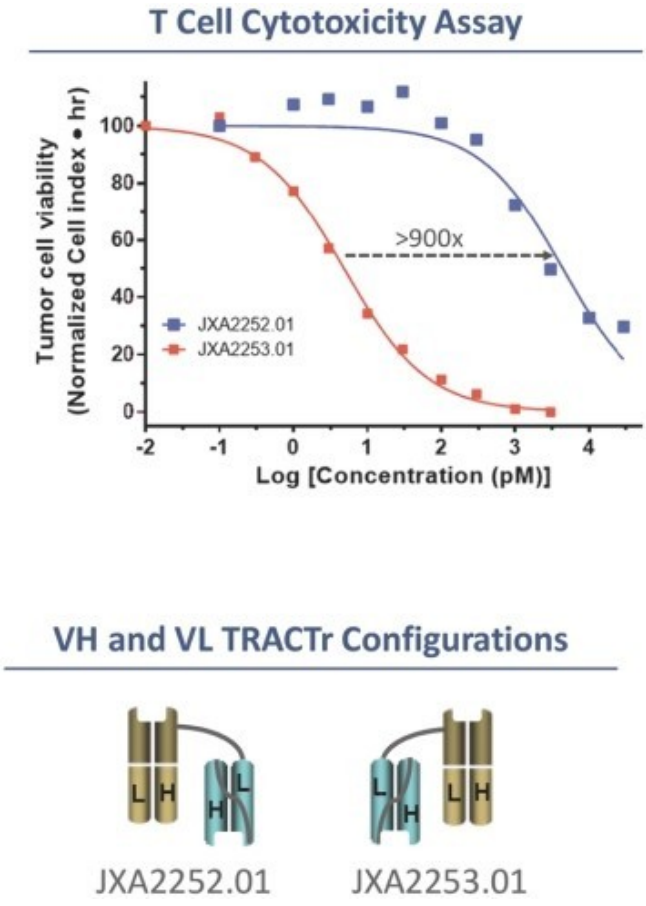


Our TRACTr and TRACIr development process

We have developed robust processes to select specific sequences for each of these components in a TRACTr or TRACIr both for their individual properties and for their ability to contribute to the desired properties of our fully assembled product candidates.

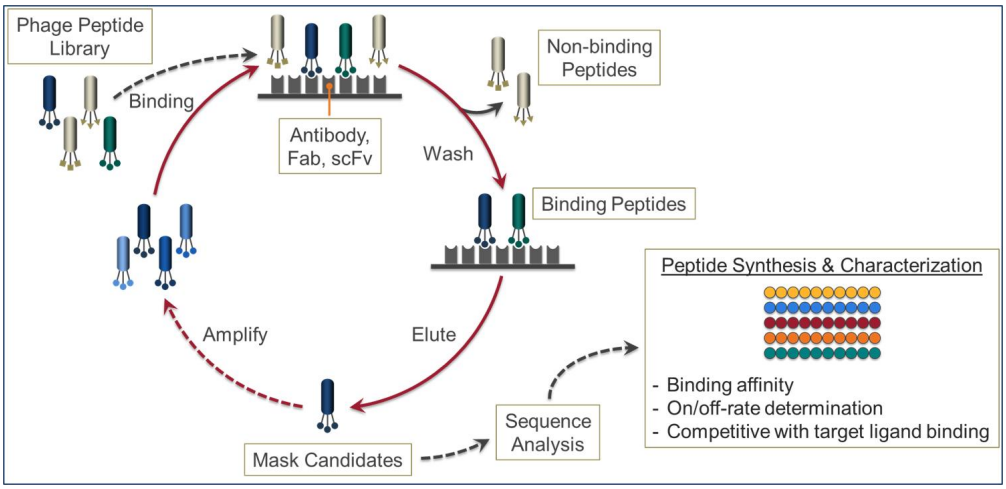
- **Antigen-binding domains.** Our initial product candidates are based on antigen binding domains, which have been incorporated into other products associated with clinical activity. As we expand our pipeline, we are developing proprietary antigen binding domains against novel targets.
- **Geometry connecting the antigen binding domains**. The orientation of a tumor-specific and a T cell-specific antigen binding domain is central to creating a TCE or non-TCE based immunomodulator with optimal T cell activation. We have found that the orientation between the two antigen-binding domains profoundly affected activity in preclinical studies. For example, we constructed two PSMA TCEs with similar binding domains but of different geometry, where their potency in T cell-directed, PSMA-specific tumor cell killing differed by over 900-fold, as shown in the figure below.

Figure 3. The orientation of the two antigen binding domains in a PSMA-TCE led to an over 900-fold difference in potency in preclinical studies (top), and the configurations of these two TCEs, VH and VL (bottom)



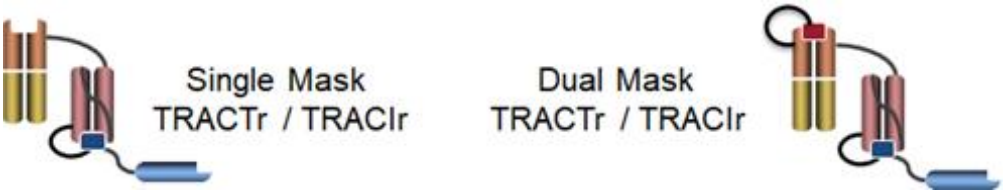
• **Mask Discovery**. Each mask sequence is designed to be optimized for a specific antigen-binding domain through an iterative process of phage display and quantitative binding assays designed to select for those masks that can prevent binding to the target antigen. We use a directed evolution-based process using proprietary phage libraries. We go through multiple cycles of selection and amplification of potential inhibitory peptides capable of blocking the antigen-binding domain from binding to its target to optimize masked TCE or non-TCE based immunomodulator stability in serum and limit cleavage to the tumor microenvironment thereby reducing toxicity. We depict our mask discovery process in the figure below.

Figure 4. Using directed evolution and phage display technology, we identify potential mask sequences that are designed to completely block antigen recognition by our antigen binding domains



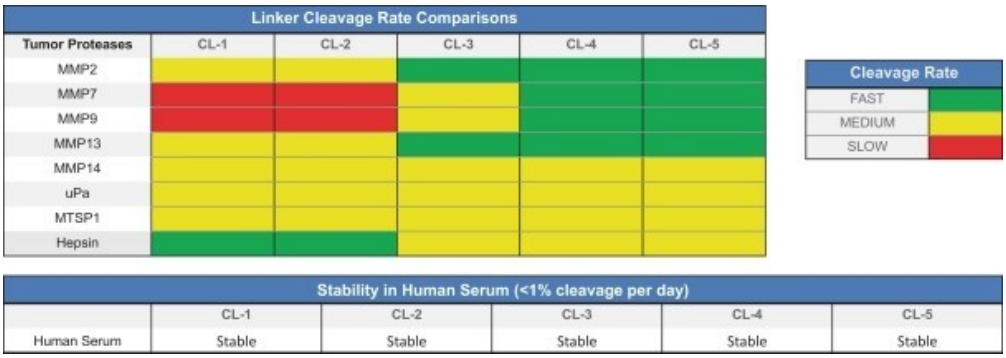
• **Single versus dual masks**. Our technology allows us to develop product candidates with either one or both antigen-binding domains masked depending on the tumor target's profile. For tumor targets with minimal healthy tissue expression or toxicity concerns, we develop single mask TRACTrs or TRACIrs designed to block the T cell-binding domain to prevent non-tumor-specific activation of T cells that contributes to CRS. For targets with high/broad healthy tissue expression or toxicity concerns, we develop dual mask TRACTrs or TRACIrs designed to mask both domains to minimize the risk of healthy tissue toxicity and CRS. We depict the single and dual mask TRACTr and TRACIr structures in the figure below.

Figure 5. We design both single and dual masked TRACTr and TRACIr product candidates based on the healthy tissue expression levels of the tumor-targeted antigen and the risk of healthy tissue toxicity



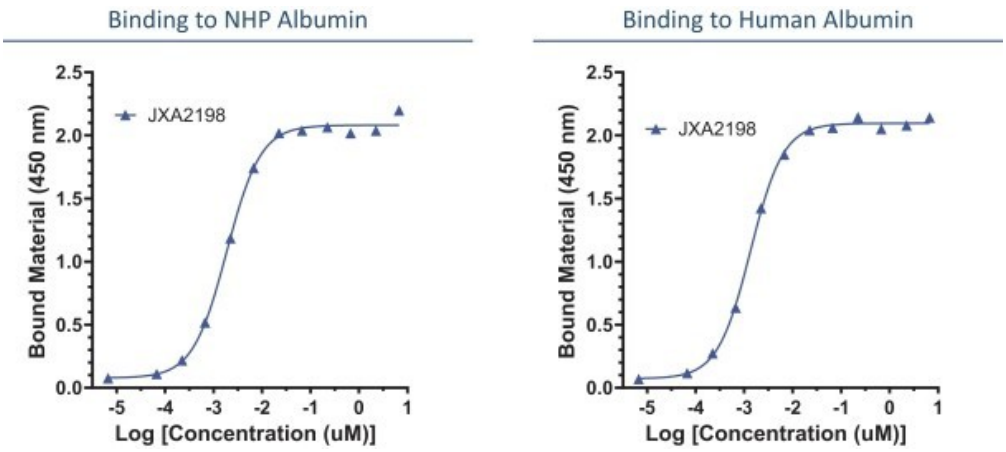
• **Cleavage linker**. We optimized the selection of cleavage linkers by a process involving identifying the predominant proteases in solid tumors and mining databases for potential substrates of these proteases. We then screened peptide sequences for their sensitivity to cleavage by these proteases. We specifically identified potential cleavage linker sequences that were rapidly cleaved by a tumor-specific protease to improve anti-tumor TRACTr or TRACIr activities potentially, yet remain stable in human, NHP, and mouse serum to limit non-tumor activation. We have identified several proprietary cleavable linkers that

we utilize to optimize efficacy and stability in our TRACTrs and TRACIrs, as shown in the schematic below.



• **Albumin-binding domain**. We developed our proprietary albumin-binding domain derived from a llama antibody optimized for its ability to bind to albumin from both humans and NHPs, the primary preclinical species in which we conduct our *in vivo* experiments due to the similarity in target sequences and immune function with humans. As shown in Figure 6 below, our albumin-binding domain has a nearly identical binding affinity to albumin from these two species.

Figure 6. Our proprietary albumin-binding domain had potent binding to both NHP and human albumin



• **Development viability.** Once we have identified the critical components for any product candidate, we assemble them and modify the assembled construct using standard techniques to make it more human-like. We then assess its feasibility for development. We are primarily concerned with the following attributes of a potential product candidate:

o Manufacturability using standard mammalian cell expression systems;

o Drug-like properties such as solubility, thermal stability, and stability in human serum; and

o Optimal performance with efficient linker cleavage, mask removal, antigen-binding, albumin-binding, and functional activity.

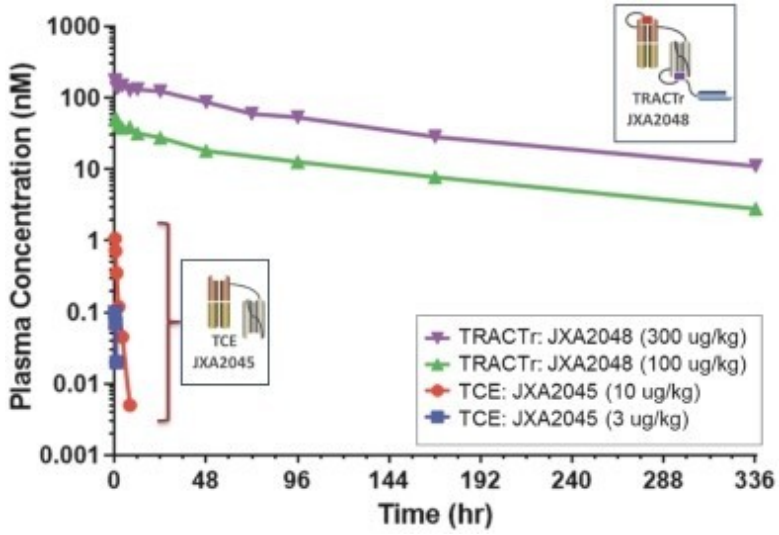
Our extensive library of masks and linkers combined with our protein engineering expertise allows us to generate product candidates that meet the high standards that we have set for therapeutic candidates that we believe have the potential to have clinical activity across a broad spectrum of indications.

Initial proof of technology study

To demonstrate proof of concept for TRACTrs, we tested a TRACTr and a first-generation TCE that targeted EGFR using identical antigen-binding domains. We assessed the risk of developing CRS by dosing both agents in non-human primates (NHPs), a species that was chosen because of the similarity in antigen binding affinities in these NHPs compared to humans, and demonstration that an EGFR bi-specific T cell engager (EGFR-BiTE, or EGFR-TCE) triggered significant CRS and healthy tissue toxicity up to and including death.

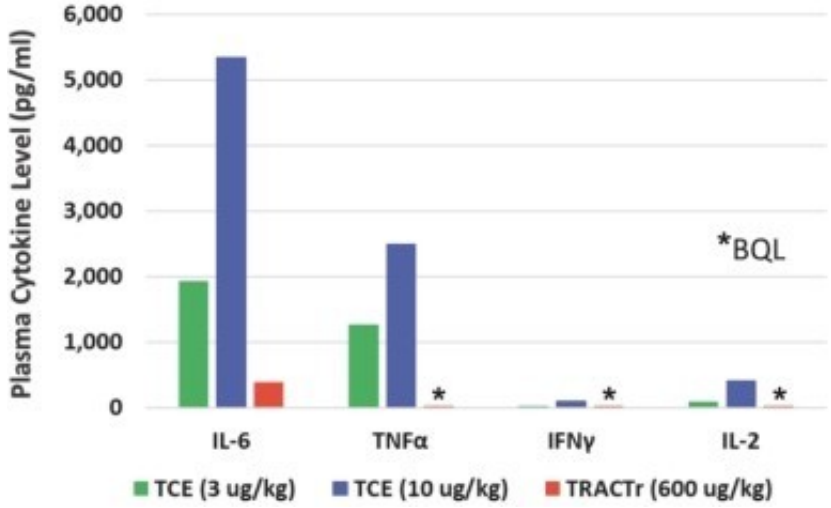
Our EGFR-TRACTr included an albumin-binding domain intended to increase its half-life in serum to extend the interval between dosing while simultaneously utilizing the protease-mediated cleavage of the linker to remove the domain once our TRACTr was activated. In NHPs, our EGFR-TRACTr was found to have a half-life of over 100 hours compared to approximately one hour for the corresponding EGFR-TCE, as demonstrated below. Furthermore, we believe the rapid elimination of the unmasked TCE minimizes the risk of TCE-induced CRS due to short circulation time in serum.

Figure 7. Our EGFR-TRACTr was shown to have an extended half-life in NHPs compared to a corresponding TCE while the unmasked form was rapidly eliminated



In this same study, a dose of 3µg/kg and 10µg/kg of the EGFR-TCE resulted in the release of high levels of the inflammatory cytokine IL-6. In comparison, 600µg/kg of our EGFR-TRACTr reduced those levels to less than 500pg/ml, shown below, even though the plasma levels were substantially higher with the TRACTr than the TCE. Published studies have shown median IL-6 levels of 122pg/ml in patients with Grade 0-3 CRS and 8,300pg/ml in Grade 4-5 CRS patients. A similar reduction in the other inflammatory cytokines measured was observed with our TRACTr compared to the EGFR-TCE.

Figure 8. Our EGFR-TRACTr did not lead to CRS in NHPs even at high doses. Inflammatory cytokines evaluated in this study included IL-6, tumor necrosis factor alpha (TNFa), interferon gamma (IFNg), and interleukin-2 (IL-2). TNFa, IFNg, and IL-2 were all below the quantification limit (BQL)

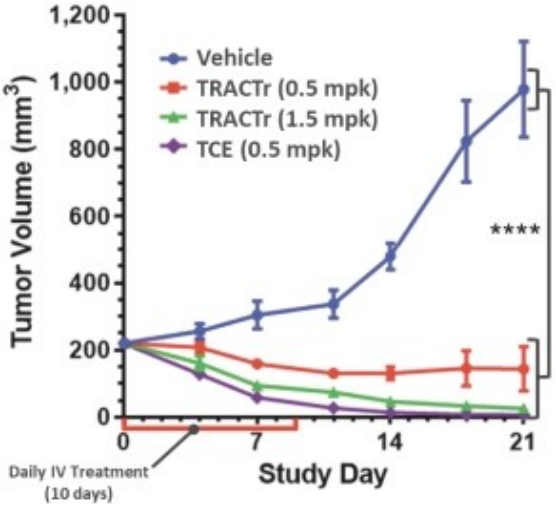


The lack of induction of inflammatory cytokines in NHPs associated with CRS in humans is consistent with the potential for the peptide masks to prevent antigen binding and thereby T cell activation. In these studies, the EGFR-TRACTr maximum tolerated dose (MTD) was higher than 600µg/kg due to a lack of CRS, lack of safety observations, and lack of healthy tissue toxicity. In contrast, a published study using a constant infusion of an EGFR-TCE observed an MTD of 30pM plasma levels and 300pM lethal dose plasma levels, where significant liver and kidney toxicities were reported. In similar models, our TRACTr dosed at 600µg/kg had no signs of toxicity and a Cmax of 360nM, further suggesting the potential for improvement in safety via masking.

In a separate study in a mouse model of human CRC using human HCT116 tumor cells and human immune cells, our EGFR-TRACTr displayed potent anti-tumor activity. As shown in the figure below, our EGFR-TRACTr dosed for 10 days at 1.5mg/kg led to significant tumor shrinkage, which was roughly equivalent to that observed with 0.5mg/kg of the EGFR-TCE.

With the observation of reduced CRS risk for our EGFR-TRACTr relative to the EGFR-TCE (at a substantially lower dose than the TRACTr) in our NHP study, and the observation of comparable anti-tumor activity of our EGFR-TRACTr and the EGFR-TCE (at one third of the dose of the our TRACTr) in our mouse model of human CRC, we believe our EGFR-TRACTr may offer reduced CRS risk relative to the EGFR-TCE when dosed at levels expected to result in anti-tumor activity in humans.

Figure 9. Our EGFR-TRACTr led to significant tumor shrinkage in an HCT116 mouse tumor model



Our Lead Programs

Our lead TRACTr clinical candidates are designed to target PSMA and EGFR. These tumor targets are clinically validated and implicated in solid tumors with high prevalence, including mCRPC, CRC, RCC, SCCHN, and NSCLC. Our wholly-owned pipeline is summarized below:

Program	Target(s)	Initial Indication(s)	Stage of Development: Discovery / IND-Enabling / Phase 1 / Phase 2 / Phase 3
TRACTr Programs			
PSMA-TRACTr JANX007	PSMAxCD3	mCRPC	
EGFR-TRACTr JANX008	EGFRxCD3	CRC, SCCHN, NSCLC, RCC	
Unnamed TRACTr Programs			
TRACTr	TxCD3	Undisclosed	
Unnamed TRACIr Programs			
TRACIr	TxCD28	Undisclosed	

Our PSMA-TRACTr (JANX007) for the treatment of mCRPC

We are developing our PSMA-TRACTr product candidate for the treatment of mCRPC. In a preclinical study, PSMA-TRACTr showed a 500-fold reduced ability to induce T cell-mediated killing of prostate cancer cells when masked compared to when unmasked. In addition, we found that our PSMA-TRACTr was well-tolerated in NHPs, substantially reduced cytokine release relative to the unmasked TCE, and had a prolonged half-life. In February 2024 we announced updated interim clinical data for JANX007 which displayed meaningful PSA drops, and a favorable safety profile, low-grade CRS, and PK, consistent with the TRACTr mechanism-of-action.

Prostate cancer overview

Excluding nonmelanoma skin cancer, prostate cancer is the most common type of cancer in men and the second most common type of cancer in the United States. Over 3 million men live with prostate cancer in the United States alone and prostate cancer represents approximately 15 percent of all new cancer cases in the United States. Approximately 13 percent of men will be diagnosed with prostate cancer at some point during their lifetime. In 2023, there was an estimated 288,300 new prostate cancer diagnoses in the United States, representing over ten percent of all new cancer diagnoses. An estimated eight percent of prostate cancer patients develop metastatic disease, which is associated with a five-year survival rate of approximately 34 percent. There were an estimated 34,700 deaths in the United States due to prostate cancer in 2023.

Treatment options for prostate cancer

Patients diagnosed with the localized, low-risk disease may be followed by active surveillance or treated with definitive therapy by prostatectomy or radiation therapy. Patients with recurrent disease are typically treated with androgen deprivation therapy (ADT), and if high risk, ADT combined with chemotherapy or addition of novel hormonal therapy. Androgens, including testosterone and dihydrotestosterone, activate androgen receptor-dependent gene transcription, which drives the growth of prostate cancer cells. ADT blocks testicular production of testosterone, otherwise known as a chemical castration, and is administered for those patients who present initially with regional or advanced disease at diagnosis or develop advanced disease at recurrence. Most ADT-treated patients develop castration-resistant prostate cancer (CRPC) and progress.

Treatment options for mCRPC

Standard therapies for these patients include novel hormonal agents, which either further suppress androgen synthesis (abiraterone), or efficiently block Androgen receptor signaling (enzalutamide). Further treatment options range from cytotoxic chemotherapy (taxanes), Radium-223, or immunotherapy (sipuleucel-T), and an autologous activated antigen presenting cell therapy. In 2022, the FDA approved Pluvicto, a targeted therapy that delivers radiation treatment directly to PSMA+ cells. Despite only being approved in third-line or later patients, the product reached sales of $980 million in 2023, displaying the high unmet need for these late-stage patients. PARP inhibitors and immune checkpoint inhibitors are also approved, but for only small subsets of patients. The median overall survival (mOS) of patients with mCRPC in multiple Phase 3 trials is approximately 12-18 months and has been augmented by only 2-5 months by the best agents, highlighting the need for more effective therapies in mCRPC.

PSMA is a validated prostate cancer antigen

PSMA is a prostate-specific transmembrane protein expressed at a 100-fold to a 1,000-fold higher level in prostate adenocarcinoma than in the benign prostate. Of importance, PSMA expression is (i) increased when patients are on ADT and (ii) highest in high-grade and mCRPC. Over half of prostate cancer patients treated with radical prostatectomy with high levels of PSMA are likely to have recurrent disease, at a rate that is twice that of patients observed with low levels of PSMA. PSMA is the target of FDA-approved imaging agent, ProstaScint, TCEs, radioisotopes, and ADCs in development.

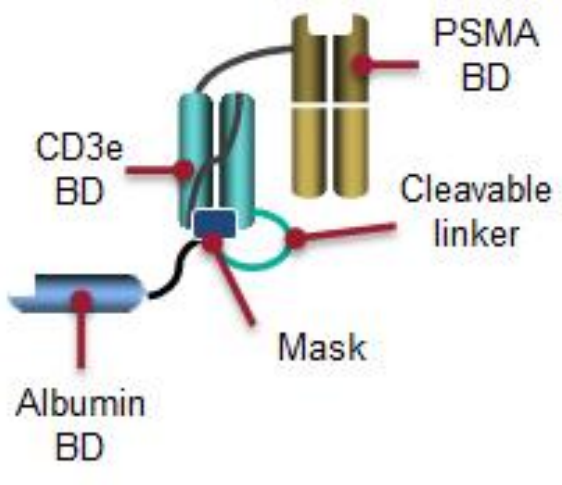
Clinical results published in the journal Immunotherapy in 2020 from a Phase 1 trial of pasotuxizumab, a PSMA-targeted TCE, highlight the potential of targeting mCRPC with a PSMA-targeted TCE and the limitations of current approaches. Patients in this trial were initially treated with daily subcutaneous injections, but anti-drug antibodies (ADAs) developed in all treated patients, likely due to the high doses administered. These high doses of the drug, which have a short half-life, were required to achieve sufficient drug exposure to the tumor. The trial was then amended so that clinicians could dose patients using continuous intravenous infusion. Prostate-specific antigen (PSA) levels are a validated measure of disease severity in prostate cancer patients. A dose-dependent reduction in serum PSA levels was observed in the intravenous group, achieving a median best PSA change from baseline of approximately 55 percent in the high dose group. The percentage of patients with PSA reduction of greater than 50 percent in the top three groups was 33 percent. Two patients had long-term PSA responses. One patient had long-term stable disease with 337 days to tumor progression. One patient had near-complete regression of lymph node lesions and bone metastases, with 500 days to disease progression. One of the patients who had initially presented with extensive metastatic disease had a reduction in PSA of greater than 96 percent. Within 43 days of treatment, the extent of the PSMA-expressing tumor was significantly reduced. By day 85, there was little evidence of tumor remaining. While no on-target healthy tissue toxicity was reported, treatment-emergent increases in alanine

aminotransferase and aspartate aminotransferase did occur, and over half of patients in this trial developed Grade 3 or Grade 4 drug-related SAEs. Three patients dosed with continuous infusion developed CRS; two were Grade 2 and one was Grade 3.

We believe that our TRACTr platform technology can be used to create a PSMA-TCE with the potential to build upon the preliminary signs of anti-tumor activity observed with pasotuxizumab through improved pharmacokinetics and reduced risk of CRS toxicity.

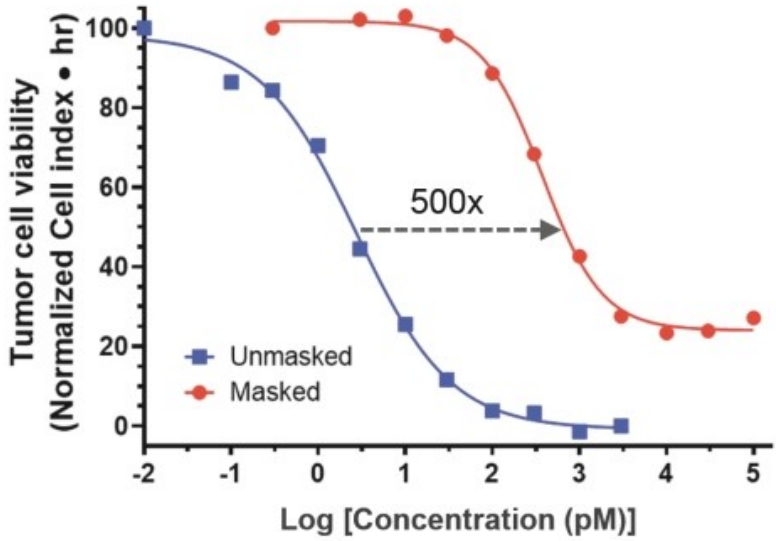
Our solution: JANX007

We designed JANX007 as a single-masked TRACTr in which the PSMA-binding domain is unmasked. The T cell-specific binding domain (CD3e) is masked to prevent CRS. We illustrate the JANX007 structure in the figure below.



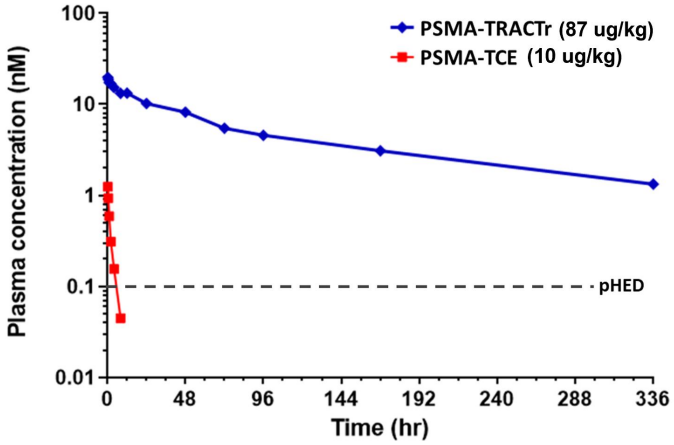
We found that our PSMA-TRACTr product candidate exhibited a 500-fold shift in activating T cell killing of PSMA expressing tumor cells in an in vitro assay when it was masked than when the mask was removed, as shown in the figure below. We believe this difference in activity has the potential to greatly reduce toxicities caused by PSMA expression outside of tumors.

Figure 10. Our masked PSMA-TRACTr was 500-fold less potent in activating T cell killing of PSMA expressing tumors than when the mask was removed in an *in vitro* assay



In NHPs, our PSMA-TRACTr demonstrated a half-life of approximately 119 hours. In comparison, pasotuxizumab was reported to have a half-life of one to three hours in humans and required continuous intravenous infusion for 5 weeks to maintain sufficient drug exposure, representing a significant burden for patients. The figure below illustrates our PSMA-TRACTr and the PSMA-TCE half-lives in NHPs. For comparison, the projected human efficacious dose (pHED) of 100pM for pasotuxizumab based on the clinical trial protocol for its Phase 1 study is also shown.

Figure 11. Our PSMA-TRACTr had a half-life of 119 hours in NHPs

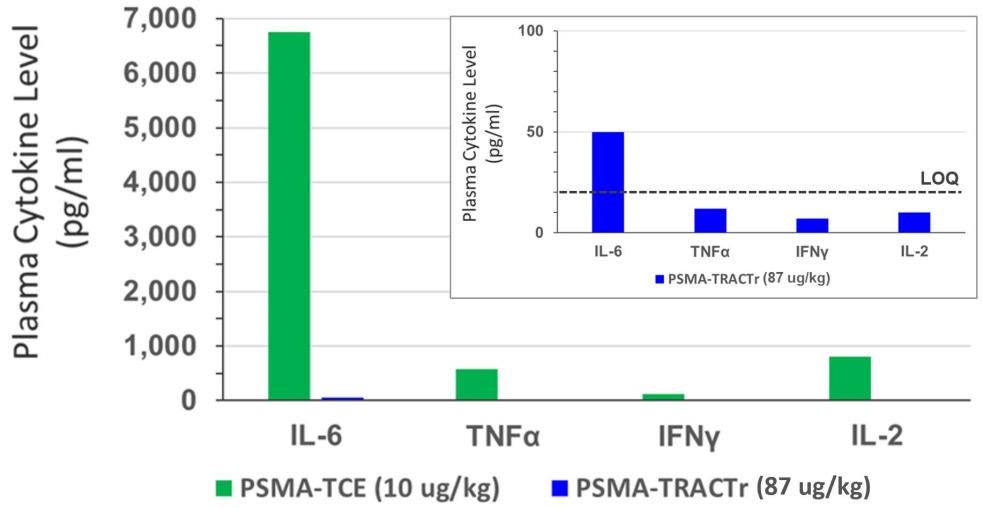


TRACTr	
Dose (ug/kg)	87
C_{max} (nM)	18
$t_{1/2}$ (hr)	119
Vd (L)	0.18
CL (mg/hr/kg)	0.34

In this same study, dosing our PSMA-TRACTr at 87µg/kg resulted in minimal levels of inflammatory cytokine production relative to an unmasked PSMA-TCE at 10µg/kg, which led to a greater than 130-fold

expression of IL-6 as shown in the figure below. We believe these data suggest our PSMA-TRACTr will have the potential to reduce CRS risk relative to an unmasked PSMA-TCE. Furthermore, in a separate study of our PSMA-TRACTr dosed at 1,000µg/kg once-weekly for three weeks in NHPs, no dose-limiting toxicities were identified.

Figure 12. Dosing of our PSMA-TRACTr in NHPs had minimal effects on inflammatory cytokine levels, several of which were below the limit of quantification (LOQ). In contrast, dosing of a PSMA-TCE led to substantial levels of IL-6 as well as elevation of other inflammatory cytokines commonly observed in CRS.



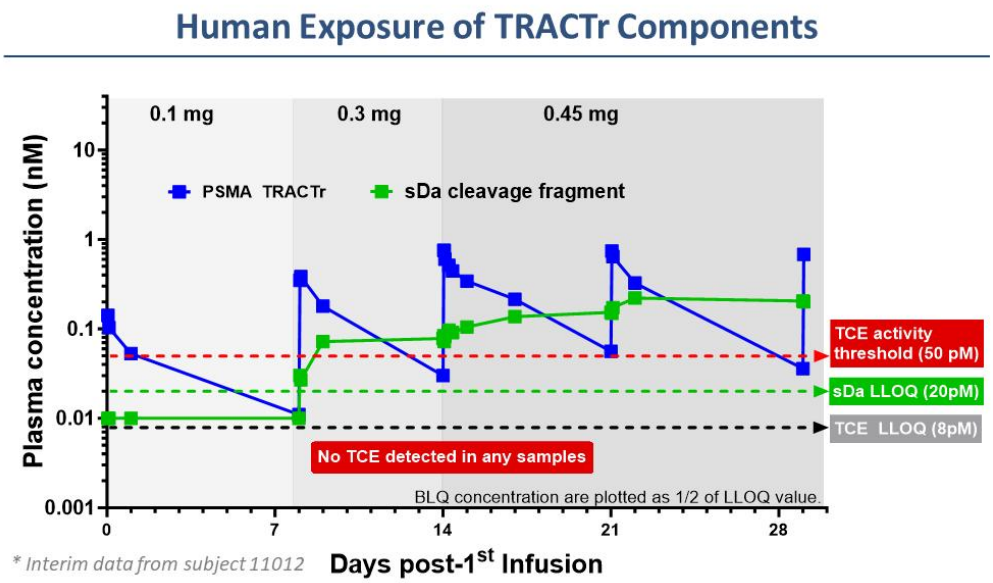
Clinical development

In October 2022, the first patient was dosed with our PSMA-TRACTr (JANX007) in our first-in-human Phase 1 clinical trial in patients with prostate cancer. This study is an open-label, multicenter study to assess the safety, tolerability, PK, PD, and the preliminary efficacy of JANX007 administered as a single agent in adult subjects with mCRPC (NCT05519449). In February 2024 we announced updated interim clinical data for JANX007 which displayed meaningful PSA drops, and a favorable safety profile, low-grade CRS, and PK, consistent with the TRACTr mechanism-of-action.

PK data

JANX007 interim PK data in humans showed consistency with tumor cleavage dependent activity and TRACTr cleavage was observed without TCE accumulation. We believe this is consistent with TRACTr design principles and our desired mechanism of action. Specifically, the sDa cleavage fragment indicates TRACTr activation is occurring and we observed TRACTr and TCE plasma levels below the preclinical activity threshold with no TCE detected in any samples, displaying activation was occurring without TCE accumulation in blood.

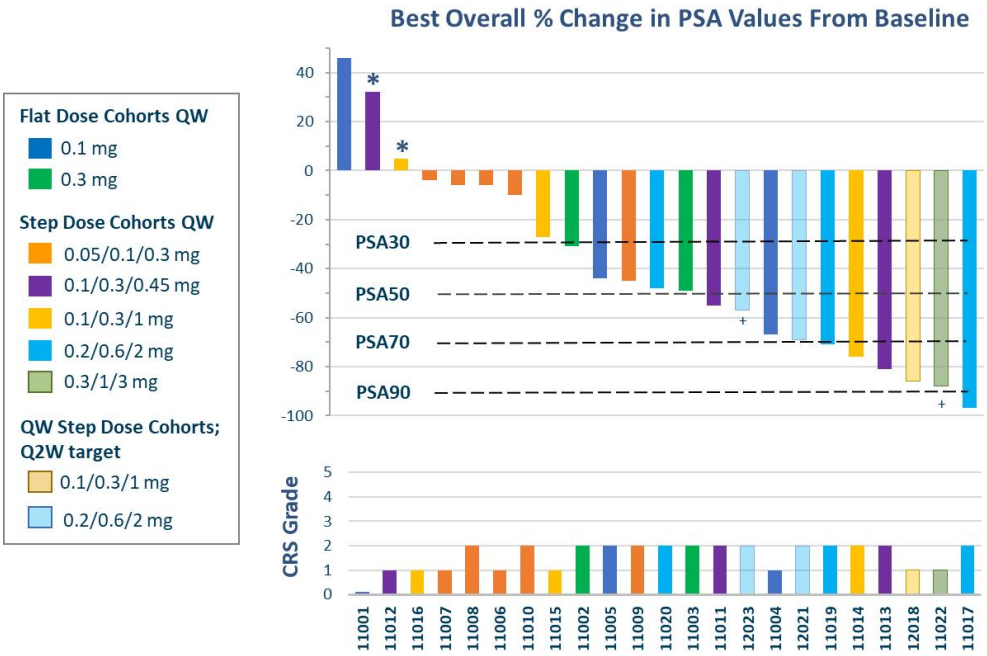
Figure 13. Interim clinical PK data has been consistent with TRACTr design principles: TRACTr cleavage without TCE accumulation observed



Safety and efficacy data

As of February 12, 2024, 23 subjects were treated with JANX007 in the dose escalation portion of the Phase 1a clinical trial. The subjects enrolled in the trial were heavily pre-treated with a median of 4+ lines of therapy. An increasing depth of PSA declines and RECIST responses at higher doses were observed, while adverse events have remained generally low-grade and transient. At a starting dose ≥ 0.1 mg, 14 of 18 (78%) subjects achieved PSA30 declines and 10 of 18 (56%) subjects achieved PSA50 declines. At a starting step dose of ≥ 0.2 mg, 6 of 6 (100%) subjects achieved PSA30 declines and 5 of 6 (83%) subjects achieved PSA50 declines. Initial step doses of JANX007 ≥ 0.2 mg drove deeper and more durable PSA responses, including one subject that achieved a PSA90 decline.

Figure 14. Meaningful PSA reductions observed with manageable CRS (February 12, 2024 cutoff)



Cytokine Release Syndrome (CRS) was observed to be temporary and mild, presenting only as low-grade 1 or 2 events, and was quickly managed with treatment. These incidents of CRS were mainly reported during the first treatment cycle, with no subsequent occurrences in later cycles. Similarly, the majority of TRAEs not associated with CRS were of low severity (Grade 1 or 2) and also primarily occurred in the initial cycle. There was a low incidence of Grade 3 TRAEs, and no Grade 4 or 5 events were observed. JANX007 has been administered at doses up to 3mg, significantly exceeding the anticipated maximum tolerable dose for the parental T cell engager, while the maximum tolerable dose for the TRACTr has not yet been established.

Figure 15. Treatment related adverse events in ≥ 2 subjects (February 12, 2024 cutoff)

Preferred Term	All Subjects (n=23)			
	Grade 1	Grade 2	Grade ≥3	All Grades
Cytokine release syndrome	8 (35)	13 (57)	0	21 (91)
Diarrhoea	6 (26)	2 (9)	0	8 (35)
Chills	4 (17)	2 (9)	0	6 (26)
ALT increased	3 (13)	1 (4)	1 (4)	5 (22)
Anaemia	1 (4)	2 (9)	2 (9)	5 (22)
AST increased	4 (17)	1 (4)	0	5 (22)
Fatigue	2 (9)	2 (9)	0	4 (17)
Decreased appetite	4 (17)	0	0	4 (17)
Nausea	3 (13)	1 (4)	0	4 (17)
Headache	3 (13)	0	0	3 (13)
Blood bilirubin increased	2 (9)	1 (4)	0	3 (13)
Hypoalbuminaemia	2 (9)	1 (4)	0	3 (13)
Hypocalcaemia	3 (13)	0	0	3 (13)
Hypophosphataemia	1 (4)	2 (9)	0	3 (13)
Leukopenia / white blood cell count decreased	3 (13)	0	0	3 (13)

Preferred Term	All Subjects (n=23)			
	Grade 1	Grade 2	Grade ≥3	All Grades
Myalgia	1 (4)	2 (9)	0	3 (13)
Platelet count decreased / thrombocytopenia	2 (9)	1 (4)	0	3 (13)
Pyrexia	2 (9)	1 (4)	0	3 (13)
Vomiting	0	2 (9)	0	3 (13)
Blood alkaline phosphatase increased	2 (9)	0	0	2 (9)
Dysgeusia	2 (9)	0	0	2 (9)
Hypomagnesaemia	2 (9)	0	0	2 (9)
Lipase increased	0	1 (4)	1 (4)	2 (9)
Stomatitis	2 (9)	0	0	2 (9)

Our EGFR-TRACTr (JANX008) for the treatment of colorectal cancer, head and neck cancer, renal cell cancer and non-small cell lung cancer

JANX008 is being studied in a Phase 1 clinical trial for the treatment of multiple solid cancers including CRC, SCCHN, RCC, and NSCLC. The first patient for this trial was dosed in April 2023 and in February 2024 we announced positive early data JANX008 that displayed anti-tumor activity in multiple tumor types with low-grade CRS and predominantly low-grade TRAEs. We believe that our EGFR-TRACTr product candidate has the potential to deliver therapeutic benefits to patients while minimizing SAEs, including on-target, off-tumor healthy tissue toxicities and dose-limiting CRS.

Colorectal cancer overview

Most colorectal cancers are a type of tumor called adenocarcinoma, cancer of the cells that line the inside tissue of the colon and rectum. However, other less frequently arising colorectal tumors include a neuroendocrine tumor of the gastrointestinal tract, gastrointestinal stromal tumor, small cell carcinoma, and lymphoma.

Excluding non-melanoma skin cancers, colorectal cancer is the fourth most common cancer diagnosed in the United States. It is estimated that there were approximately 153,020 new cases of colorectal cancer in the United States in 2023 and approximately 52,550 deaths. Approximately 25 percent of patients have metastatic disease at diagnosis, meaning the disease has spread to other organs, and about 50 percent of patients with CRC will eventually develop metastases. Approximately 35 percent of the patients with a new diagnosis of CRC, and approximately 85 percent of patients with a new metastatic CRC diagnosis, will die within five years. Furthermore, the cumulative recurrence rate of CRC at four years is 100 percent.

EGFR is a validated colorectal cancer target

EGFR is the most commonly overexpressed membrane protein in cancer. In CRC, up to approximately 80 percent of patients overexpress EGFR, and higher expression levels have been linked to more aggressive metastatic disease, which is associated with poor prognosis, including decreased disease-free survival and overall survival (OS). However, EGFR expression is not limited to tumors and is widely expressed throughout the body, resulting in systemic toxicities with EGFR-directed therapies.

Treatment options for mCRC

Treatment of CRC typically involves cytotoxic chemotherapy in a regimen containing folinic acid, fluorouracil, and irinotecan, called FOLFIRI, and radiation. Anti-EGFR mAbs such as cetuximab (ERBITUX, marketed by Eli Lilly) and panitumumab (VECTIBIX, marketed by Amgen and Takeda) can be added to standard

therapy. However, only a relatively small percentage of patients respond to mAb therapies, and of those that do, resistance often develops. Of the CRC patients that are resistant to EGFR mAb treatment, 35 percent to 45 percent are resistant due to KRAS mutations. Treatment with EGFR mAbs is not recommended for patients with KRAS mutations. This suggests that if an anti-EGFR therapeutic that could treat all EGFR overexpressing patients harboring KRAS mutations was developed, the potential treatable population could be significantly expanded.

A combination of nivolumab (OPDIVO) and ipilimumab (YERVOY), which are both marketed by Bristol Myers Squibb, as well as pembrolizumab monotherapy (KEYTRUDA, marketed by Merck & Co.), have been approved for the treatment of microsatellite instability-high (MSI-high) CRC. This is a small subset of CRC patients with mutations that lead to high genetic instability. These results suggest that EGFR-directed immunotherapies have the potential to treat CRC and that, at least in some patients, there are sufficient T cells to mount an effective immune response.

Head and neck cancer overview

Cancers known collectively as head and neck cancers usually begin in the squamous cells that line the moist, mucosal surfaces inside the head and neck, otherwise known as squamous cell carcinomas. Cancers of the head and neck are further categorized by the area of the head or neck in which they begin: oral cavity, pharynx, larynx, paranasal sinuses and nasal cavity and salivary glands. Head and neck cancers account for approximately four percent of all cancers in the United States and are more than twice as common among men as they are among women. Researchers estimate that approximately 66,920 men and women in the United States were diagnosed with head and neck cancers in 2023. Additionally, there were an estimated 15,400 deaths from head and neck cancer in 2023. EGFR is overexpressed in approximately 90 percent of head and neck cancers.

Treatment options for SCCHN

Locoregional SCCHN is treated with curative intent but at the cost of functional impairment and locoregional recurrence or metastatic disease. Standard first-line treatment for recurrent or metastatic (R/M) disease that is not amenable to local therapy was for more than a decade, cetuximab, an EGFR antibody, plus chemotherapy with platinum and 5-fluorouracil (the EXTREME regimen), which provides a mOS of about 10 months and is associated with substantial adverse events.

A significant number of cancer patients fail to respond to immunomodulatory agents regardless of PD-L1 expression, presumably because of tumor resistance mechanisms against immune attacks.

Non-small cell lung cancer overview

It is estimated that there were approximately 238,340 new lung cancer cases and 127,070 lung cancer deaths in the United States in 2023. NSCLC accounts for approximately 80 to 85 percent of lung cancer cases. The overall five-year survival for all patients diagnosed with NSCLC is approximately 28 percent.

Treatment options for NSCLC

Targeted therapies have been developed for NSCLC patients with tumors containing alterations in EGFR and anaplastic lymphoma kinase gene (ALK); however, less than thirty percent of patients are eligible for these therapies. Patients ineligible or resistant to these therapies can be treated with immune checkpoint inhibitors. This treatment regimen significantly improves progression-free survival (PFS) and OS compared to standard chemotherapy. However, despite the availability of these therapies, very few patients are cured of their disease, and the prognosis in NSCLC remains poor.

Renal cell carcinoma overview

Renal cell carcinoma, or kidney cancer, is a disease in which malignant cells are found in the lining of tubules in the kidney. RCC is the deadliest urological neoplasm and late-stage disease has a five-year survival rate of approximately 22%. The American Cancer Society's estimates for kidney cancer in the United States for 2023 are approximately 81,800 new cases of kidney cancer were diagnosed and approximately 14,890 people will die from this disease.

Treatment options for RCC

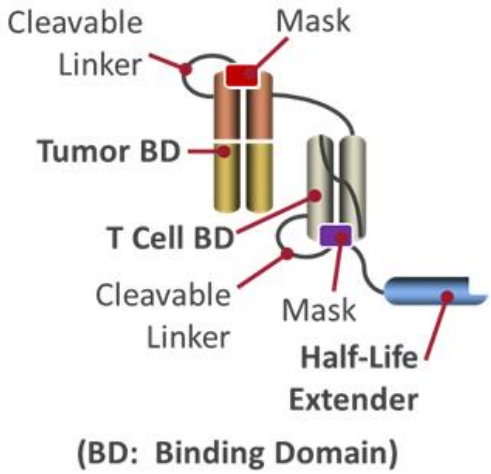
In RCC, greater than 90 percent of patients express EGFR. Treatment of 1L mRCC typically involves the combination of a PD1 or PDL1 checkpoint inhibitor (pembrolizumab, nivolumab, avelumab) with an anti-VEGFR TKI such as axitinib, cabozantinib or lenvatinib. Alternatively, nivolumab may be combined with the CTLA-4 checkpoint inhibitor ipilimumab. The use of single agent anti-VEGF TKI's such as sunitinib is declining due to data from the checkpoint combinations, however usage still remains as an option in the more favorable risk patients. In the 1L setting with checkpoint inhibitor combinations, the objective response rates range from approximately 40-70% with median PFS (mPFS) from 12-24 months and mOS typically being greater than 37 months.

Almost all 1L patients become resistant to standard therapy with less than 50% being eligible to receive 2L therapy. The majority of 2L patients typically receive an anti-VEGR agent such as cabozantinib. Limited data exists for anti-VEGF therapy outcomes in checkpoint refractory patients. The most widely used 2L treatment option is cabozantinib, which has reported objective response rates of only 17%, with mPFS of 7.4 months and mOS of only 21 months. Over 80% of patients receive little to no benefit of SOC 2L treatment options.

Our solution: JANX008

We designed JANX008 as a dual-masked TRACTr in which both the EGFR and T cell-binding domains are designed to be masked. We illustrate the JANX008 structure below.

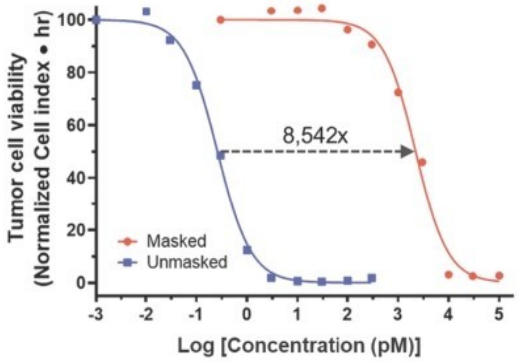
Figure 16. Structure of JANX008



We found that our EGFR-TRACTr product candidate exhibited an 8,500-fold shift in activating T cell killing of EGFR expressing HCT116 tumor cells in an in vitro assay when it was masked than when the mask was removed, as shown below. We believe this differential in activity can significantly reduce healthy tissue toxicities caused by EGFR expression outside of tumors.

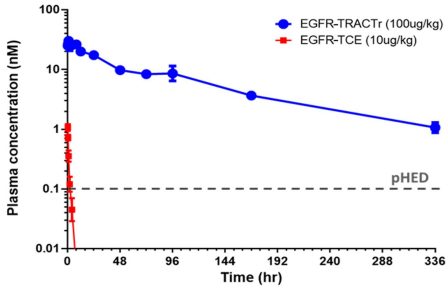
Since these cells harbor KRAS mutations and are resistant to anti-EGFR antibodies, the observed EGFR-TCE activity suggests that EGFR inhibitor-resistant (including KRAS mutants sensitive to our EGFR-TRACTr) CRC will be sensitive to our EGFR-TRACTr. Our observation is consistent with published studies demonstrating EGFR-TCE activity in cell lines resistant to EGFR mAbs and harbored KRAS mutations. The results of our study are depicted in the figure below.

Figure 17. Our masked EGFR-TRACTr was over 8,500-fold less potent at T cell-mediated killing of EGFR-expressing tumor cells than an equivalent unmasked TCE in an *in vitro* assay



In NHPs, our EGFR-TRACTr demonstrated a half-life of approximately 94 hours. This compares to the half-life of the unmasked EGFR-TCE of approximately one hour. In figure 16, we illustrate our EGFR-TRACTr and the EGFR-TCE half-lives in a study in NHPs.

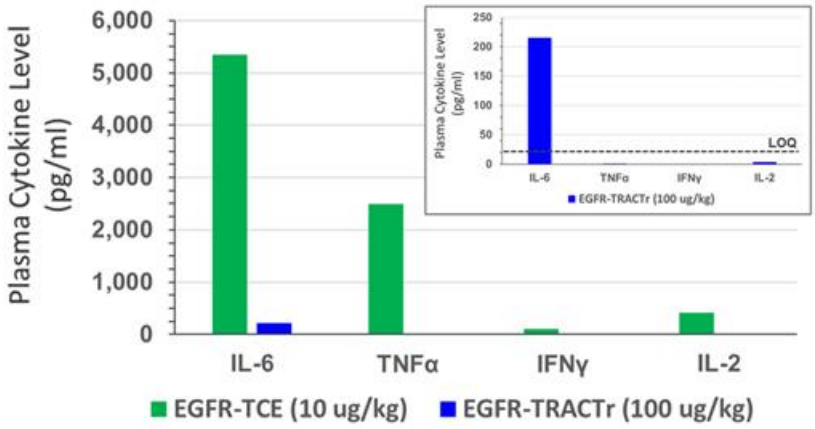
Figure 18. Our EGFR-TRACTr had a half-life of approximately 94 hours in NHPs



TRACTr	
Dose (ug/kg)	100
C_{max} (nM)	27
$t_{1/2}$ (hr)	94
Vd (L)	0.12
CL (mg/hr/kg)	0.28

In this same study, dosing our EGFR-TRACTr at 100µg/kg resulted in minimal levels of inflammatory cytokine release, relative to an unmasked EGFR-TCE at 10µg/kg, which led to a greater than 20-fold expression of IL-6. We believe these data suggest that our EGFR-TRACTr has the potential to reduce CRS risk relative to an unmasked EGFR-TCE. Furthermore, in a separate, study of our EGFR-TRACTr dosed at 600µg/kg once-weekly for three weeks in NHPs, no dose-limiting toxicities were identified.

Figure 19. Dosing of our EGFR-TRACTr in NHPs had minimal effects on inflammatory cytokine levels. In contrast, dosing of an EGFR-TCE led to substantial levels of IL-6 as well as elevation of other inflammatory cytokines commonly observed in CRS



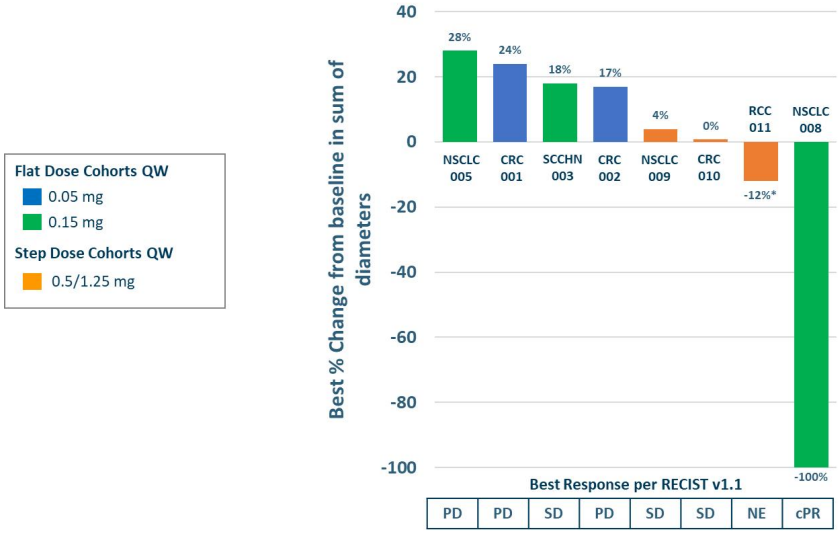
Clinical development

JANX008 is being studied in a Phase 1 clinical trial for the treatment of multiple solid cancers including CRC, SCCHN, RCC, and NSCLC. The first patient for this trial was dosed in April 2023 and in February 2024 we announced positive early data JANX008 that displayed anti-tumor activity in multiple tumor types with low-grade CRS and predominantly low-grade TRAEs.

Safety and efficacy data

As of February 12, 2024, 11 heavily pre-treated, late-stage subjects across all four tumor types have been enrolled. Encouraging signs of clinical activity were observed, while a favorable safety profile was maintained. In one subject with NSCLC treated with JANX008 at 0.15mg once weekly (QW), a confirmed partial response (PR) by RECIST criteria with 100% reduction of the target lung lesion and elimination of liver metastasis with no CRS or TRAEs has been observed. This subject remains on treatment and their PR has been maintained through their week-18 scan. One subject with RCC experienced a 12% reduction in the size of a large RCC mass and significant clinical benefit with Grade 1 CRS.

Figure 20. Encouraging anti-tumor activity observed in early cohorts (February 12, 2024 cutoff)



The early safety data for JANX008 has been consistent with the TRACTr design principles of tumor-specific activation while avoiding healthy tissue toxicity with a broadly expressed target. In the 11 subjects enrolled at doses up to 1.25mg, which is significantly above the projected maximum tolerable dose of the parental T cell engager, Grade 1 CRS was observed in only two subjects and no Grade 2 or higher CRS was seen. The majority of non-CRS TRAEs were also low-Grade 1 or 2 and occurred predominantly in cycle one. No treatment related serious adverse events or dose-limiting toxicities have been observed.

Figure 21. Treatment related adverse events (February 12, 2024 cutoff)

TRAE Preferred Term	All Subjects (n=11)			
	Grade 1	Grade 2	Grade ≥3	All Grades
Arthralgia	3 (27)	0	0	3 (27)
Anemia	0	1 (9)	1 (9)	2 (18)
Cytokine release syndrome	2 (18)	0	0	2 (18)
Dermatitis acneiform	2 (18)	0	0	2 (18)
Nausea	2 (18)	0	0	2 (18)
Rash maculopapular	1 (9)	1 (9)	0	2 (18)
Back pain	1 (9)	0	0	1 (9)
Diarrhea	1 (9)	0	0	1 (9)
Dizziness	1 (9)	0	0	1 (9)
Fatigue	1 (9)	0	0	1 (9)
Headache	0	1 (9)	0	1 (9)
Hyperglycemia	1 (9)	0	0	1 (9)
Hypokalemia	1 (9)	0	0	1 (9)
Hypophosphatemia	1 (9)	0	0	1 (9)
Injection site irritation	1 (9)	0	0	1 (9)

TRAE Preferred Term	All Subjects (n=11)			
	Grade 1	Grade 2	Grade ≥3	All Grades
Lymphocyte count decreased	0	1 (9)	0	1 (9)
Oedema peripheral	1 (9)	0	0	1 (9)
Oral pain	0	1 (9)	0	1 (9)
Pain in extremity	1 (9)	0	0	1 (9)
Pyrexia	1 (9)	0	0	1 (9)
Vomiting	1 (9)	0	0	1 (9)

Manufacturing

Certain features of our TRACTr and TRACIr molecules allow for their development, manufacturing and control processes to closely resemble those used for standard monoclonal antibodies. First, our TRACTr and TRACIr molecules are readily expressed at high levels recombinantly in common Chinese hamster ovary cells. Second, our TRACTr and TRACIr molecules bind protein A via the anti-albumin-binding domain. Protein A affinity chromatography is the standard technique for capturing recombinant monoclonal antibodies and is a very robust purification procedure due to its specificity. After the protein A affinity chromatography step, TRACTrs and TRACIrs are further purified and polished using standard ion exchange, hydrophobic-interaction and/or multi-modal chromatography, virus filtration, and ultrafiltration/diafiltration formulation steps. Our dosing strategy gives us the advantage of manufacturing at relatively modest scale and formulating our drug products at low protein concentrations in typical formulation matrices. Through developability and manufacturability assessments, we continue to verify that our TRACTr and TRACIr constructs have advantageous properties that include high solubility, minimal aggregation, and good stability. We believe all these attributes allow our products to be manufactured at a substantially lower cost than monoclonal antibodies.

We do not own or operate and currently have no plans to establish current good manufacturing practice (cGMP) manufacturing facilities and laboratories. We currently rely on third-party manufacturers and suppliers for the raw materials and starting components used to make our TRACTrs and TRACIrs, and we expect to continue to do so to meet our development, clinical and commercial needs. Our third-party manufacturers are qualified to manufacture our product candidates under cGMP requirements and other applicable laws, guidance and regulations. We believe there are multiple sources for all of the materials and components required for the manufacture of our product candidates.

All of our TRACTrs and TRACIrs are and will continue to be manufactured from a vial of a master cell bank or working cell bank of that biologic therapeutic's production cell line. We have or intend to have one master cell bank for each TRACTr and TRACIr that was or will be produced and tested in accordance with cGMP and applicable regulations. Each master cell bank is or will be stored in two independent locations, and we intend to produce working cell banks for each product candidate later in the course of product development. It is possible that we could lose our cell banks from our storage locations and have our manufacturing severely impacted by the need to replace the cell banks. However, we believe we have an adequate backup should any particular cell bank be lost in a catastrophic event.

We currently and plan to continue to obtain bulk drug substance (BDS) for our TRACTrs and TRACIrs from a single-source third-party contract manufacturer. While any reduction or halt in the supply of BDS from this contract manufacturer could limit our ability to develop our product candidates until a replacement contract manufacturer is found and qualified, we believe that we will have sufficient BDS to support current and future clinical trial programs. We have developed our supply chain for each of our product candidates and intend to continue to put in place agreements under which our third-party contract manufacturers will generally provide us with necessary quantities of BDS and drug product on a project-by-project basis, based on our development and commercial supply needs.

Competition

The pharmaceutical and biotechnology industries are characterized by rapidly advancing technologies, intense competition, and a strong emphasis on proprietary products. While we believe that our technology, development experience, and scientific knowledge provide us with competitive advantages, we face potential competition from many different sources, including large pharmaceutical and biotechnology companies, academic institutions, government agencies, and other public and private research organizations that conduct research, seek patent protection, and establish collaborative arrangements for the research, development, manufacturing, and commercialization of cancer immunotherapies. Any product candidates that we successfully develop and commercialize will compete with new immunotherapies that may become available in the future.

We compete in the segments of the pharmaceutical, biotechnology, and other related markets that develop immuno oncology treatments. Many other companies have commercialized and/or are developing immuno oncology treatments for cancer including large pharmaceutical and biotechnology companies, such as AbbVie, Amgen, AstraZeneca, Bristol Myers Squibb, Gilead, Johnson & Johnson, Merck & Co., Novartis, Pfizer, Regeneron and Roche/Genentech.

We face significant competition from pharmaceutical and biotechnology companies that target specific tumor-associated antigens using immune cells or other cytotoxic modalities. These generally include immune cell

redirecting therapeutics (e.g., T cell engagers, T cell immunomodulators), adoptive cellular therapies (e.g., CAR T cell therapies), antibody-drug conjugates, targeted radiopharmaceuticals, targeted immunotoxin, and targeted cancer vaccines.

With respect to our lead PSMA-TRACTr, we are aware of other competing PSMA-targeting clinical-stage therapeutics, which include, but are not limited to: T cell engagers from Amgen, Crescendo Biologics, Johnson and Johnson, Lava Therapeutics, Chugai/Roche and Regeneron; T cell immunomodulators from Regeneron and Johnson & Johnson; antibody-drug conjugates from Ambrx; CAR T cell therapies from Tmunity Therapeutics/Gilead; and radiopharmaceuticals from Novartis, Lantheus/Lilly/Point Biopharma, Fusion Pharmaceuticals, Telix and Bayer.

With respect to our EGFR-TRACTr, we face competition from several targeted therapies approved by the FDA to treat NSCLC, SCCHN, RCC and CRC, including, but not limited to, Genmab/Janssen's amivantamab, Roche's bevacizumab, Amgen's panitumumab, Eli Lilly/Merck KGaA's cetuximab, Bayer's regorafenib, and Eli Lilly's ramucirumab. We also face competition from other anti-EGFR immunotherapies that are in clinical development. We believe that the most advanced candidates are those being developed by Amgen/CytomX, AstraZeneca/Fusion, Bristol Myers Squibb, Dragonfly, Lava Therapeutics/Pfizer, Merus, Regeneron, Chugai/Roche, and Takeda.

With respect to our CD28 TRACIr platform, we are aware of other CD28-based multispecifics that are in clinical development for solid tumors. We believe the most advanced candidates are Regeneron's nezastomig, REGN5668 and REGN7075, Sanofi's SAR443216, and Janssen/Xencor's XmAb808 and Johnson & Johnson's JNJ-9401. Additional competition may come from other companies developing costimulatory multispecifics, including, but not limited to Genmab/BioNTech, Inhibrx, Incyte/Merus, and Chugai/Roche.

We are currently developing a pipeline of TRACTr and other protease-activated therapeutics that face increasing competition from other biologic prodrug developers, which include, but are not limited to, Adagene, BioAtla, Chugai Pharmaceutical Co./Roche Holding AG, CytomX Therapeutics, Harpoon Therapeutics, Merck & Co., Sanofi, and Xilio Therapeutics.

Many of the companies against which we are competing or against which we may compete in the future have significantly greater financial resources and expertise in research and development, manufacturing, preclinical testing, conducting clinical trials, obtaining regulatory approvals, and marketing approved drugs than we do. Mergers and acquisitions in the pharmaceutical, biotechnology, and diagnostic industries may result in even more resources being concentrated among a smaller number of our competitors. Smaller or early-stage companies may also prove to be significant competitors, particularly through collaborative arrangements with large and established companies. These competitors also compete with us in recruiting and retaining qualified scientific and management personnel and establishing clinical trial sites, and enrolling subjects for any future clinical trials, as well as in acquiring technologies complementary to, or necessary for, our programs.

We could see a reduction or elimination of our commercial opportunity 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 any products that we or our collaborators may develop. Our competitors also may obtain FDA or foreign regulatory approval for their products more rapidly than we may obtain approval for our product candidates, which could result in our competitors establishing a strong market position before we or our collaborators are able to enter the market. The key competitive factors affecting the success of all of our programs are likely to be efficacy, safety, and convenience. If we are not successful in developing, commercializing, and achieving higher levels of reimbursement than our competitors, we will not be able to compete against them and our business would be materially harmed.

Research Collaboration and Exclusive License Agreement with Merck Sharp & Dohme Corp.

On December 15, 2020, we and Merck Sharp & Dohme Corp. (Merck), entered into a research collaboration and exclusive license agreement (the Merck Agreement). The Merck Agreement provides that we and Merck will use commercially reasonable efforts to engage in certain research and development activities related to our TRACTr platform technology that are to be funded by Merck up to specified annual limits. Pursuant to the agreement, Merck had the right to designate up to two TRACTr product candidates in each case to be developed against a target (a Collaboration Target). We granted Merck an exclusive, worldwide, royalty-bearing, sublicensable license to certain of our patent rights and know-how with respect to the Collaboration Targets, in each case once designated by Merck, to research, develop, make, have made, use, import, offer to sell, and sell compounds and any licensed

products related thereto. Merck selected one of the Collaboration Targets upon execution of the Merck Agreement and selected the second Collaboration Target in May 2022. Following the research term, Merck will have the sole right to research, develop, manufacture, and commercialize the licensed compounds and products directed against the Collaboration Targets.

In consideration of the rights granted to Merck under the Merck Agreement, Merck paid us a one-time upfront payment of $8.0 million in respect of the first Collaboration Target and paid us an additional one-time payment of $8.0 million upon the selection of the second Collaboration Target. In addition, Merck is required to make milestone payments to us upon the successful completion of certain regulatory and development milestones, in an aggregate amount not to exceed $142.5 million for each of the two Collaboration Targets ($285.0 million collectively for both Collaboration Targets). Merck is also required to make milestone payments to us upon the successful completion of certain sales milestones, in an aggregate amount not to exceed $350.0 million for each licensed product under either of the Collaboration Targets.

Merck is also required to make tiered royalty payments on a product-by-product and country-by-country basis, ranging from low single-digit to low teens percentage royalty rates, on specified portions of annual net sales for licensed products under either of the Collaboration Targets that are commercialized. Such royalties are subject to reduction, on a product-by-product and country-by-country basis, for licensed products not covered by patent claims, or that require Merck to obtain a license to third-party intellectual property in order to commercialize the licensed product, or that are subject to compulsory licensing. Merck's royalty obligation with respect to a given licensed product in a given country begins upon, and ends no less than 10 years following, the first sale of such product in such country.

The Merck Agreement will terminate at the end of the calendar year in which the expiration of all royalty obligations occurs for all licensed products under the agreement. Merck has the unilateral right to terminate the agreement in its entirety or on a Collaboration Target by Collaboration Target basis at any time and for any reason upon prior written notice to us. Both parties have the right to terminate the agreement for an uncured material breach, certain illegal or unethical activities, and insolvency of the other party. Upon expiration of the agreement but not early termination thereof, and provided all payments due under the agreement have been made, Merck's exclusive licenses under the agreement will become fully paid-up and perpetual.

License Agreement with WuXi Biologics (Hong Kong) Limited

In April 2021, we entered into a cell line license agreement (Cell Line License Agreement) with WuXi Biologics (Hong Kong) Limited (WuXi Biologics), pursuant to which we received a non-exclusive, worldwide, sublicensable license under certain of WuXi Biologics' patent rights, know-how and biological materials (WuXi Biologics Licensed Technology), to use the WuXi Biologics Licensed Technology to make, use, sell, offer for sale and import certain therapeutic products produced through the use of the cell line licensed by WuXi Biologics under the Cell Line License Agreement (WuXi Biologics Licensed Product). Specifically, the WuXi Biologics Licensed Technology is used to manufacture a component of our PSMA-TRACTr and EGFR-TRACTr product candidates.

In consideration for the license, we agreed to pay WuXi Biologics a non-refundable, one-time license fee of $0.2 million upon Wuxi Biologics' achievement of a certain technical milestone, which was achieved in May 2021. Additionally, if we do not engage WuXi Biologics or its affiliates to manufacture the WuXi Biologics Licensed Products for our commercial supplies, we are required to make royalty payments to WuXi Biologics in an amount equal to a low single-digit percentage of specified portions of net sales of WuXi Biologics Licensed Products manufactured by a third-party manufacturer. We have the right (but not the obligation) to buy out our remaining royalty obligations with respect to each WuXi Biologics Licensed Product by paying WuXi Biologics a one-time payment in an amount ranging from low single digit million dollars to a maximum of $15.0 million depending on the development and commercialization stage of the WuXi Biologics Licensed Product (the Buyout Option), and upon such payment, our license with respect to such WuXi Biologics Licensed Product will become fully paid-up, irrevocable, and perpetual. The royalty obligations will remain in effect during the term of the Cell Line License Agreement so long as we have not exercised the Buyout Option.

The Cell Line License Agreement will continue indefinitely unless terminated (i) by us upon three months' prior written notice and our payment of all amounts due to WuXi Biologics through the effective date of termination, (ii) by either party for the other party's material breach that remains uncured for 30 days after written notice, and (iii) by WuXi Biologics if we fail to make a payment and such failure continues for 30 days after receiving notice of such failure.

Intellectual Property

We strive to protect and enhance the proprietary technology, inventions, and improvements that are commercially important to our business, including seeking, maintaining and defending patent rights, whether developed internally or licensed from third parties. We own the patents and patent applications relating to our TRACTr and TRACIr platform technologies. Our intellectual property policy includes seeking to protect our proprietary position by, among other methods, striving to obtain issued patents by filing and prosecuting patent applications in the United States and in jurisdictions outside of the United States, directed to our proprietary technology, inventions, improvements, and product candidates that are important to the development and implementation of our business. We also rely on trade secrets and know-how relating to our proprietary technology and product candidates, continued innovation, and in-licensing opportunities to develop, strengthen and maintain our proprietary position in the field of immunotherapy. We also plan to rely on data exclusivity, market exclusivity, and patent term extensions when available. Our commercial success will depend in part on our ability to obtain and maintain patent and other proprietary protection for our technology, inventions, and improvements; to preserve the confidentiality of our trade secrets and know-how; to obtain and maintain licenses to use intellectual property owned by third parties; to defend and enforce our proprietary rights, including any patents that we may own in the future; and to operate without infringing on the valid and enforceable patents and other proprietary rights of third parties.

As of February 16, 2024, we own 24 pending U.S. provisional and non-provisional patent applications, two U.S. patents, seven pending patent applications filed under the Patent Cooperation Treaty (PCT) and 72 foreign patent applications. Specifically, we have one U.S. non-provisional patent application and five foreign patent applications directed to compositions of our TRACTr and TRACIr platform technologies that are applicable across our product candidates for our PSMA-TRACTr (JANX007) and EGFR-TRACTr (JANX008) programs. We also have one U.S. patent, two U.S. non-provisional patent applications, 17 foreign patent applications that cover compositions and applications of various components and aspects of our TRACTr and TRACIr platform technologies and have general applicability across product candidates. We have one U.S. non-provisional patent application, eight foreign patent applications, one PCT patent application, and one U.S. provisional patent application that covers compositions and applications of components of our TRACTr platform technology that has general applicability to TRACTr product candidates or backup sequences for future development. We further have one U.S. patent, one U.S. provisional patent application, one PCT patent application, three U.S. non-provisional patent applications, and 12 foreign patent applications specific to JANX007 and two U.S. non-provisional patent applications, two PCT patent applications, and 12 foreign patent applications specific to JANX008.We have three U.S. provisional patent applications, five U.S. non-provisional patent applications, three PCT patent applications, and 18 foreign patent applications that are directed to unnamed TRACTr and TRACIr programs for potential future development and one U.S. provisional patent application that covers components and aspects of TRACIr platform technology. In addition, we have one U.S. provisional patent application and four U.S. non-provisional patent applications relating to compositions of our other proprietary antibodies, compounds, technology, inventions, improvements, and other aspects of our technology. Any patents that issue from these pending patent applications are expected to expire between 2038 and 2044, absent any patent term adjustments or extensions. We also possess substantial know-how and trade secrets relating to the development and commercialization of our product candidates, including related manufacturing processes and technology.

With respect to our product candidates and processes, we intend to develop and commercialize in the normal course of business, and we intend to pursue patent protection directed to, when possible, compositions, methods of use, methods of making, dosing, and formulations. We may also pursue patent protection with respect to manufacturing, therapeutic development processes and technologies, and therapeutic delivery technologies.

Issued patents can provide protection for varying periods of time, depending upon the date of filing of the patent application, the date of patent issuance, and the legal term of patents in the countries in which they are obtained. In general, patents issued for applications filed in the United States can provide exclusionary rights for 20 years from the earliest effective filing date excluding U.S. provisional applications. In addition, in certain instances, the term of an issued U.S. patent that is directed to or claims an FDA approved product can be extended to recapture a portion of the term effectively lost as a result of the FDA regulatory review period, which is called patent term extension. The restoration period cannot be longer than five years and the total patent term, including the restoration period, must not exceed 14 years following FDA approval. The term of patents outside of the United States varies in accordance with the laws of the foreign jurisdiction, but typically is also 20 years from the earliest effective filing date excluding U.S. provisional applications. However, the actual protection afforded by a patent varies on a

product-by-product basis, from country-to-country, and depends upon many factors, including the type of patent, the scope of its claims, the availability of regulatory-related extensions, the availability of legal remedies in a particular country, and the validity and enforceability of the patent.

The patent positions of companies like ours are generally uncertain and involve complex legal and factual questions. No consistent policy regarding the scope of claims allowable in patents in the field of immunotherapy has emerged in the United States. The relevant patent laws and their interpretation outside of the United States is also uncertain. Changes in either the patent laws or their interpretation in the United States and other countries may diminish our ability to protect our technology or product candidates and enforce the patent rights that we may license, and could affect the value of such intellectual property. In particular, our ability to stop third parties from making, using, selling, offering to sell, or importing products that infringe our intellectual property will depend in part on our success in obtaining and enforcing patent claims that cover our technology, inventions, and improvements. With respect to company-owned intellectual property, we cannot guarantee that patents will be granted with respect to any of our pending patent applications or with respect to any patent applications we may file in the future, nor can we be sure that any patents that may be granted to us in the future will be commercially useful in protecting our products, the methods of use or manufacture of those products. Moreover, even the issued patents that we license do not guarantee us the right to practice our technology in relation to the commercialization of our products. Patent and other intellectual property rights in the pharmaceutical and biotechnology space are evolving and involve many risks and uncertainties. For example, third parties may have blocking patents that could be used to prevent us from commercializing our product candidates and practicing our proprietary technology, and the issued patents that we may in-license and those that may issue in the future may be challenged, invalidated, or circumvented, which could limit our ability to stop competitors from marketing related products or could limit the term of patent protection that otherwise may exist for our product candidates. In addition, the scope of the rights granted under any issued patents may not provide us with protection or competitive advantages against competitors with similar technology. Furthermore, our competitors may independently develop similar technologies that are outside the scope of the rights granted under any issued patents that we own or that we may exclusively in-license. For these reasons, we may face competition with respect to our product candidates. Moreover, because of the extensive time required for development, testing and regulatory review of a potential product, it is possible that, before any particular product candidate can be commercialized, any patent protection for such product may expire or remain in force for only a short period following commercialization, thereby reducing the commercial advantage the patent provides. A comprehensive discussion on risks relating to intellectual property is provided under the section of this Annual Report titled “Risk Factors—Risks Related to Our Intellectual Property.”

Government Regulation

Government authorities in the United States at the federal, state and local level and in other countries and jurisdictions, including the European Union, extensively regulate, among other things, the research, development, testing, manufacture, quality control, approval, labeling, packaging, storage, record-keeping, promotion, advertising, distribution, post-approval monitoring and reporting, marketing and export and import of drug and biological products, such as our investigational medicines and any future investigational medicines. Generally, before a new drug or biologic can be marketed, considerable data demonstrating its quality, safety and efficacy must be obtained, organized into a format specific for each regulatory authority, submitted for review and approved by the regulatory authority.

Regulatory Approval in the United States

In the United States, pharmaceutical products are subject to extensive regulation by the FDA. The Federal Food, Drug, and Cosmetic Act (FDCA) and the Public Health Service Act (PHSA), and other federal and state statutes and regulations, govern, among other things, the research, development, testing, manufacture, storage, recordkeeping, approval, labeling, promotion and marketing, distribution, post-approval monitoring and reporting, sampling, and import and export of biologic products. Failure to comply with applicable U.S. requirements may subject a company to a variety of administrative or judicial sanctions, such as clinical hold, FDA refusal to approve pending biologics license applications (BLAs), warning or untitled letters, product recalls, product seizures, total or partial suspension of production or distribution, injunctions, fines, civil penalties and criminal prosecution.

A biologic must be approved by the FDA pursuant to a BLA before it may be legally marketed in the United States. The process generally involves the following:

• completion of extensive preclinical laboratory and animal studies in accordance with applicable regulations, including studies conducted in accordance with good laboratory practice (GLP) requirements;

• submission to the FDA of an investigational new drug application (IND), which must become effective before human clinical trials may begin;

• approval by an institutional review board (IRB) or independent ethics committee at each clinical trial site before each clinical trial may be commenced;

• performance of adequate and well-controlled human clinical trials in accordance with applicable IND regulations, good clinical practice (GCP) requirements and other regulations to establish the safety and efficacy of the investigational product for each proposed indication;

• submission to the FDA of a BLA;

• payment of any user fees for FDA review of the BLA;

• a determination by the FDA within 60 days of its receipt of a BLA to accept the filing for review;

• satisfactory completion of one or more FDA pre-approval inspections of the manufacturing facility or facilities where the biologic, or components thereof, will be produced to assess compliance with current good manufacturing processes (cGMP) requirements to assure that the facilities, methods and controls are adequate to preserve the biologic's identity, strength, quality and purity;

• satisfactory completion of any potential FDA audits of the clinical trial sites that generated the data in support of the BLA to assure compliance with GCPs and integrity of the clinical data;

• FDA review and approval of the BLA, including consideration of the views of any FDA advisory committee; and

• compliance with any post-approval requirements, including REMS, where applicable, and post- approval studies required by the FDA as a condition of approval.

Preclinical Studies

Before testing any biological product candidates in humans, the product candidate must undergo rigorous preclinical testing. Preclinical studies include laboratory evaluation of product candidates and formulations, as well as in vitro and animal studies to assess the potential for adverse events and in some cases to establish a rationale for therapeutic use. The conduct of preclinical studies is subject to federal regulations and requirements, including GLP regulations for safety/toxicology studies. An IND sponsor must submit the results of the preclinical tests, together with manufacturing information, analytical data, any available clinical data or literature and plans for clinical studies, among other things, to the FDA as part of an IND. An IND is a request for authorization from the FDA to administer an investigational product to humans and must become effective before human clinical trials may begin. Some long-term preclinical testing may continue after the IND is submitted. An IND automatically becomes effective 30 days after receipt by the FDA, unless before that time the FDA raises concerns or questions related to one or more proposed clinical trials and places the trial on clinical hold. In such a case, the IND sponsor and the FDA must resolve any outstanding concerns before the clinical trial can begin. As a result, submission of an IND may not result in the FDA allowing clinical trials to commence.

Clinical Trials

The clinical stage of development involves the administration of the investigational product to healthy volunteers or patients under the supervision of qualified investigators, generally physicians not employed by or under the trial sponsor's control. Clinical trials must be conducted: (i) in compliance with federal regulations; (ii) in compliance with GCPs, an international standard meant to protect the rights and health of patients and to define the roles of clinical trial sponsors, administrators and monitors; as well as (iii) under protocols detailing, among other things, the objectives of the trial, the parameters to be used in monitoring safety and the effectiveness criteria to be evaluated in the trial. Each protocol involving testing on U.S. patients and subsequent protocol amendments must be submitted to the FDA as part of the IND. Furthermore, each clinical trial must be reviewed and approved by an IRB for each institution at which the clinical trial will be conducted to ensure that the risks to individuals participating in

the clinical trials are minimized and are reasonable in relation to anticipated benefits. The IRB also approves the informed consent form that must be provided to each clinical trial subject or his or her legal representative and must monitor the clinical trial until completed. There also are requirements governing the reporting of ongoing clinical trials and completed clinical trial results to public registries. Information about certain clinical trials, including clinical trial results, must be submitted within specific timeframes for publication on the www.clinicaltrials.gov website. Information related to the product, patient population, phase of investigation, clinical trial sites and investigators and other aspects of the clinical trial is then made public as part of the registration.

A sponsor who wishes to conduct a clinical trial outside of the United States may, but need not, obtain FDA authorization to conduct the clinical trial under an IND. If a foreign clinical trial is not conducted under an IND, the sponsor may submit data from the clinical trial to the FDA in support of a BLA. The FDA will accept a well-designed and well-conducted foreign clinical trial not conducted under an IND if the clinical trial was conducted in accordance with GCP requirements, and the FDA is able to validate the data through an onsite inspection if deemed necessary.

Clinical trials are generally conducted in three sequential phases, known as Phase 1, Phase 2 and Phase 3, which may overlap or be combined:

- Phase 1 clinical trials generally involve a small number of healthy volunteers or disease-affected patients who are initially exposed to a single dose and then multiple doses of the product candidate. The primary purpose of these clinical trials is to assess the metabolism, pharmacokinetics, pharmacologic action, side effect tolerability, safety of the product candidate, and, if possible, early evidence of effectiveness.

- Phase 2 clinical trials generally involve studies in disease-affected patients to evaluate proof of concept and/or determine the dosing regimen(s) for subsequent investigations. At the same time, safety and further pharmacokinetic and pharmacodynamic information is collected, possible adverse effects and safety risks are identified, and a preliminary evaluation of efficacy is conducted.

- Phase 3 clinical trials generally involve a large number of patients at multiple sites and are designed to provide the data necessary to demonstrate the effectiveness of the product for its intended use, its safety in use and to establish the overall benefit/risk relationship of the product and provide an

- adequate basis for product labeling. In most cases, the FDA requires two adequate and well-controlled Phase 3 clinical trials to demonstrate the efficacy of the biologic.

A single Phase 3 or Phase 2 trial with other confirmatory evidence may be sufficient in rare instances to provide substantial evidence of effectiveness (generally subject to the requirement of additional post-approval studies).

The FDA, the IRB, or the sponsor may suspend or terminate a clinical trial at any time on various grounds, including non-compliance with regulatory requirements or a finding that the patients are being exposed to an unacceptable health risk. Similarly, an IRB can suspend or terminate approval of a clinical trial at its institution if the clinical trial is not being conducted in accordance with the IRB's requirements or if the drug or biologic has been associated with unexpected serious harm to patients. Additionally, some clinical trials are overseen by an independent group of qualified experts organized by the clinical trial sponsor, known as a data safety monitoring board or committee. This group provides authorization for whether a trial may move forward at designated checkpoints based on access to certain data from the trial.

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

FDA Review Process

Following completion of the clinical trials, the results of preclinical studies and clinical trials are submitted to the FDA as part of a BLA, along with proposed labeling, chemistry and manufacturing information to ensure product quality and other relevant data. To support marketing approval, the data submitted must be sufficient in quality and quantity to establish the safety, purity, and potency of the investigational product to the satisfaction of the FDA. FDA approval of a BLA must be obtained before a biologic or drug may be marketed in the United States. The cost of preparing and submitting a BLA is substantial. Under the PDUFA, each BLA must be accompanied by a substantial user fee. The FDA adjusts the PDUFA user fees on an annual basis. Fee waivers or reductions are available in certain circumstances, including a waiver of the application fee for the first application filed by a small business. Additionally, no user fees are assessed on BLAs for products designated as orphan drugs, unless the product also includes a non-orphan indication. The applicant under an approved BLA is also subject to an annual program fee.

The FDA reviews all submitted BLAs before it accepts them for filing and may request additional information. The FDA must make a decision on accepting a BLA for filing within 60 days of receipt, and such decision could include a refusal to file by the FDA. Once the submission is accepted for filing, the FDA begins an in-depth review of the BLA. Under the goals and policies agreed to by the FDA under PDUFA, the FDA has 10 months, from the filing date, in which to complete its initial review of an original BLA and respond to the applicant, and six months from the filing date of an original BLA designated for priority review. The FDA does not always meet its PDUFA goal dates for standard and priority BLAs, and the review process can be extended by FDA requests for additional information or clarification.

Before approving a BLA, the FDA will generally conduct a pre-approval inspection of the manufacturing facilities for the new product to determine whether they comply with cGMP requirements. The FDA will not approve the product 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.

The FDA also may audit data from clinical trials to ensure compliance with GCP requirements and the integrity of the data supporting safety and efficacy. Additionally, the FDA may refer applications for novel products or products that present difficult questions of safety or efficacy to an advisory committee, typically a panel that includes clinicians and other experts, for review, evaluation and a recommendation as to whether the application should be approved and under what conditions, if any. The FDA is not bound by recommendations of an advisory committee, but it generally follows such recommendations when making decisions on approval. The FDA likely will reanalyze the clinical trial data, which could result in extensive discussions between the FDA and the applicant during the review process.

After the FDA evaluates a BLA, it will issue either an approval letter or a Complete Response Letter. An approval letter authorizes commercial marketing of the biologic with specific prescribing information for specific indications. A Complete Response Letter indicates that the review cycle of the application is complete and the application will not be approved in its present form. A Complete Response Letter generally outlines the deficiencies in the BLA and may require additional clinical data, additional pivotal clinical trial(s) and/or other significant and time-consuming requirements related to clinical trials, preclinical studies or manufacturing in order for FDA to reconsider the application. If a Complete Response Letter is issued, the applicant may either resubmit the BLA, addressing all of the deficiencies identified in the letter, or withdraw the application or request an opportunity for a hearing. Even if such data and information are submitted, the FDA may decide that the BLA does not satisfy the criteria for approval.

As a condition of BLA approval, the FDA may require a Risk Evaluation and Mitigation Strategy (REMS) to help ensure that the benefits of the biologic outweigh the potential risks to patients. A REMS can include medication guides, communication plans for healthcare professionals and elements to assure a product's safe use (ETASU). An ETASU can include, but is not limited to, special training or certification for prescribing or dispensing the product, dispensing the product only under certain circumstances, special monitoring and the use of patient-specific registries. The requirement for a REMS can materially affect the potential market and profitability of the product. Moreover, the FDA may require substantial post-approval testing and surveillance to monitor the product's safety or efficacy.

Orphan Drug Designation

Under the Orphan Drug Act, the FDA may grant orphan designation to a biological product intended to treat a rare disease or condition, which is generally a disease or condition that affects fewer than 200,000 individuals in the

United States, or more than 200,000 individuals in the United States but for which there is no reasonable expectation that the cost of developing and making the product for this type of disease or condition will be recovered from sales of the product in the United States.

Orphan drug designation must be requested before submitting a BLA. After the FDA grants orphan drug designation, the identity of the therapeutic agent and its potential orphan use are disclosed publicly by the FDA. Orphan drug designation on its own does not convey any advantage in or shorten the duration of the regulatory review and approval process.

Among the other benefits of orphan drug designation are tax credits for certain research and a waiver of the BLA application user fee. In addition, if a product that has orphan designation subsequently receives the first FDA approval for the disease or condition for which it has such designation, the product is entitled to orphan drug exclusivity, which means that the FDA may not approve any other applications to market the same product for the same indication for seven years from the date of such approval, except in limited circumstances, such as a showing of clinical superiority to the product with orphan exclusivity by means of greater effectiveness, greater safety, or providing a major contribution to patient care, or in instances of drug supply issues. Competitors, however, may receive approval of either a different product for the same indication or the same product for a different indication. In the latter case, because healthcare professionals are free to prescribe products for off-label uses based on their independent medical judgement, the competitor's product could be used for the orphan indication despite another product's orphan exclusivity.

An orphan-designated product may not receive orphan drug exclusivity if it is approved for a use that is broader than the indication for which it received orphan designation. In addition, exclusive marketing rights in the United States may be lost if the FDA later determines that the request for designation was materially defective or if the manufacturer is unable to assure sufficient quantities of the product to meet the needs of patients with the rare disease or condition.

Expedited Development and Review Programs

The FDA offers a number of expedited development and review programs for qualifying product candidates.

For example, the fast track program is intended to expedite or facilitate the process for reviewing new products that meet certain criteria. Specifically, product candidates are eligible for fast track designation if they are intended to treat a serious or life-threatening disease or condition and demonstrate the potential to address unmet medical needs for the disease or condition. Fast track designation applies to both the product and the specific indication for which it is being studied. The sponsor of a new biologic candidate can request the FDA to designate the candidate for a specific indication for fast track status concurrent with, or after, the submission of the IND for the candidate. The FDA must determine if the biologic candidate qualifies for fast track designation within 60 days of receipt of the sponsor's request. 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 BLA before the application is complete. This "rolling review" is available if the sponsor provides a schedule for the submission of the sections of the BLA, the FDA agrees to accept sections of the BLA and determines that the schedule is acceptable, and the sponsor pays any required user fees upon submission of the first section of the BLA. Any product submitted to the FDA for marketing, including under a fast track program, may be eligible for other types of FDA programs intended to expedite development and review, such as breakthrough therapy, priority review and accelerated approval.

Breakthrough therapy designation may be granted for products that are intended, alone or in combination with one or more other products, to treat a serious or life-threatening condition and preliminary clinical evidence indicates that the product may demonstrate substantial improvement over currently approved therapies on one or more clinically significant endpoints, such as substantial treatment effects observed early in clinical development. Under the breakthrough therapy program, the sponsor of a new biologic candidate may request that the FDA designate the candidate for a specific indication as a breakthrough therapy concurrent with, or after, the submission of the IND for the biologic candidate. The FDA must determine if the biological product qualifies for breakthrough therapy designation within 60 days of receipt of the sponsor's request. 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 design the clinical studies in an efficient manner.

Priority review may be granted for products that are intended to treat a serious or life-threatening condition and, if approved, would provide a significant improvement in safety and effectiveness compared to available therapies. The FDA will attempt to direct additional resources to the evaluation of an application designated for priority review in an effort to facilitate the review, and for original BLAs, priority review designation means the FDA's goal is to take action on the marketing application within six months of the 60-day filing date (as compared to ten months under standard review).

Accelerated approval may be granted for products that are intended to treat a serious or life-threatening disease or condition on the basis of either a surrogate endpoint that is reasonably likely to predict clinical benefit, or on a clinical endpoint that can be measured earlier than irreversible morbidity or mortality, that is reasonably likely to predict an effect on irreversible morbidity or mortality or other clinical benefit, taking into account the severity, rarity or prevalence of the condition and the availability or lack of alternative treatments. In clinical trials, a surrogate endpoint is a measurement of laboratory or clinical signs of a disease or condition that substitutes for a direct measurement of how a patient feels, functions or survives. 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 studies to demonstrate a clinical or survival benefit. As a condition of accelerated approval, the FDA will generally require the sponsor to perform adequate and well-controlled post-marketing clinical studies to verify and describe the anticipated effect on irreversible morbidity or mortality or other clinical benefit. Products receiving accelerated approval may be subject to expedited withdrawal procedures if the sponsor fails to conduct the required post-marketing studies or if such studies fail to verify the predicted clinical benefit. In addition, the FDA currently requires as a condition for accelerated approval pre-approval of promotional materials, which could adversely impact the timing of the commercial launch of the product.

Even if a product qualifies for one or more of these programs, the FDA may later decide that the product no longer meets the conditions for qualification or the time period for FDA review or approval may not be shortened. Furthermore, fast track designation, breakthrough therapy designation, priority review and accelerated approval do not change the standards for approval, but may expedite the development or approval process.

Pediatric Information

Under the Pediatric Research Equity Act (PREA), BLAs or supplements to BLAs must contain data to assess the safety and effectiveness of the biological product for the claimed indications in all relevant pediatric subpopulations and to support dosing and administration for each pediatric subpopulation for which the biological product is safe and effective. The FDA may grant full or partial waivers, or deferrals, for submission of data.

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

Post-Approval Requirements

Once a BLA is approved, a product will be subject to certain post-approval requirements. For instance, the FDA closely regulates the post-approval marketing and promotion of biologics, including standards and regulations for direct-to-consumer advertising, off-label promotion, industry-sponsored scientific and educational activities and promotional activities involving the Internet. Biologics may be marketed only for the approved indications and in a manner consistent with the provisions of the approved labeling. Although physicians may prescribe products for off-label uses as the FDA and other regulatory authorities do not regulate a physician's choice of drug treatment made in the physician's independent medical judgment, they do restrict promotional communications from companies or their sales force with respect to off-label uses of products for which marketing clearance has not been issued. Companies may only share truthful and not misleading information that is otherwise consistent with a product's FDA approved labeling.

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

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 studies 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, complete withdrawal of the product from the market or product recalls;
- fines, warning or other enforcement-related letters or holds on post-approval clinical studies;
- refusal of the FDA to approve pending BLAs or supplements to approved BLAs, or suspension or revocation of product 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.

Biosimilars and Exclusivity

The Biologics Price Competition and Innovation Act of 2009 (the BPCIA) created an abbreviated approval pathway for biological products shown to be biosimilar to, or interchangeable with, an FDA-licensed reference biological product. Biosimilarity, which requires that the biological product be highly similar to the reference product notwithstanding minor differences in clinically inactive components and that there be no clinically meaningful differences between the biological product and the reference product in terms of safety, purity and potency, can be shown through analytical studies, animal studies and a clinical trial or trials. Interchangeability requires that a biological product be biosimilar to the reference product and that the product can be expected to produce the same clinical results as the reference product in any given patient and, for products administered multiple times to an individual, that the product and the reference product may be alternated or switched after one has been previously administered without increasing safety risks or risks of diminished efficacy relative to exclusive use of the reference biological product without such alternation or switch. A reference biological product is granted 12 years of 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. "First licensure" typically means the initial date the particular product at issue was licensed in the United States. Date of first licensure does not include the date of licensure of (and a new period of exclusivity is not available for) a biological product if the licensure is for a supplement for the biological product or for a subsequent application by the same sponsor or manufacturer of the biological product (or licensor, predecessor in interest or other related entity) for a change (not including a modification to the structure of the
biological product) that results in a new indication, route of administration, dosing schedule, dosage form, delivery system, delivery device or strength, or for a modification to the structure of the biological product that does not result in a change in safety, purity or potency.

Regulatory Approval in the European Union

The EMA is an agency of the European Union. It coordinates the evaluation and monitoring of centrally authorized medicinal products. Through its Committees, particularly the Committee on Human Medicinal Products (CHMP) it conducted scientific evaluation of applications for EU marketing authorizations, as well as the development of technical guidance and the provision of scientific advice to sponsors.

There are similarities between the process regarding approval of medicinal products in the European Union and that in the United States.

Clinical Trials in the EU

In the EU, clinical trials are governed by the new Clinical Trials Regulation (EU) No 536/2014 (CTR), which entered into application that came into force on January 31, 2022 repealing and replacing the former Clinical Trials Directive 2001/20 (CTD). The CTR aims to simplify and streamline the approval of clinical trials in the European Union. The Clinical Trials Regulation introduces a complete overhaul of the existing legislation governing clinical trials for medicinal products in the EU. The main characteristics of the regulation include: a streamlined application procedure via a single entry point, the "EU portal"; a single set of documents to be prepared and submitted for the application as well as simplified reporting procedures for clinical trial sponsors; and a harmonized procedure for the assessment of applications for clinical trials, which is divided in two parts. Part I is assessed by the competent authorities of all EU member states in which an application for authorization of a clinical trial has been submitted (member states concerned). Part II is assessed separately by each member state concerned. Strict deadlines have been established for the assessment of clinical trial applications. The role of the relevant ethics committees in the assessment procedure will continue to be governed by the national law of the concerned EU member state. However, overall related timelines will be defined by the Clinical Trials Regulation. The extent to which on-going clinical trials will be governed by the CTR will depend on the duration of the individual clinical trial. For clinical trials in relation to which an application for approval was made on the basis of the CTD before January 31, 2023, the CTD will continue to apply on a transitional basis until January 31, 2025. By that date, all ongoing trials will become subject to the provisions of the CTR. The CTR will apply to clinical trials from an earlier date if the related clinical trial application was made on the basis of the CTR or if the clinical trial has already transitioned to the CTR framework before January 31, 2025.

In all cases, clinical trials must be conducted in accordance with GCP and the applicable regulatory requirements and the ethical principles that have their origin in the Declaration of Helsinki. Medicinesused in clinical trials, including ATMPs, must be manufactured in accordance with the guidelines on cGMP and in a GMP licensed facility, which can be subject to GMP inspections.

Manufacturing and import into the EU of investigational medicinal products is subject to the holding of appropriate authorizations and must be carried out in accordance with cGMP.

Review and Approval

Authorization to market a product in the European Union member states proceeds under one of four procedures: a centralized authorization procedure, a mutual recognition procedure, a decentralized procedure or a national procedure. Since our products by their virtue of being antibody-based biologics fall under the centralized procedure, only this procedure will be described here.

Certain drugs, including medicinal products developed by means of biotechnological processes, must be approved via the centralized authorization procedure for marketing authorization. A successful application under the centralized authorization procedure results in a marketing authorization from the European Commission, which is automatically valid in all European Union member states. The other European Economic Area (EEA) countries (namely Norway, Iceland and Liechtenstein) are also obligated to recognize the European Commission decision. The EMA and the European Commission administer the centralized authorization procedure.

Under the centralized authorization procedure, the Committee for Medicinal Products for Human Use (the CHMP), serves as the scientific committee that renders opinions about the safety, efficacy and quality of human products on behalf of the EMA. The CHMP is composed of experts nominated by each member state's national drug authority, with one of them appointed to act as Rapporteur for the co-ordination of the evaluation with the assistance of a further member of the CHMP acting as a Co-Rapporteur. The CHMP is required to issue an opinion within 210 days of receipt of a valid application, though the clock is stopped if it is necessary to ask the applicant for

clarification or further supporting data. The process is complex and involves extensive consultation with the regulatory authorities of member states and a number of experts. Once the procedure is completed, a European Public Assessment Report is produced. If the CHMP concludes that the quality, safety and efficacy of the medicinal product is sufficiently proven, it adopts a positive opinion. The CHMP's opinion is sent to the European Commission, which uses the opinion as the basis for its decision whether or not to grant a marketing authorization.

After a medicinal product has been authorized by the European Commission and launched in the EEA, it is a condition of maintaining the marketing authorization that all aspects relating to its quality, safety and efficacy must be kept under review by the MAH. Sanctions may be imposed for failure to adhere to the conditions of the marketing authorization. In extreme cases, the authorization may be revoked, resulting in withdrawal of the product from sale.

Conditional Approval and Accelerated Assessment

As per Article 14-a of Regulation (EC) 726/2004, a medicine that is demonstrated to fulfill an unmet medical need may, if its immediate availability is in the interest of public health, be the subject of a conditional marketing authorization on the basis of less complete clinical data than are normally required, subject to specific obligations being imposed on the authorization holder. Fulfilment of these specific obligations is reviewed annually by the EMA. A conditional authorization is valid for 12 months, and may be renewed.

When an application is submitted for a marketing authorization in respect of a medicinal product for human use which is of major interest from the point of view of public health and in particular from the viewpoint of therapeutic innovation, the applicant may request an accelerated assessment procedure pursuant to Article 14.9 of Regulation (EC) 726/2004. Under the accelerated assessment procedure, the CHMP is required to issue an opinion within 150 days of receipt of a valid application, subject to clock stops. We believe that some of the disease indications in which our product candidates are currently being or may be developed in the future qualify for this provision, and we will take advantage of this provision as appropriate.

Period of Authorization and Renewals

A marketing authorization is initially valid for five years and may then be renewed on the basis of a re-evaluation of the risk-benefit balance by the EMA or by the competent authority of the authorizing member state. Once renewed, the marketing authorization shall be valid for an unlimited period, unless the European Commission or the competent authority decides, on justified grounds relating to pharmacovigilance, to proceed with one additional five-year renewal period. Any authorization which is not followed by the actual placing of the drug on the EU market (in case of centralized procedure) or on the market of the authorizing member state within three years after authorization shall cease to be valid (the "sunset clause").

The EU provides opportunities for data and market exclusivity related to certain types of marketing authorizations. Upon grant of related marketing authorization, innovative medicinal products generally benefit from eight years of data exclusivity and 10 years of market exclusivity. Data exclusivity, if granted, prevents regulatory authorities in the EEA from referencing the innovator's data to assess a generic application or biosimilar application for eight years from the date of authorization of the innovative product, after which a generic or biosimilar marketing authorization application can be submitted, and the innovator's data may be referenced. The market exclusivity period prevents a successful generic or biosimilar applicant from commercializing its product in the EEA until 10 years have elapsed from the initial marketing authorization of the reference product in the EEA. The overall ten year period may, occasionally, be extended for a further year to a maximum of 11 years if, during the first eight years of those ten years, the marketing authorization holder obtains an authorization for one or more new therapeutic indications which, during the scientific evaluation prior to their authorization, are held to bring a significant clinical benefit in comparison with existing therapies. However, there is no guarantee that a product will be considered by the EU's regulatory authorities to be a new chemical/biological entity, and products may not qualify for data exclusivity.

Pediatric Development

In the EU, Regulation (EC) No 1901/2006 provides that all MAAs for new medicinal products have to include the results of trials conducted in the pediatric population, in compliance with a pediatric investigation plan (PIP) agreed with the EMA's Pediatric Committee (PDCO). The PIP sets out the timing and measures proposed to

generate data to support a pediatric indication of the medicinal product for which MA is being sought. The PDCO can grant a deferral of the obligation to implement some or all of the measures provided in the PIP until there are sufficient data to demonstrate the efficacy and safety of the product in adults. Further,the obligation to provide pediatric clinical trial data can be waived by the PDCO when these data are not needed or appropriate because the product is likely to be ineffective or unsafe in children, the disease or condition for which the product is intended occurs only in adult populations, or when the product does not represent a significant therapeutic benefit over existing treatments for pediatric patients.Once the MA is obtained in all EU Member States and study results are included in the product information, even when negative, the product is eligible for a six-month extension to the Supplementary Protection Certificate (SPC), if any is in effect at the time of authorization or, in the case of orphan medicinal products,a two-year extension of orphan market exclusivity.

Orphan Medicinal Product Designation

Regulation (EC) No. 141/2000, as implemented by Regulation (EC) No. 847/2000 provides that a medicinal product can be designated as an orphan medicinal product by the European Commission if its sponsor can establish that (1) the product is intended for the diagnosis, prevention or treatment of a life-threatening or chronically debilitating condition; (2) either (a) such condition affects no more than five in ten thousand persons in the EU when the application is made, or (b) the product, without the benefits derived from orphan status, would not generate sufficient return in the EU; and (3) 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 product will be of significant benefit to those affected by that condition.

In the EU, an application for designation as an orphan product can be made any time prior to the filing of the MAA. Orphan medicinal product designation entitles an applicant to incentives such fee reductions or fee waivers, protocol assistance, and access to the centralized MA procedure. Upon grant of an MA, orphan medicinal products are entitled to a ten-year period of market exclusivity for the approved therapeutic indication, which means that the EMA cannot accept another MAA, or grant an MA, or accept an application to extend an MA for a similar product for the same indication for a period of ten years. The period of market exclusivity is extended by two years for orphan medicinal products that have also complied with an agreed PIP. No extension to any supplementary protection certificate can be granted on the basis of pediatric studies for orphan indications. Orphan medicinal product designation does not convey any advantage in, or shorten the duration of, the regulatory review and approval process.

The period of market exclusivity may, however, be reduced to six years if, at the end of the fifth year, it is established that the product no longer meets the criteria on the basis of which it received orphan medicinal product destination, including where it can be demonstrated on the basis of available evidence that the original orphan medicinal product is sufficiently profitable not to justify maintenance of market exclusivity or where the prevalence of the condition has increased above the threshold. Additionally, an MA may be granted to a similar medicinal product with the same orphan indication during the 10 year period if: (i) if the applicant consents to a second original orphan medicinal product application, (ii) if the manufacturer of the original orphan medicinal product is unable to supply sufficient quantities; or (iii) if the second applicant can establish that its product, although similar, is safer, more effective or otherwise clinically superior to the original orphan medicinal product. A company may voluntarily remove a product from the register of orphan products.

Post-Approval Requirements

Where an MA is granted in relation to a medicinal product in the EU, the holder of the MA is required to comply with a range of regulatory requirements applicable to the manufacturing, marketing, promotion and sale of medicinal products.

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

All new MAAs must include a risk management plan, or RMP, describing the risk management system that the company will put in place and documenting measures to prevent or minimize the risks associated with the

product. The regulatory authorities may also impose specific obligations as a condition of the MA. Such risk-minimization measures or post-authorization obligations may include additional safety monitoring, more frequent submission of PSURs, or the conduct of additional clinical trials or post-authorization safety studies.

In the EU, the advertising and promotion of medicinal products are subject to both EU and EU member states' laws governing promotion of medicinal products, interactions with physicians and other healthcare professionals, misleading and comparative advertising and unfair commercial practices. Although general requirements for advertising and promotion of medicinal products are established under EU directives, the details are governed by regulations in each member state and can differ from one country to another. For example, applicable laws require that promotional materials and advertising in relation to medicinal products comply with the product's Summary of Product Characteristics, or SmPC, as approved by the competent authorities in connection with an MA. The SmPC is the document that provides information to physicians concerning the safe and effective use of the product. Promotional activity that does not comply with the SmPC is considered off-label and is prohibited in the EU. Direct-to-consumer advertising of prescription medicinal products is also prohibited in the EU.

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

Data Privacy and Security Laws

In the ordinary course of our business, we may process personal or other sensitive, proprietary, and confidential information. Accordingly, we are or may become subject to numerous data privacy and security obligations, including federal, state, local, and foreign laws, regulations, guidance, and industry standards related to data privacy and security. Such obligations may include, without limitation, the Federal Trade Commission Act, the Telephone Consumer Protection Act of 1991, the Children's Online Privacy Protection Act of 1998, the Controlling the Assault of Non-Solicited Pornography And Marketing Act of 2003, the California Consumer Privacy Act of 2018, as amended by the California Privacy Rights Act of 2020 (CPRA) (collectively, CCPA), the Canadian Personal Information Protection and Electronic Documents Act, Canada's Anti-Spam Legislation, the European Union's General Data Protection Regulation 2016/679 (EU GDPR), the EU GDPR as it forms part of United Kingdom (UK) law by virtue of section 3 of the European Union (Withdrawal) Act 2018 (UK GDPR) (EU GDPR and UK GDPR collectively as GDPR), the ePrivacy Directive, and the Payment Card Industry Data Security Standard (PCI DSS). Several states within the United States have enacted or proposed data privacy and security laws. For example, Virginia, Colorado, Connecticut, and Utah have passed comprehensive data privacy and security laws. Additionally, we are, or may become, subject to various U.S. federal and state consumer protection laws which require us to publish statements that accurately and fairly describe how we handle personal information and choices individuals may have about the way we handle their personal information.

The CCPA and GDPR are examples of the increasingly stringent and evolving regulatory frameworks related to personal information processing that may increase our compliance obligations and exposure for any noncompliance. For example, the CCPA imposes obligations on covered businesses to provide specific disclosures related to a business's collection, use , and disclosure of personal information and to respond to certain requests from California residents related to their personal information (for example, requests to know of the business's personal information processing activities, to delete the individual's personal data, and to opt out of certain personal information disclosures). Also, the CCPA provides for civil penalties and a private right of action for data breaches which may include an award of statutory damages. In addition, the CPRA, which became effective January 1, 2023, expanded the CCPA by, among other things, giving California residents the ability to limit use of certain sensitive personal information, establishing restrictions on personal information retention, expanding the types of data breaches that are subject to the CCPA's private right of action, and establishing a new California Privacy Protection Agency to implement and enforce the new law.

Foreign data privacy and security laws (including but not limited to the GDPR) impose significant and complex compliance obligations on entities that are subject to those laws. As one example, the EU GDPR applies to any company established in the EEA and to companies established outside the EEA that process personal information in connection with the offering of goods or services to data subjects in the EEA or the monitoring of the behavior of data subjects in the EEA. These obligations may include limiting personal information processing to only what is necessary for specified, explicit, and legitimate purposes; requiring a legal basis for personal information processing; requiring the appointment of a data protection officer in certain circumstances; increasing

transparency obligations to data subjects; requiring data protection impact assessments in certain circumstances; limiting the collection and retention of personal information; increasing rights for data subjects; formalizing a heightened and codified standard of data subject consents; requiring the implementation and maintenance of technical and organizational safeguards for personal information; mandating notice of certain personal information breaches to the relevant supervisory authority(ies) and affected individuals; and mandating the appointment of representatives in the UK and/or the EU in certain circumstances.

See the section titled “Risks Related to Government Regulation” for additional information about the laws and regulations to which we may become subject and about the risks to our business associated with such laws and regulations.

Marketing

Similarly to the Anti-Kickback Statute prohibition in the United States, 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 EU. The provision of benefits or advantages to physicians is governed by the national anti-bribery laws of European Union member states, and, in the U. K, the U.K. Bribery Act 2010. Infringement of these laws could result in substantial fines and imprisonment.

Payments made to physicians in certain European Union member states must be publicly disclosed on the basis of applicable sunshine rules. Moreover, agreements with physicians often must be the subject of prior notification and approval by the physician’s employer, their 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 individual European Union member states. Failure to comply with these requirements could result in reputational risk, public reprimands, administrative penalties, fines or imprisonment.

International Regulation

In addition to regulations in the United States and the European Union, a variety of foreign regulations govern clinical trials, commercial sales and distribution of product candidates. The approval process varies from country to country and the time to approval may be longer or shorter than that required for FDA or European Commission approval.

Other Healthcare Laws and Regulations and Legislative Reform

Healthcare Laws and Regulations

Healthcare providers, including physicians, and third-party payors will play a primary role in the recommendation and prescription of any product candidates for which we obtain marketing approval. Our operations, including any arrangements with healthcare providers, physicians, third-party payors and customers may expose us to broadly applicable fraud and abuse and other healthcare laws that may affect the business or financial arrangements and relationships through which we would research, as well as market, sell and distribute any products for which we obtain marketing approval. Our current and future operations are subject to regulation by various federal, state and local authorities in addition to the FDA, including but not limited to the Centers for Medicare and Medicaid Services (CMS), U.S. Department of Health and Human Services, (HHS) (including the Office of Inspector General, Office for Civil Rights and the Health Resources and Service Administration), the U.S. Department of Justice (DOJ) and individual U.S. Attorney offices within the DOJ, and state and local governments. The healthcare laws that may affect our ability to operate include, but are not limited to:

- The federal Anti-Kickback Statute, which prohibits any person or entity from, among other things, knowingly and willfully soliciting, receiving, offering or paying any remuneration, directly or indirectly, overtly or covertly, in cash or in kind, to induce or reward either the referral of an individual for, or the purchase, order or recommendation of an item or service reimbursable, in whole or in part, under a federal healthcare program, such as the Medicare and Medicaid programs. The term “remuneration” has been broadly interpreted to include anything of value. A person or entity does not need to have actual knowledge of the federal Anti-Kickback Statute or specific intent to violate it to have committed a violation. The federal Anti-Kickback Statute has also been interpreted to apply to arrangements between

pharmaceutical manufacturers on the one hand and prescribers, purchasers and formulary managers on the other hand. There are a number of statutory exceptions and regulatory safe harbors protecting some common activities from prosecution, but the exceptions and safe harbors are drawn narrowly and require strict compliance in order to offer protection.

• Federal civil and criminal false claims laws, such as the False Claims Act (FCA), which can be enforced by private citizens on behalf of the government through civil whistleblower or qui tam actions, and the federal civil monetary penalty laws prohibit individuals or entities from, among other things, knowingly presenting, or causing to be presented, false, fictitious or fraudulent claims for payment of federal funds, and knowingly making, using or causing to be made or used a false record or statement material to a false or fraudulent claim to avoid, decrease or conceal an obligation to pay money to the federal government. For example, pharmaceutical companies have been prosecuted under the FCA in connection with their alleged off-label promotion of drugs, purportedly concealing price concessions in the pricing information submitted to the government for government price reporting purposes, and allegedly providing free product to customers with the expectation that the customers would bill federal healthcare programs for the product. In addition, a claim including items or services resulting from a violation of the federal Anti-Kickback Statute constitutes a false or fraudulent claim for purposes of the FCA. As a result of a modification made by the Fraud Enforcement and Recovery Act of 2009, a claim includes “any request or demand” for money or property presented to the U.S. government. In addition, manufacturers can be held liable under the FCA even when they do not submit claims directly to government payors if they are deemed to “cause” the submission of false or fraudulent claims.

• HIPAA, among other things, imposes criminal liability for executing or attempting to execute a scheme to defraud any healthcare benefit program, including private third-party payors, knowingly and willfully embezzling or stealing from a healthcare benefit program, willfully obstructing a criminal investigation of a healthcare offense, and creates federal criminal laws that prohibit knowingly and willfully falsifying, concealing or covering up a material fact or making any materially false, fictitious or fraudulent statement or representation, or making or using any false writing or document knowing the same to contain any materially false, fictitious or fraudulent statement or entry in connection with the delivery of or payment for healthcare benefits, items or services. Similar to the federal Anti-Kickback Statute, a person or entity does not need to have actual knowledge of the statute or specific intent to violate it in order to have committed a violation.

• In addition, HIPAA, as amended by Health Information Technology for Economic and Clinical Health Act of 2009 (HITECH), imposes certain requirements on covered entities, which include certain healthcare providers, health plans and healthcare clearinghouses, and their business associates and covered subcontractors that receive or obtain protected health information in connection with providing a service on behalf of a covered entity relating to the privacy, security and transmission of individually identifiable health information.

• The federal transparency requirements under the Physician Payments Sunshine Act, created under the Patient Protection and Affordable Care Act (the Affordable Care Act), which requires, among other things, certain manufacturers of drugs, devices, biologics and medical supplies reimbursed under Medicare, Medicaid, or the Children’s Health Insurance Program (with certain exceptions) to report annually to CMS information related to payments and other transfers of value provided to physicians (defined to include doctors, dentists, optometrists, podiatrists and chiropractors), other healthcare professionals (such as physicians assistants or nurse practitioners), and teaching hospitals and physician ownership and investment interests, including such ownership and investment interests held by a physician’s immediate family members.

• Analogous state and foreign anti-kickback and false claims laws that may apply to sales or marketing arrangements and claims involving healthcare items or services reimbursed by non-governmental third-party payors, including private insurers, or that apply regardless of payor; state and foreign laws that require pharmaceutical companies to comply with the pharmaceutical industry’s voluntary compliance guidelines and the relevant compliance guidance promulgated by the government; state and local laws that require drug manufacturers to report information related to payments and other transfers of value to physicians and other healthcare providers or marketing expenditures; and state and foreign laws that

require the reporting of information related to drug pricing; state and local laws requiring the registration of pharmaceutical sales representatives.

Any action brought against us for violation of these laws or regulations, even if we successfully defend against it, could cause us to incur significant legal expenses and divert our management's attention from the operation of our business. If our operations are found to be in violation of any of these laws and regulations, we may be subject to any applicable penalty associated with the violation, including, among others, significant administrative, civil and criminal penalties, damages, fines, disgorgement, reputational harm, imprisonment, integrity oversight and reporting obligations, and exclusion from participation in federal healthcare programs such as Medicare and Medicaid or comparable foreign programs.

Many EU Member States periodically review their reimbursement procedures for medicinal products, which could have an adverse impact on reimbursement status. We expect that legislators, policymakers and healthcare insurance funds in the EU Member States will continue to propose and implement cost-containing measures, such as lower maximum prices, lower or lack of reimbursement coverage and incentives to use cheaper, usually generic, products as an alternative to branded products, and/or branded products available through parallel import to keep healthcare costs down. Moreover, in order to obtain reimbursement for our products in some EEA countries, including some EU Member States, we may be required to compile additional data comparing the cost-effectiveness of our products to other available therapies. Health Technology Assessment, or HTA, of medicinal products is becoming an increasingly common part of the pricing and reimbursement procedures in some EU Member States, including those representing the larger markets. The HTA process is the procedure to assess therapeutic, economic and societal impact of a given medicinal product in the national healthcare systems of the individual country. The outcome of an HTA will often influence the pricing and reimbursement status granted to these medicinal products by the competent authorities of individual EU Member States. The extent to which pricing and reimbursement decisions are influenced by the HTA of the specific medicinal product currently varies between EU Member States.

Legislative Reform

We operate in a highly regulated industry, and new laws, regulations and judicial decisions, or new interpretations of existing laws, regulations and decisions, related to healthcare availability, the method of delivery and payment for healthcare products and services could negatively affect our business, financial condition and prospects. There is significant interest in promoting healthcare reforms, and it is likely that federal and state legislatures within the United States and the governments of other countries will continue to consider changes to existing healthcare legislation.

For example, the United States and state governments continue to propose and pass legislation designed to reduce the cost of healthcare. In 2010, the U.S. Congress enacted the Affordable Care Act, which included changes to the coverage and reimbursement of drug products under government healthcare programs such as:

- increased the minimum Medicaid rebates owed by manufacturers under the Medicaid Drug Rebate Program;
- established a branded prescription drug fee that pharmaceutical manufacturers of certain branded prescription drugs must pay to the federal government;
- expanded the list of covered entities eligible to participate in the 340B drug pricing program by adding new entities to the program;
- established a new Medicare Part D coverage gap discount program, in which manufacturers must agree to offer 50% (increased to 70% pursuant to the Bipartisan Budget Act of 2018, effective as of 2019) point-of-sale discounts off negotiated prices of applicable brand drugs to eligible beneficiaries during their coverage gap period, as a condition for the manufacturer's outpatient drugs to be covered under Medicare Part D;
- extended manufacturers' Medicaid rebate liability to covered drugs dispensed to individuals who are enrolled in Medicaid managed care organizations;
- expanded eligibility criteria for Medicaid programs by, among other things, allowing states to offer Medicaid coverage to additional individuals and by adding new mandatory eligibility categories for

individuals with income at or below 133% of the federal poverty level, thereby potentially increasing manufacturers' Medicaid rebate liability;

• created a new methodology by which rebates owed by manufacturers under the Medicaid Drug Rebate Program are calculated for certain drugs and biologics, including our product candidates, that are inhaled, infused, instilled, implanted or injected;

• established a new Patient-Centered Outcomes Research Institute to oversee, identify priorities in, and conduct comparative clinical effectiveness research, along with funding for such research;

• established a Center for Medicare and Medicaid Innovation at the CMS to test innovative payment and service delivery models to lower Medicare and Medicaid spending, potentially including prescription drug spending; and

• created a licensure framework for follow-on biologic products.

There have been executive, judicial and congressional challenges to certain aspects of the Affordable Care Act. For example, in 2017, the U.S. Congress enacted legislation informally titled the Tax Cuts and Jobs Act of 2017 (Tax Act), which eliminated the tax-based shared responsibility payment imposed by the Affordable Care Act on certain individuals who fail to maintain qualifying health coverage for all or part of a year that is commonly referred to as the "individual mandate." On June 17, 2021 the U.S. Supreme Court dismissed a challenge on procedural grounds that argued the Affordable Care Act is unconstitutional in its entirety because the "individual mandate" was repealed by Congress. Further, prior to the U.S. Supreme Court ruling, on January 28, 2021, President Biden issued an executive order that initiated a special enrollment period for purposes of obtaining health insurance coverage through the Affordable Care Act marketplace. The executive order also instructed certain governmental agencies to review and reconsider their existing policies and rules that limit access to healthcare, including among others, reexamining Medicaid demonstration projects and waiver programs that include work requirements, and policies that create unnecessary barriers to obtaining access to health insurance coverage through Medicaid or the Affordable Care Act. In addition, on August 16, 2022, President Biden signed the Inflation Reduction Act of 2022 (IRA) into law, which among other things, extends enhanced subsidies for individuals purchasing health insurance coverage in Affordable Care Act marketplaces through plan year 2025. The IRA also eliminates the "donut hole" under the Medicare Part D program beginning in 2025 by significantly lowering the beneficiary maximum out-of-pocket cost and creating a new manufacturer discount program. It is possible that the Affordable Care Act will be subject to judicial or Congressional challenges in the future. It is unclear how any such challenges and the healthcare reform measures of the Biden administration will impact the Affordable Care Act.

In addition, there have been and continue to be a number of initiatives at the federal and state level in the United States that seek to reduce healthcare costs. In 2011, the U.S. Congress enacted the Budget Control Act, which included provisions intended to reduce the federal deficit. The Budget Control Act resulted in the imposition of 2% reductions in Medicare payments to providers beginning in 2013 and, due to subsequent legislative amendments to the statute, will remain in effect through 2032. On March 11, 2021, President Biden signed the American Rescue Plan Act of 2021 into law, which eliminates the statutory Medicaid drug rebate cap, currently set at 100% of a drug's average manufacturer price, for single source and innovator multiple source drugs, effective January 1, 2024. In addition, in 2012, the U.S. Congress enacted the American Taxpayer Relief Act, which, among other things, further reduced Medicare payments to several types of providers, including hospitals, imaging centers and cancer treatment centers, and increased the statute of limitations period for the government to recover overpayments to providers from three to five years.

Furthermore, there has been heightened governmental scrutiny over the manner in which manufacturers set prices for their marketed products, which has resulted in several presidential executive orders, congressional inquiries and proposed legislation designed to, among other things, bring more transparency to product pricing, review the relationship between pricing and manufacturer patient programs and reform government program reimbursement methodologies for drug products. For example, in July 2021, the Biden administration released an executive order, "Promoting Competition in the American Economy," with multiple provisions aimed at prescription drugs. In response to Biden's executive order, on September 9, 2021, HHS released a Comprehensive Plan for Addressing High Drug Prices that outlines principles for drug pricing reform and sets out a variety of potential legislative policies that Congress could pursue to advance these principles. The IRA also, among other things, (1) directs HHS to negotiate the price of certain single-source drugs and biologics covered under Medicare and (2) imposes rebates under Medicare Part B and Medicare Part D to penalize price increases that outpace inflation. These

provisions take effect progressively starting in fiscal year 2023. On August 29, 2023, HHS announced the list of the first ten drugs that will be subject to price negotiations, although the Medicare drug price negotiation program is currently subject to legal challenges. It is currently unclear how the IRA will be implemented but is likely to have a significant impact on the pharmaceutical industry. In response to the Biden administration's October 2022 executive order, on February 14, 2023, HHS released a report outlining three new models for testing by the CMS Innovation Center which will be evaluated on their ability to lower the cost of drugs, promote accessibility, and improve quality of care. It is unclear whether the models will be utilized in any health reform measures in the future. Further, on December 7, 2023, the Biden administration announced an initiative to control the price of prescription drugs through the use of march-in rights under the Bayh-Dole Act. On December 8, 2023, the National Institute of Standards and Technology published for comment a Draft Interagency Guidance Framework for Considering the Exercise of March-In Rights which for the first time includes the price of a product as one factor an agency can use when deciding to exercise march-in rights. While march-in rights have not previously been exercised, it is uncertain if that will continue under the new framework. Individual states in the United States have also become increasingly active in passing legislation and implementing regulations designed to control pharmaceutical product pricing, including price or patient reimbursement constraints, discounts, restrictions on certain product access and marketing cost disclosure and transparency measures, and, in some cases, designed to encourage importation from other countries and bulk purchasing. In addition, regional healthcare 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 healthcare programs. We expect that additional state and federal healthcare reform measures will be adopted in the future.

In December 2021, Regulation No 2021/2282 on Health Technology Assessment, or HTA, amending Directive 2011/24/EU, was adopted in the EU. This Regulation, which entered into force in January 2022 and will apply as of January 2025, is intended to boost cooperation among EU Member States in assessing health technologies, including new medicinal products, and providing the basis for cooperation at EU level for joint clinical assessments in these areas. The Regulation foresees a three-year transitional period and 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 most 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 technologies, and making decisions on pricing and reimbursement. If we are unable to maintain favorable pricing and reimbursement status in EU Member States for product candidates that we may successfully develop and for which we may obtain regulatory approval, any anticipated revenue from and growth prospects for those products in the EU could be negatively affected.

In addition, on April 26, 2023, the European Commission adopted a proposal for a new Directive and Regulation to revise the existing pharmaceutical legislation. If adopted in the form proposed, the recent European Commission proposals to revise the existing EU laws governing authorization of medicinal products may result in a decrease in data and market exclusivity opportunities for our product candidates in the EU and make them open to generic or biosimilar competition earlier than is currently the case with a related reduction in reimbursement status.

Environmental, Health and Safety Laws and Regulations

We and our third-party contractors are subject to numerous environmental, health and safety laws and regulations, including those governing laboratory procedures and the use, generation, manufacture, distribution, storage, handling, treatment, remediation and disposal of hazardous materials and wastes. Hazardous chemicals, including flammable and biological materials, are involved in certain aspects of our business, and we cannot eliminate the risk of injury or contamination from the use, generation, manufacture, distribution, storage, handling, treatment or disposal of hazardous materials and wastes. In the event of contamination or injury, or failure to comply with environmental, health and safety laws and regulations, we could be held liable for any resulting damages, fines and penalties associated with such liability could exceed our assets and resources. Environmental, health and safety laws and regulations are becoming increasingly more stringent. We may incur substantial costs in order to comply with current or future environmental, health and safety laws and regulations.

Pharmaceutical Coverage, Pricing and Reimbursement

The availability and extent of coverage and adequate reimbursement by governmental and private third-party payors are essential for most patients to be able to afford expensive medical treatments. In both domestic and foreign markets, sales of our product candidates, if approved, will depend substantially on the extent to which the costs of our product candidates will be covered by third-party payors, such as government health programs, commercial insurance and managed healthcare organizations. These third-party payors decide which products will be covered and establish reimbursement levels for those products.

Coverage and reimbursement by a third-party payor may depend upon a number of factors, including the third-party payor's determination that use of a product is:

- a covered benefit under its health plan;
- safe, effective and medically necessary;
- appropriate for the specific patient;
- cost-effective; and
- neither experimental nor investigational.

Obtaining coverage approval and reimbursement for a product from a government or other third-party payor is a time-consuming and costly process that could require us to provide supporting scientific, clinical and cost-effectiveness data for the use of our products to the payor. We may not be able to provide data sufficient to gain acceptance with respect to coverage and reimbursement at a satisfactory level. If coverage and adequate reimbursement of our future products, if any, are unavailable or limited in scope or amount, such as may result where alternative or generic treatments are available, we may be unable to achieve or sustain profitability. Adverse coverage and reimbursement limitations may hinder our ability to recoup our investment in our product candidates, even if such product candidates obtain regulatory approval. For products administered under the supervision of a physician, obtaining coverage and adequate reimbursement may be particularly difficult because of the higher prices often associated with such products. Additionally, separate reimbursement for the product itself or the treatment or procedure in which the product is used may not be available, which may impact physician utilization.

There is significant uncertainty related to the insurance coverage and reimbursement of newly approved products. There is no uniform policy for coverage and reimbursement in the United States and, as a result, coverage and reimbursement can differ significantly from payor to payor. In the United States, private payors often, but not always, follow Medicare coverage and reimbursement policies with respect to newly approved products. It is difficult to predict what third-party payors will decide with respect to coverage and reimbursement for fundamentally novel products such as ours, as there is no body of established practices and precedents for these new products. Further, one payor's determination to provide coverage and adequate reimbursement for a product does not assure that other payors will also provide coverage and adequate reimbursement for that product. We may need to conduct expensive pharmaco-economic studies in order to demonstrate the medical necessity and cost-effectiveness of our product candidates. There can be no assurance that our product candidates will be considered medically necessary or cost-effective. In addition to third-party payors, professional organizations and patient advocacy groups such as the National Comprehensive Cancer Network and the American Society of Clinical Oncology can influence decisions about reimbursement for new medicines by determining standards for care. Therefore, it is possible that any of our product candidates, even if approved, may not be covered by third-party payors or the reimbursement limit may be so restrictive that we cannot commercialize the product candidates profitably.

Reimbursement agencies in the European Union may be more restrictive than payors in the United States. For example, a number of cancer products have been approved for reimbursement in the United States but not in certain European countries. In Europe, pricing and reimbursement schemes vary widely from country to country. For example, some countries provide that products may be marketed only after an agreement on reimbursement price has been reached. Such pricing negotiations with governmental authorities can take considerable time after receipt of marketing approval for a product. Political, economic and regulatory developments may further complicate pricing negotiations, and pricing negotiations may continue after reimbursement has been obtained. Other countries require the completion of additional health technology assessments that compare the cost- effectiveness of a particular product candidate to currently available therapies. In addition, the European Union provides options for its member states to restrict the range of products for which their national health insurance systems provide reimbursement and to control the prices of medicinal products for human use. European Union member states may

approve a specific price for a product, may adopt a system of direct or indirect controls on the profitability of the company placing the product on the market or monitor and control prescription volumes and issue guidance to physicians to limit prescriptions. Reference pricing used by various European Union member states and parallel distribution, or arbitrage between low-priced and high-priced member states, can further reduce prices. Furthermore, many countries in the European Union have increased the amount of discounts required on pharmaceutical products, and these efforts could continue as countries attempt to manage healthcare expenditures, especially in light of the severe fiscal and debt crises experienced by many countries in the European Union. The downward pressure on healthcare costs in general, and prescription products in particular, has become increasingly intense. As a result, there are increasingly higher barriers to entry for new products. There can be no assurance that any country that has reimbursement limitations for pharmaceutical products will allow favorable reimbursement and pricing arrangements for any of our products, if approved in those countries. Accordingly, the reimbursement for any products in the European Union may be reduced compared with the United States and may be insufficient to generate commercially reasonable revenues and profits.

Furthermore, the containment of healthcare costs has become a priority of foreign and domestic governments as well as private third-party payors. The prices of drugs have been a focus in this effort. Governments and private third-party payors have attempted to control costs by limiting coverage and the amount of reimbursement for particular medications, which could affect our ability to sell our product candidates profitably. We also expect to experience pricing pressures due to the trend towards managed healthcare, the increasing influence of health maintenance organizations and additional legislative changes. These and other cost-control initiatives could cause us to decrease the price we might establish for products, which could result in lower-than-anticipated product revenues. In addition, the publication of discounts by third-party payors or authorities may lead to further pressure on the prices or reimbursement levels within the country of publication and other countries. If pricing is set at unsatisfactory levels or if coverage and adequate reimbursement of our products is unavailable or limited in scope or amount, our revenues and the potential profitability of our product candidates in those countries would be negatively affected.

Legal Proceedings

From time to time, we may become involved in legal proceedings or be subject to claims arising in the ordinary course of our business. We are not currently a party to any material legal proceedings. Regardless of outcome, such proceedings or claims can have an adverse impact on us because of defense and settlement costs, diversion of resources and other factors, and there can be no assurances that favorable outcomes will be obtained.

Facilities

Our corporate headquarters is located in San Diego, California, where we lease office and laboratory space pursuant to a lease agreement which commenced in July, 2022 and expires in January, 2033. We believe that our existing facilities are adequate for the foreseeable future. As we expand, we believe that suitable additional alternative spaces will be available in the future on commercially reasonable terms, if required.

Corporate Information

We were incorporated under the laws of the State of Delaware on June 27, 2017. Our principal executive offices are located at 10955 Vista Sorrento Parkway, Suite 200, San Diego, California, and our telephone number is (858) 751-4493. Our corporate website address is www.januxrx.com. Information contained on, or accessible through, our website shall not be deemed incorporated into and is not a part of this Annual Report on Form 10-K. Our Annual Reports on Form 10-K, Quarterly Reports on Form 10-Q, Current Reports on Form 8-K and amendments to such reports filed or furnished pursuant to Section 13(a) and 15(d) of the Securities Exchange Act of 1934, as amended (the Exchange Act), are available free of charge on the Investors & Media portion of our website as soon as reasonably practical after we electronically file such material with, or furnish it to, the SEC.

All brand names or trademarks appearing in this Annual Report are the property of their respective holders. Use or display by us of other parties' trademarks, trade dress, or products in this Annual Report is not intended to, and does not, imply a relationship with, or endorsements or sponsorship of, us by the trademark or trade dress owners.

Employees and Human Capital Resources

As of December 31, 2023, we had 64 full-time employees. Of these employees, 47 were engaged in research and development and 17 were engaged in general and administrative activities. As of December 31, 2023, we had 59 employees based at our headquarters in San Diego, California. Our employees are not 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 believe that we have been successful in attracting and retaining talented personnel to support our expanding business, though competition for personnel in our industry is intense. We monitor recruiting efforts using a variety of metrics, including cycle times, cost per hire, information on the retention of business-critical hires, and the percentage of budgeted openings filled on time and on budget. We also track voluntary and involuntary turnover rates for business-critical talent, time in role, and job level.

We offer competitive pay and benefits designed to attract and retain exceptional talent and drive company performance. In setting appropriate compensation levels, we look at the average base pay rate for each position based on market data. We also offer equity incentive plans designed to assist in attracting, retaining and motivating selected employees, consultants and directors through the granting of stock-based compensation awards.

Our standard employee benefits include paid and unpaid leaves, medical, dental and vision insurance coverage, a 401(k) plan, short- and long-term disability, life insurance, health savings and flexible spending accounts, paid time off, and an employee stock purchase plan. We also offer a variety of voluntary benefits that allow employees to select options that meet their needs, including a long-term care plan, an employee assistance program, and wellness programs. We benchmark our benefits program against others in our industry on an annual basis.

Item 1A. Risk Factors.

We operate in a dynamic and rapidly changing environment that involves numerous risks and uncertainties. Certain factors may have a material adverse effect on our business, financial condition and results of operations, and you should carefully consider them. Accordingly, in evaluating our business, we encourage you to consider the following discussion of risk factors, in its entirety, in addition to other information contained in this Annual Report on Form 10-K and our other public filings with the SEC. Other events that we do not currently anticipate or that we currently deem immaterial may also affect our results of operations and financial condition.

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

We have a limited operating history, have incurred net losses since our inception, and anticipate that we will continue to incur significant losses for the foreseeable future. We may never generate any revenue or become profitable or, if we achieve profitability, may not be able to sustain it.

We are an early-stage biopharmaceutical company with a limited operating history that may make it difficult to evaluate the success of our business to date and to assess our future viability. Our operations to date have been limited to organizing and staffing our company, business planning, business development, raising capital, developing and optimizing our technology platform, identifying potential product candidates, undertaking research and preclinical studies for our lead programs, establishing and enhancing our intellectual property portfolio and providing general and administrative support for these operations. All of our product candidates and research programs other than JANX007 and JANX008 are in preclinical development, and none have been approved for commercial sale. We have never generated any revenue from product sales and have incurred net losses each year since we commenced operations. For the years ended December 31, 2023 and 2022, our net losses were $58.3 million and $63.1 million, respectively. We expect that it will be several years, if ever, before we have a product candidate ready for regulatory approval and commercialization. We expect to incur increasing levels of operating losses over the next several years and for the foreseeable future as we advance our product candidates through clinical development. Our prior losses, combined with expected future losses, have had and will continue to have an adverse effect on our stockholders' equity and working capital.

To become and remain profitable, we must develop and eventually commercialize a product or products with significant market potential. This will require us to be successful in a range of challenging activities, including completing preclinical studies and clinical trials of our product candidates, obtaining marketing approval for these product candidates, manufacturing, marketing and selling those products for which we may obtain marketing approval and satisfying any post-marketing requirements. We may never succeed in these activities and, even if we succeed in commercializing one or more of our product candidates, we may never generate revenue that is significant or large enough to achieve profitability. In addition, as a young business, we may encounter unforeseen expenses, difficulties, complications, delays and other known and unknown challenges. If we do achieve profitability, we may not be able to sustain or increase profitability on a quarterly or annual basis and we will continue to incur substantial research and development and other expenditures to develop and market additional product candidates. Our failure to become and remain profitable would decrease the value of the company and could impair our ability to raise capital, maintain our research and development efforts, expand our business or continue our operations. A decline in the value of our company could also cause the loss of all or part of investments.

If we are unable to raise additional capital when needed, we may be forced to delay, reduce or eliminate our product development programs or other operations.

Since our inception, we have used substantial amounts of cash to fund our operations and expect our expenses to increase substantially during the next few years. The development of biopharmaceutical product candidates is capital intensive. As our product candidates enter and advance through preclinical studies and potential clinical trials, we will need substantial additional funds to expand our clinical, regulatory, quality and manufacturing capabilities. In addition, if we obtain marketing approval for any of our product candidates, we expect to incur significant commercialization expenses related to marketing, sales, manufacturing and distribution.

As of December 31, 2023, we had $344.0 million in cash and cash equivalents and short-term investments. Based upon our current operating plan, we estimate that our existing cash and cash equivalents and short-term investments will be sufficient to fund our operating expenses and capital expenditure requirements for at least the next 12 months following the date of this Annual Report. However, we believe that our existing cash and cash equivalents and short-term investments will not be sufficient to fund any of our product candidates through regulatory approval, and we will need to raise substantial additional capital to complete the development and commercialization of our product candidates.

We have based these estimates on assumptions that may prove to be incorrect or require adjustment as a result of business decisions, and we could utilize our available capital resources sooner than we currently expect. Our future capital requirements will depend on many factors, including:

- the initiation, trial design, progress, timing, costs and results of drug discovery, preclinical studies and clinical trials of our product candidates, and in particular the clinical trials for JANX007 and JANX008;
- the number and characteristics of clinical programs that we pursue;
- the outcome, timing and costs of seeking FDA, European Commission and any other comparable regulatory approvals for any future drug candidates;
- the costs of manufacturing our product candidates;
- the costs associated with hiring additional personnel and consultants as our preclinical, manufacturing and clinical activities increase;
- the receipt of marketing approval and revenue received from any commercial sales of any of our product candidates, if approved;
- the cost of commercialization activities for any of our product candidates, if approved, including marketing, sales and distribution costs;
- the ability to establish and maintain strategic collaboration, licensing or other arrangements and the financial terms of such agreements;
- the extent to which we in-license or acquire other products and technologies;
- the costs involved in preparing, filing, prosecuting, maintaining, expanding, defending and enforcing patent claims, including litigation costs and the outcome of such litigation;
- our implementation of additional internal systems and infrastructure, including operational, financial and management information systems;
- our costs associated with expanding our facilities or building out our laboratory space;
- the effects of the disruptions to and volatility in the credit and financial markets in the United States and worldwide resulting from geopolitical and macroeconomic conditions, including COVID-19, the military conflict in Ukraine and Russia, the war in the Middle East and bank failures; and
- the costs of operating as a public company.

Because we do not expect to generate revenue from product sales for many years, if at all, we will need to obtain substantial additional funding in connection with our continuing operations and expected increases in expenses. Until such time as we can generate significant revenue from sales of our product candidates, if ever, we expect to finance our cash needs through equity offerings, debt financings or other capital sources, including potentially grants, collaborations, licenses or other similar arrangements. 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. If we are unable to raise capital when needed or on attractive terms, we would be forced to delay, reduce or eliminate our research and development programs or future commercialization efforts.

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

Until such time, if ever, as we can generate substantial product revenue, we expect to finance our operations through equity offerings, debt financings or other capital sources, including potentially grants, collaborations, licenses or other similar arrangements. To the extent that we raise additional capital through the sale of equity or convertible debt securities, current stockholders will be diluted, and the terms of these securities may include liquidation or other preferences that adversely affect the rights of existing stockholders. Debt financing, if available, may involve agreements that include covenants limiting or restricting our ability to take specific actions, such as limitations on our ability to incur additional debt, make capital expenditures or declare dividends.

To the extent we raise funds through collaborations 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. For example, we have entered into a collaboration with Merck to develop certain specified product candidates, which contains exclusive license rights in favor of Merck. If Merck decides not to pursue the collaboration, we will not receive the benefit of the milestone and royalty payments that we would otherwise potentially receive pursuant to our collaboration with Merck and accordingly may need to raise capital from other sources. If we are unable to raise additional funds when needed, we may be required to delay, limit, reduce or terminate our product development or future commercialization efforts or grant rights to develop and market product candidates that we would otherwise prefer to develop and market ourselves. Our ability to raise additional funds may be adversely impacted by potential worsening global economic conditions and disruptions to and volatility in the credit and financial markets in the United States and worldwide. Because of the numerous risks and uncertainties associated with product development, we cannot predict the timing or amount of increased expenses and cannot assure you that we will ever be profitable or generate positive cash flow from operating activities.

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

We are early in our development efforts and all of our product candidates and research programs other than JANX007 and JANX008 are in the preclinical development or discovery stage. We have a very limited history of conducting clinical trials to test our product candidates in humans.

We are early in our development efforts and most of our operations to date have been limited to developing our platform technologies and conducting drug discovery and preclinical studies. Other than JANX007 and JANX008, our platform technologies and product candidates remain in the preclinical or discovery stage and our product candidates are based on novel technologies. As a result, we have limited infrastructure, experience conducting clinical trials as a company and regulatory interactions, and cannot be certain that our clinical trials will be completed on time, if at all, that our planned development programs would be acceptable to the FDA, the EMA or other comparable foreign regulatory authorities, or that, if approval is obtained, such product candidates could be successfully commercialized.

Because of the early stage of development of our products candidates, our ability to eventually generate significant revenues from product sales will depend on a number of factors, including:

- completion of additional preclinical studies with favorable results;
- acceptance of INDs by the FDA or similar regulatory filing with comparable foreign regulatory authorities for the conduct of clinical trials of our product candidates and our proposed design of future clinical trials;
- successful enrollment in, and completion of, clinical trials and achieving positive results from the trials;
- demonstrating a risk-benefit profile acceptable to regulatory authorities;

- receipt of marketing approvals from applicable regulatory authorities, including biologics license applications (BLAs), from the FDA and equivalent approvals from comparable foreign regulatory authorities and maintaining such approvals;

- making arrangements with third-party manufacturers, or establishing manufacturing capabilities for clinical supply and, if and when approved, for commercial supply;

- establishing sales, marketing and distribution capabilities and launching commercial sales of our products, if and when approved, whether alone or in combination with others;

- acceptance of our products, if and when approved, by patients, the medical community and third-party payors;

- effectively competing with other therapies;

- obtaining and maintaining third-party coverage and adequate reimbursement;

- obtaining and maintaining patent, trade secret and other intellectual property protection and regulatory exclusivity for our product candidates; and

- maintaining a continued acceptable safety profile of any product following approval, if any.

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 JANX007 and JANX008, as well as our other product candidates, which may never occur. In the future, we may also become dependent on other product candidates that we may develop or acquire; however, given our early stage of development, it may be several years, if at all, before we have demonstrated the safety and efficacy of a treatment sufficient to warrant approval for commercialization. If we are unable to develop, or obtain regulatory approval for, or, if approved, successfully commercialize our product candidates, we may not be able to generate sufficient revenue to continue our business.

Preclinical and clinical development is a lengthy, expensive and uncertain process. The results of preclinical studies and early clinical trials are not always predictive of future results. JANX007, JANX008 and any other product candidate that we advance into clinical trials may not achieve favorable results in later clinical trials, if any, or receive marketing approval.

Preclinical and clinical development is expensive and can take many years to complete, and their outcome is inherently uncertain. Failure or delay can occur at any time during the drug development process including due to factors outside of our control. Success in preclinical testing and early clinical trials does not ensure that later clinical trials will be successful. A number of companies in the biopharmaceutical industry have suffered significant setbacks in clinical trials, even after promising results in earlier preclinical or clinical trials. These setbacks have been caused by, among other things, preclinical findings made while clinical trials were underway and safety or efficacy observations made in clinical trials, including previously unreported adverse events. The results of preclinical and early clinical trials of our product candidates may not be predictive of the results of later-stage clinical trials. Product candidates in later stages of clinical trials may fail to show the desired safety and efficacy traits despite having progressed through preclinical and initial clinical trials. Notwithstanding any potential promising results in earlier studies, we cannot be certain that we will not face similar setbacks. Even if our clinical trials are completed, the results may not be sufficient to obtain regulatory approval for our product candidates.

We may experience delays in conducting our current clinical trials and initiating our future clinical trials for our product candidates and we cannot be certain that the trials or any other future clinical trials for our product candidates will begin on time, need to be redesigned, enroll an adequate number of patients on time or be completed on schedule, if at all. Clinical trials can be delayed or terminated for a variety of reasons, including delay or failure related to:

- the FDA, the EMA or comparable foreign regulatory authorities disagreeing as to the design or implementation of our clinical trials, or the sufficiency of preclinical data to initiate clinical trials;
- the size of the study population for further analysis of the study's primary endpoints;
- obtaining regulatory approval to commence a trial;
- reaching agreement on acceptable terms with prospective CROs and clinical trial sites, the terms of which can be subject to extensive negotiation and may vary significantly among different CROs and trial sites;
- obtaining IRB approval or ethics committee positive opinions;
- recruiting suitable patients to participate in a trial;
- having patients complete a trial or return for post-treatment follow-up;
- addressing patient safety concerns that arise during the course of a trial;
- addressing any conflicts with new or existing laws or regulations;
- adding a sufficient number of clinical trial sites; or
- manufacturing sufficient quantities of product candidate for use in clinical trials.

Our product candidates may be used in combination with other cancer drugs, such as other immuno-oncology agents, monoclonal antibodies or other protein-based drugs or small molecule anti-cancer agents such as targeted agents or chemotherapy, which can cause side effects or adverse events that are unrelated to our product candidate but may still impact the success of our clinical trials. Additionally, our product candidates could potentially cause adverse events. The inclusion of critically ill patients in our clinical trials may result in deaths or other adverse medical events due to other therapies or medications that such patients may be using. As described above, any of these events could prevent us from obtaining regulatory approval or achieving or maintaining market acceptance of our product candidates and impair our ability to commercialize our products. Because all of our product candidates are derived from our platform technologies, a clinical failure of one of our product candidates may also increase the actual or perceived likelihood that our other product candidates will experience similar failures.

Of the large number of products in development, only a small percentage successfully complete the FDA, the European Commission's or comparable foreign regulatory authorities' approval processes and are commercialized. The lengthy approval process as well as the unpredictability of future clinical trial results may result in our failing to obtain regulatory approval to market our product candidates, which would significantly harm our business, financial condition, results of operations and prospects.

Even if we eventually complete clinical testing and receive approval of a BLA or foreign marketing application for our product candidates, the FDA, the European Commission or the comparable foreign regulatory authorities may grant approval contingent on the performance of costly additional clinical trials, including post-market clinical trials. The FDA, the European Commission or the comparable foreign regulatory authorities also may approve a product candidate for a more limited indication or patient population than we originally request, and the FDA, the European Commission or comparable foreign regulatory authorities may not approve the labeling that we believe is necessary or desirable for the successful commercialization of a product candidate. Any delay in obtaining, or inability to obtain, applicable regulatory approval would delay or prevent commercialization of that product candidate and would adversely impact our business and prospects.

In addition, the FDA, the EMA and the European Commission or comparable foreign regulatory authorities may change their policies, adopt additional regulations or revise existing regulations or take other actions, which may prevent or delay approval of our future product candidates under development on a timely basis. Such policy or regulatory changes could impose additional requirements upon us that could delay our ability to obtain approvals, increase the costs of compliance or restrict our ability to maintain any marketing authorizations we may have obtained.

Our product candidates are based on novel technologies, which make it difficult to predict the timing, results and cost of product candidate development and likelihood of obtaining regulatory approval.

We have concentrated our research and development efforts on product candidates using our proprietary technology, and our future success depends on the successful development of this approach. We have not yet succeeded and may not succeed in demonstrating efficacy and safety for any product candidates based on our platform technologies in clinical trials or in obtaining marketing approval thereafter, and use of our platform technologies may not ever result in marketable products. Additionally, although JAN007 and JANX008 have been in Phase 1 clinical development since October 2022 and April 2023, respectively, our clinical data are limited, and nonclinical data from animal models and preclinical cell lines may not translate into humans and may not accurately predict the safety and efficacy of our product candidates in humans. Our approach may be unsuccessful in identifying product candidates for our development programs. We may also experience delays in developing a sustainable, reproducible and scalable manufacturing process or transferring that process to commercial partners or establishing our own commercial manufacturing capabilities, which may prevent us from completing our ongoing and planned clinical trials or commercializing any products on a timely or profitable basis, if at all. Further, because all of our product candidates and development programs are based on the same platform technologies, adverse developments with respect to one of our programs may have a significant adverse impact on the actual or perceived likelihood of success and value of our other programs.

The clinical trial requirements of the FDA, EMA and other comparable foreign regulatory authorities, and the criteria regulators use to determine the safety and efficacy of a product candidate vary substantially according to the type, complexity, novelty and intended use and market of the potential products. The regulatory approval process for novel product candidates such as ours can be more expensive and take longer than for other, better known or extensively studied pharmaceutical or other product candidates.

The immuno-oncology industry is also rapidly developing, and our competitors may introduce new technologies that render our technologies obsolete or less attractive, or limit the commercial value of our product candidates. New technology could emerge at any point in the development cycle of our product candidates. By contrast, adverse developments with respect to other companies that attempt to use a similar approach to our approach may adversely impact the actual or perceived value and potential of our product candidates.

If any of these events occur, we may be forced to abandon our development efforts for a program or programs, which would have a material adverse effect on our business and could potentially cause us to cease operations.

If we experience delays in or difficulties enrolling our ongoing and planned clinical trials, our research and development efforts and business, financial condition and results of operations could be materially adversely affected.

We may not be able to initiate or continue our ongoing and planned clinical trials for our product candidates if we are unable to identify and enroll a sufficient number of eligible patients to participate in these trials as required by the FDA, the EMA, or comparable foreign regulatory authorities. Patient enrollment, a significant factor in the timing of clinical trials, is affected by many factors including the size and nature of the patient population, the proximity of patients to clinical sites, the eligibility criteria for the clinical trial, the design of the clinical trial, competing clinical trials and clinicians' and patients' perceptions as to the potential advantages of the product candidate being studied in relation to other available therapies, including any new drugs that may be approved for the indications we are investigating.

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 or retention in our clinical trials for a variety of reasons. The enrollment of patients depends on many factors, including:

- the patient eligibility criteria defined in the protocol;
- the size of the patient population required for analysis of the trial's primary endpoints;
- the proximity of patients to study 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 product 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; and
- the risk that patients enrolled in clinical trials will drop out of the trials before completion.

In addition, our ongoing and planned clinical trials may compete with other clinical trials 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. Further, because our ongoing and planned clinical trials are in patients with relapsed/refractory cancer, the patients are typically in the late stages of their disease and may experience disease progression independent from our product candidates, making them unevaluable for purposes of the clinical trial and requiring additional patient enrollment.

Delays in patient enrollment may result in increased costs or may affect the timing or outcome of our ongoing and planned clinical trials, which could prevent completion of these trials and adversely affect our ability to advance the development of our product candidates.

Serious adverse events, undesirable side effects or other unexpected properties of our product candidates may be identified during development or after approval, which could lead to the discontinuation of our clinical development programs, refusal by regulatory authorities to approve our product candidates or, if discovered following marketing approval, revocation of marketing authorizations or limitations on the use of our product candidates thereby limiting the commercial potential of such product candidate.

As we continue developing and conducting clinical trials of our product candidates, serious adverse events (SAEs), undesirable side effects, relapse of disease or unexpected characteristics may emerge causing us to abandon these product candidates or limit their development to more narrow uses or subpopulations in which the SAEs or undesirable side effects or other characteristics are less prevalent, less severe or more acceptable from a risk-benefit perspective or in which efficacy is more pronounced or durable. Should we observe any SAEs in our ongoing or planned clinical trials or identify other undesirable side effects or other unexpected findings depending on their severity, our trials could be delayed or even stopped and our development programs may be halted entirely, such as imposition of a clinical hold by the FDA or comparable actions of foreign regulatory authorities and institutional review boards and ethics committees. The class of TCEs has been associated with overactivation of the immune system leading to cytokine release syndrome (CRS) and on-target healthy tissue toxicities, and while we have designed our TRACTr and TRACIr platform technologies and product candidates to mitigate these safety risks, until such time as we complete large-scale human trials there can be no assurances that our product candidates will not experience similar effects.

Even if our product candidates initially show positive results in early clinical trials, the side effects of biological products are frequently only detectable after they are tested in larger, longer and more extensive clinical trials or, in some cases, after they are made available to patients on a commercial scale after approval. Sometimes, it can be difficult to determine if the serious adverse or unexpected side effects were caused by the product candidate or another factor, especially in oncology subjects who may suffer from other medical conditions and be taking other medications. If serious adverse or unexpected side effects are identified during development or after approval and are determined to be attributed to our product candidate, we may be required to develop a Risk Evaluation and Mitigation Strategy (REMS) or equivalent foreign procedure to ensure that the benefits of treatment with such product candidate outweigh the risks for each potential patient, which may include, among other things, a communication plan to health care practitioners, patient education, extensive patient monitoring or distribution systems and processes that are highly controlled, restrictive and more costly than what is typical for the industry. Product-related side effects could also result in potential product liability claims. Any of these occurrences may harm our business, financial condition and prospects significantly.

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

- regulatory authorities may suspend, vary, withdraw, or limit approvals of such product, or seek an injunction against its manufacture or distribution;
- regulatory authorities may require additional warnings on the label, including “boxed” warnings, or issue safety alerts, Dear Healthcare Provider letters, press releases or other communications containing warnings or other safety information about the product;
- we may be required to create a medication guide outlining the risks of such side effects for distribution to patients;
- we may be required to change the way a product is administered or conduct additional clinical trials;
- the product may become less competitive, and our reputation may suffer;
- we may be obliged to, need to, or decide to recall or remove the product from the marketplace; and
- we may be subject to fines, injunctions or the imposition of civil or criminal penalties.

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

From time to time, we may publicly disclose preliminary, interim or topline data from our preclinical studies or clinical trials, which may be subject to change following a more comprehensive review of the data related to the particular study or trial. We also make assumptions, estimations, calculations and conclusions as part of our analyses of data, and we may not have received or had the opportunity to fully and carefully evaluate all data. As a result, the interim, topline or preliminary results that we report may differ from future results of the same studies, or different conclusions or considerations may qualify such results, once additional data have been received and fully evaluated. Topline data also remain subject to audit and verification procedures that may result in the final data being materially different from the preliminary data we previously published. As a result, interim, topline and preliminary data should be viewed with caution until the final data are available. From time to time, we may also disclose interim data from our clinical trials. Interim, topline, or preliminary data from clinical trials that we may complete are subject to the risk that one or more of the clinical outcomes may materially change as patient enrollment continues and more patient data become available. Adverse differences between preliminary, interim or topline data and final data could significantly harm our business prospects.

Further, others, including regulatory authorities, may not accept or agree with our assumptions, estimates, calculations, conclusions or analyses or may interpret or weigh the importance of data differently, which could impact the value of the particular program, the approvability or commercialization of the particular product candidate or product and our company in general. In addition, the information we choose to publicly disclose regarding a particular study or clinical trial is based on what is typically extensive information, and you or others may not agree with what we determine to be material or otherwise appropriate information to include in our disclosure, and any information we determine not to disclose may ultimately be deemed significant with respect to future decisions, conclusions, views, activities or otherwise regarding a particular product candidate or our business. If the interim, topline, or preliminary data that we report differ from actual results, or if others, including regulatory authorities, disagree with the conclusions reached, our ability to obtain approval for and commercialize our product candidates, our business, operating results, prospects or financial condition may be harmed.

The regulatory approval process is lengthy, expensive and uncertain, and we may be unable to obtain regulatory approval for our product candidates under applicable regulatory requirements. The denial or delay of any such approval would delay commercialization of our product candidates and adversely impact our ability to generate revenue, our business and our results of operations.

The development, research, testing, manufacturing, labeling, approval, selling, import, export, marketing, promotion and distribution of drug products are subject to extensive and evolving regulation by federal, state and

local governmental authorities in the United States, principally the FDA, and by foreign regulatory authorities, which regulations may differ from country to country. Neither we nor any current or future collaborator is permitted to market any of our product candidates in the United States until we receive regulatory approval of a BLA from the FDA. Equivalent limitations are imposed by comparable foreign regulatory authorities within their territories.

Obtaining regulatory approval of a BLA, or in an equivalent foreign process, can be a lengthy, expensive and uncertain process. Prior to obtaining approval to commercialize a product candidate in the United States or abroad, we or our collaborators must demonstrate with substantial evidence from well-controlled clinical trials, and to the satisfaction of the FDA, the EMA and the European Commission, or other foreign regulatory authorities, that such product candidates are safe and effective for their intended uses. The number of nonclinical studies and clinical trials that will be required for FDA, European Commission or comparable foreign regulatory approval varies depending on the product candidate, the disease or condition that the product candidate is designed to address, and the regulations applicable to any particular product candidate.

Results from nonclinical studies and clinical trials can be interpreted in different ways. Even if we believe the nonclinical or clinical data for our product candidates are positive, such data may not be sufficient to support approval by the FDA, the European Commission or other comparable foreign regulatory authorities. Administering product candidates to humans may produce undesirable side effects, which could interrupt, delay or halt clinical trials and result in the FDA, the European Commission or other comparable foreign regulatory authorities denying approval of a product candidate for any or all indications. The FDA, the EMA, the European Commission or other comparable foreign regulatory authorities, may also require us to conduct additional studies or trials for our product candidates either prior to or post-approval, or may object to elements of our clinical development program such as the number of subjects in our clinical trials from the United States or abroad.

The FDA, the EMA, the European Commission or other comparable foreign regulatory authorities can delay, limit or deny approval of our product candidates or require us to conduct additional nonclinical or clinical testing or abandon a program for many reasons, including:

- the FDA, the EMA or comparable foreign regulatory authorities' disagreement with the design or implementation of our ongoing or planned clinical trials;
- negative or ambiguous results from our clinical trials or results that may not meet the level of statistical significance required by the FDA, the EMA, the European Commission or comparable foreign regulatory authorities for approval;
- serious and unexpected drug-related side effects experienced by participants in our clinical trials or by individuals using drugs similar to our product candidates;
- our inability to demonstrate to the satisfaction of the FDA, the EMA and the European Commission or comparable foreign regulatory authorities that our product candidates are safe and effective for the proposed indication;
- the FDA's, the EMA's, or comparable foreign regulatory authorities' disagreement with the interpretation of data from nonclinical studies or clinical trials;
- our inability to demonstrate the clinical and other benefits of our product candidates outweigh any safety or other perceived risks;
- the FDA's, the EMA's or a comparable foreign regulatory authorities' requirement for additional nonclinical studies or clinical trials;
- the FDA's, the EMA's, the European Commission's or comparable foreign regulatory authorities' disagreement regarding the formulation, labeling and/or the specifications of our product candidates;
- the FDA's or comparable foreign regulatory authorities' failure to approve the manufacturing processes or facilities of third-party manufacturers with which we contract; or
- the potential for approval policies or regulations of the FDA, the European Commission or comparable foreign regulatory authorities' to significantly change in a manner rendering our clinical data insufficient for approval.

Of the large number of drugs in development, only a small percentage successfully complete the FDA, the European Commission, or other regulatory approval processes and are commercialized. The lengthy approval process as well as the unpredictability of future clinical trial results may result in our failing to obtain regulatory approval to market our product candidates, which would significantly harm our business, financial condition, results of operations and prospects.

Even if we eventually complete clinical testing and receive approval of a BLA or foreign marketing authorization application for our product candidates, the FDA, the European Commission, or the applicable foreign regulatory authority may grant approval contingent on the performance of costly additional clinical trials, including Phase 4 clinical trials, and/or in the case of the FDA, the implementation of a REMS, and in the case of comparable foreign regulatory authorities equivalent actions, which may be required to ensure safe use of the drug after approval. The FDA or the applicable foreign regulatory authority also may approve a product candidate for a more limited indication or a narrower patient population than we originally requested, and the FDA, European Commission, or applicable foreign regulatory authority may not approve the labeling that we believe is necessary or desirable for the successful commercialization of a product candidate. Any delay in obtaining, or inability to obtain, applicable regulatory approval would delay or prevent commercialization of that product candidate and would materially adversely impact our business and prospects.

Even if we obtain regulatory approval for our product candidates, they will remain subject to ongoing regulatory oversight. Additionally, our product candidates, if approved, could be subject to labeling and other restrictions on marketing or withdrawal from the market, and we may be subject to penalties if we fail to comply with regulatory requirements or if we experience unanticipated problems with our product candidates, when and if any of them are approved.

Even if we obtain regulatory approval for any of our product candidates, they will be subject to extensive and ongoing regulatory requirements for manufacturing, labeling, packaging, distribution, adverse event reporting, storage, advertising, promotion, sampling and record-keeping. These requirements include submissions of safety and other post-marketing information and reports, registration, as well as continued compliance with current cGMP regulations, as well as GCPs for any clinical trials that we conduct post-approval, all of which may result in significant expense and limit our ability to commercialize such products. In addition, any regulatory approvals that we receive for our product candidates may also be subject to limitations on the approved indicated uses for which the product may be marketed or to the conditions of approval, or contain requirements for potentially costly post-marketing testing, including Phase 4 clinical trials, and surveillance to monitor the safety and efficacy of the product candidate. The FDA may also require a REMS and the European Commission, or comparable foreign regulatory authorities may require equivalent actions as a condition of approval of our product candidates, which could include requirements for a medication guide, physician communication plans or additional elements to ensure safe use, such as restricted distribution methods, patient registries and other risk minimization tools. Such regulatory requirements may differ from country to country depending on where we have received regulatory approval.

The FDA's, EMA's, European Commission, and other regulatory authorities' policies may change and additional government regulations may be enacted that could prevent, limit or delay regulatory approval of our product candidates. We cannot predict the likelihood, nature or extent of government regulation that may arise from future legislation or administrative action, either in the United States or abroad. If we are slow or unable to adapt to changes in existing requirements or the adoption of new requirements or policies, or if we are not able to maintain regulatory compliance, we may lose any marketing approval that we may have obtained and we may not achieve or sustain profitability. Moreover, if there are changes in the application of legislation or regulatory policies, or if problems are discovered with a product or our manufacture of a product, or if we or one of our distributors, licensees or co-marketers fails to comply with regulatory requirements, the regulators could take various actions. These include:

- issuing warning or untitled letters;
- mandating modifications to promotional materials or require us to provide corrective information to healthcare professionals, or require other restrictions on the labeling or marketing of such products;
- seeking an injunction or imposing civil or criminal penalties or monetary fines;

- suspension or imposition of restrictions on operations, including product manufacturing;
- seizure or detention of products, refusal to permit the import or export of products or request that we initiate a product recall;
- suspension, modification or withdrawal of our marketing authorizations;
- suspension of any ongoing clinical trials;
- refusal to approve pending applications or supplements to applications submitted by us;
- refusal to permit the import or export of products; or
- requiring us to conduct additional clinical trials, change our product labeling or submit additional applications for marketing authorization.

Moreover, the FDA and other regulatory authorities strictly regulate the promotional claims that may be made about biologic products. In particular, while physicians may choose to prescribe products for uses that are not described in the product's labeling and for uses that differ from those tested in clinical trials and approved by the regulatory authorities, a product may not be promoted for uses that are not approved by the FDA, the European Commission or other comparable foreign regulatory authorities as reflected in the product's approved labeling. The FDA and other comparable foreign regulatory authorities 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 civil, criminal and administrative penalties. These penalties could include delays or refusal to authorize the conduct of clinical trials, or to grant marketing authorization, product withdrawals and recalls, product seizures, suspension, withdrawal or variation of the marketing authorization, total or partial suspension of production, distribution, manufacturing or clinical trials, operating restrictions, injunctions, suspension of licenses, fines and criminal penalties.

Any government investigation of alleged violations of law could require us to expend significant time and resources in response and could generate negative publicity. The occurrence of any event or penalty described above may inhibit our ability to commercialize our product candidates and harm our business, financial condition, results of operations and prospects.

If any of these events occurs, our ability to sell such product may be impaired, and we may incur substantial additional expense to comply with regulatory requirements, which could harm our business, financial condition, results of operations and prospects.

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

The ability of the FDA, EMA, European Commission, and other foreign regulatory authorities to review applications for approval 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 FDA have fluctuated in recent years as a result. In addition, government funding of other government agencies that fund research and development activities is subject to the political process, which is inherently fluid and unpredictable.

Disruptions at the FDA and other foreign regulatory authorities may also slow the time necessary for new biologics to be reviewed and/or approved by necessary foreign regulatory authorities, which would adversely affect our business. For example, over the last several years, including for 35 days beginning on December 22, 2018, the U.S. government has shut down several times and certain regulatory authorities, such as the FDA, have had to furlough critical FDA employees and stop critical activities. If a prolonged government shutdown 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.

Separately, the FDA and regulatory authorities outside the United States have and may adopt restrictions or other policy measures in response to public health crises that divert resources and delay their attention from any submissions we may make. If a prolonged government shutdown occurs, or if global health concerns continue to prevent the FDA or other foreign regulatory authorities from conducting their regular inspections, reviews, or other regulatory activities, it could significantly impact the ability of the FDA or other foreign regulatory authorities to timely review and process our regulatory submissions, which could have a material 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.

Because we have limited financial and managerial resources, we must prioritize our research programs and will need to focus our discovery and development on select product candidates and indications. Correctly prioritizing our research and development activities is particularly important for us due to the breadth of potential product candidates and indications that we believe could be pursued using our platform technologies. As a result, we may forego or delay pursuit of opportunities with other product candidates or for other indications that later prove to have greater commercial potential. Our resource allocation decisions may cause us to fail to capitalize on viable commercial products or profitable market opportunities. Our spending on current and future research and development programs and product candidates for specific indications may not yield any commercially viable products. If we do not accurately evaluate the commercial potential or target market for a particular product candidate, we may also relinquish valuable rights to that product candidate through collaboration, licensing or other royalty arrangements in cases in which it would have been more advantageous for us to retain sole development and commercialization rights to such product candidate.

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

Our research programs may initially show promise in identifying potential product candidates, yet fail to yield product candidates for clinical development for a number of reasons, including:

- our inability to design such product candidates with the properties that we desire; or
- potential product candidates may, on further study, be shown to have harmful side effects or other characteristics that indicate that they are unlikely to be products that will receive marketing approval and achieve market acceptance.

Research programs to identify new product candidates require substantial technical, financial and human resources. If we are unable to identify suitable additional candidates for preclinical and clinical development, our opportunities to successfully develop and commercialize therapeutic products will be limited.

Risks Related to Manufacturing, Commercialization and Reliance on Third Parties

We may rely on third parties to conduct, supervise, and monitor our ongoing and planned clinical trials and perform some of our research and preclinical studies. If these third parties do not satisfactorily carry out their contractual duties or fail to meet expected deadlines, our development programs may be delayed or subject to increased costs, each of which may have an adverse effect on our business and prospects.

We do not have the ability to conduct all aspects of our preclinical testing or clinical trials ourselves. As a result, we are and expect to remain dependent on third parties to conduct our preclinical studies, ongoing clinical trials and any future clinical trials of our product candidates. The timing of the initiation and completion of these studies and trials will therefore be partially controlled by such third parties and may result in delays to our development programs. Nevertheless, we are responsible for ensuring that each of our preclinical studies and clinical trials is conducted in accordance with the applicable protocol, legal requirements, and scientific standards, and our reliance on the CROs and other third parties does not relieve us of our regulatory responsibilities. We and our CROs are required to comply with GLP and GCP requirements, which are regulations and guidelines enforced by the FDA, the Competent Authorities of EEA countries, and comparable foreign regulatory authorities for all of our product candidates in clinical development. Regulatory authorities enforce these GLP and GCP requirements through

periodic inspections of preclinical study sites, trial sponsors, clinical trial investigators and clinical trial sites. If we or any of our CROs or clinical trial sites fail to comply with applicable GLP or GCP requirements, the data generated in our preclinical studies and clinical trials may be deemed unreliable, and the FDA, the EMA or comparable foreign regulatory authorities may require us to perform additional preclinical or clinical trials before approving our marketing authorization applications. In addition, our clinical trials must be conducted with product produced under cGMP regulations. Our failure to comply with these regulations may require us to stop and/or repeat clinical trials, which would delay the marketing approval process.

There is no guarantee that any such CROs, clinical trial investigators or other third parties on which we rely will devote adequate time and resources to our development activities or perform as contractually required. If any of these third parties fail to meet expected deadlines, adhere to our clinical protocols or meet regulatory requirements, otherwise performs in a substandard manner, or terminates its engagement with us, the timelines for our development programs may be extended or delayed or our development activities may be suspended or terminated. If any of our clinical trial sites terminates for any reason, we may experience the loss of follow-up information on subjects enrolled in such clinical trials unless we are able to transfer those subjects to another qualified clinical trial site, which may be difficult or impossible. In addition, clinical trial investigators for our clinical trials may serve as scientific advisors or consultants to us from time to time and may receive cash or equity compensation in connection with such services. If these relationships and any related compensation result in perceived or actual conflicts of interest, or the FDA, the EMA or any comparable foreign regulatory authority concludes that the financial relationship may have affected the interpretation of the trial, the integrity of the data generated at the applicable clinical trial site may be questioned and the utility of the clinical trial itself may be jeopardized, which could result in the delay or rejection of any marketing authorization application we submit by the FDA, the EMA or any comparable foreign regulatory authority. Any such delay or rejection could prevent us from commercializing our product candidates.

Furthermore, these third parties may also have relationships with other entities, some of which may be our competitors. If these third parties do not successfully carry out their contractual duties, meet expected deadlines or conduct our clinical trials in accordance with regulatory requirements or our stated protocols, we will not be able to obtain, or may be delayed in obtaining, marketing approvals for our product candidates and will not be able to, or may be delayed in our efforts to, successfully commercialize our products.

We contract with third parties for the manufacturing and supply of certain of our product candidates for use in preclinical testing and clinical trials, which supply may become limited or interrupted or may not be of satisfactory quality and quantity.

We do not have any manufacturing facilities. We produce in our laboratory relatively small quantities of product for evaluation in our research programs. We rely on third parties for the manufacture of our product candidates for clinical testing and we will continue to rely on such third parties for commercial manufacture if any of our product candidates are approved. We currently have limited manufacturing arrangements and expect that the BDS for each of our product candidates will only be covered by single source suppliers for the foreseeable future. This reliance increases the risk that we will not have sufficient quantities of our product candidates or products, if approved, or such quantities at an acceptable cost or quality, which could delay, prevent or impair our development or commercialization efforts.

Furthermore, all entities involved in the preparation of therapeutics for clinical trials or commercial sale, including our existing contract manufacturers for our product candidates, are subject to extensive regulation. Components of a finished therapeutic product approved for commercial sale or used in clinical trials must be manufactured in accordance with cGMP requirements. These regulations govern manufacturing processes and procedures, including record keeping, and the implementation and operation of quality systems to control and assure the quality of investigational products and products approved for sale. Poor control of production processes can lead to the introduction of contaminants, or to inadvertent changes in the properties or stability of our product candidates that may not be detectable in final product testing. We or our contract manufacturers must supply all necessary documentation in support of a BLA, or equivalent foreign application, on a timely basis and must adhere to the relevant Good Laboratory Practice regulations and cGMP regulations enforced by the FDA, and competent authorities of EEA countries, through their facilities inspection program. Comparable foreign regulatory authorities may require compliance with similar requirements. The facilities and quality systems of our third-party contract

manufacturers must pass a pre-approval inspection for compliance with the applicable regulations as a condition of marketing approval of our product candidates. We do not control the manufacturing activities of, and are completely dependent on, our contract manufacturers for compliance with cGMP regulations.

In the event that any of our manufacturers fails to comply with such requirements or to perform its 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 commercially reasonable terms, if at all. In particular, any replacement of our manufacturers could require significant effort and expertise because there may be a limited number of qualified replacements. In some cases, the technical skills or technology required to manufacture our product candidates may be unique or proprietary to the original manufacturer and we may have difficulty transferring such skills or technology to another third-party and a feasible alternative may not exist. In addition, certain of our product candidates and our own proprietary methods have never been produced or implemented outside of our company, and we may therefore experience delays to our development programs if and when we attempt to establish new third-party manufacturing arrangements for these product candidates or methods. These factors would increase our reliance on such manufacturer or require us to obtain a license from such manufacturer in order to have another third-party manufacture our product candidates. If we are required to or voluntarily change manufacturers for any reason, we will be required to verify that the new manufacturer maintains facilities and procedures that comply with quality standards and with all applicable regulations and guidelines and that the product produced is equivalent to that produced in a prior facility. The delays associated with the verification of a new manufacturer and equivalent product could negatively affect our ability to develop product candidates in a timely manner or within budget.

Our or a third-party's failure to execute on our manufacturing requirements, do so on commercially reasonable terms and timelines and comply with cGMP requirements could adversely affect our business in a number of ways, including:

- inability to meet our product specifications and quality requirements consistently;
- an inability to initiate or continue preclinical studies or clinical trials of our product candidates under development;
- delay in submitting regulatory applications, or receiving marketing approvals, for our product candidates, if at all;
- loss of the cooperation of future collaborators;
- subjecting third-party manufacturing facilities or our manufacturing facilities to additional inspections by regulatory authorities;
- requirements to cease development or to recall batches of our product candidates; and
- in the event of approval to market and commercialize our product candidates, an inability to meet commercial demands for our product or any other future product candidates.

Manufacturing our product candidates is complex and our third-party manufacturers may encounter difficulties in production. If any of our third-party manufacturers encounter such difficulties, our ability to provide supply of our product candidates for clinical trials or our products for patients, if approved, could be delayed or prevented.

Manufacturing our product candidates is complex and requires the use of technologies directed to handle living cells. Manufacturing these products requires facilities specifically designed for and validated for this purpose and sophisticated quality assurance and quality control procedures are necessary. Slight deviations anywhere in the manufacturing process, including filling, labeling, packaging, storage and shipping and quality control and testing, may result in lot failures, product recalls or expiry. When changes are made to the manufacturing process, we may be required to provide preclinical and clinical data showing the comparable identity, strength, quality, purity or potency of the products before and after such changes. If microbial, viral or other contaminations are discovered at manufacturing facilities, such facilities may need to be closed for an extended period of time to investigate and remedy the contamination, which could delay clinical trials and adversely harm our business. The use of biologically

derived ingredients can also lead to allegations of harm, including infections or allergic reactions, or closure of product facilities due to possible contamination.

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

Due to the early nature of our product candidates, the drug product may not be stable over time causing changes to be made to the manufacturing, formulation or storage process, which may result in delays or stopping the development of the product candidate.

Changes in methods of product candidate manufacturing may result in additional costs or delays.

As product candidates progress through preclinical to late-stage clinical trials to marketing approval and commercialization, it is common that various aspects of the development program, such as manufacturing methods, are altered along the way in an effort to optimize yield, manufacturing batch size, change drug product dosage form, minimize costs and achieve consistent quality and results. Such changes carry the risk that they will not achieve these intended objectives. Any of these changes could cause our product candidates to perform differently and affect the results of clinical trials or other future clinical trials conducted with the altered materials. This could delay completion of clinical trials, require the conduct of bridging clinical trials or the repetition of one or more clinical trials, increase clinical trial costs, delay approval of our product candidates and jeopardize our ability to commercialize our product candidates and generate revenue.

Any approved products may fail to achieve the degree of market acceptance by physicians, patients, hospitals, cancer treatment centers, healthcare payors and others in the medical community necessary for commercial success.

If any of our product candidates receive marketing approval, they may nonetheless fail to gain sufficient market acceptance by physicians, patients, healthcare payors and others in the medical community. For example, current cancer treatments like chemotherapy and radiation therapy are well established in the medical community, and physicians may continue to rely on these treatments. Most of our product candidates target mechanisms for which there are limited or no currently approved products, which may result in slower adoption by physicians, patients and payors. If our product candidates do not achieve an adequate level of acceptance, we may not generate significant product revenue and we may not become profitable. The degree of market acceptance of our product candidates, if approved for commercial sale, will depend on a number of factors, including:

- efficacy and potential advantages compared to alternative treatments;
- our ability to offer our products for sale at competitive prices;
- convenience and ease of administration compared to alternative treatments;
- the willingness of the target patient population to try new therapies and of physicians to prescribe these therapies;
- the availability of coverage and adequate reimbursement from third-party payors, and the willingness of patients to pay out of pocket in the absence of coverage or limited third-party payor reimbursement;
- the strength of marketing and distribution support; and
- the prevalence and severity of any side effects.

We may not be able to successfully commercialize our product candidates, if approved, due to unfavorable pricing regulations or third-party coverage and reimbursement policies, which could make it difficult for us to sell our product candidates profitably.

Obtaining coverage and reimbursement approval for a product from a government or other third-party payor is a time-consuming and costly process, with uncertain results, that could require us to provide supporting scientific, clinical and cost effectiveness data for the use of our products to the payor. There may be significant delays in obtaining such coverage and reimbursement for newly approved products, and coverage may not be available, or may be more limited than the purposes for which the product is approved by the FDA, the European Commission, or comparable foreign regulatory authorities. Moreover, eligibility for coverage and reimbursement does not imply that a product will be paid for in all cases or at a rate that covers our costs, including research, development, intellectual property, manufacture, sale and distribution expenses. Interim reimbursement levels for new products, if applicable, may also not be sufficient to cover our costs and may not be made permanent. Reimbursement rates may vary according to the use of the product and the clinical setting in which it is used, may be based on reimbursement levels already set for lower cost products and may be incorporated into existing payments for other services. Net prices for products may be reduced by mandatory discounts or rebates required by government healthcare programs or private payors, by any future laws limiting drug prices and by any future relaxation of laws that presently restrict imports of product from countries where they may be sold at lower prices than in the United States.

There is significant uncertainty related to the insurance coverage and reimbursement of newly approved products. In the United States, there is no uniform policy among third-party payors for coverage and reimbursement. Third-party payors often rely upon Medicare coverage policy and payment limitations in setting reimbursement policies, but also have their own methods and approval process apart from Medicare coverage and reimbursement determinations. Therefore, one third-party payor's determination to provide coverage for a product does not assure that other payors will also provide coverage for the product. The approach to pricing and reimbursement also varies widely between third countries, including between EEA countries.

Coverage and reimbursement by a third-party payor may depend upon a number of factors, including the third-party payor's determination that use of a product is:

- a covered benefit under its health plan;
- safe, effective and medically necessary;
- appropriate for the specific patient;
- cost-effective; and
- neither experimental nor investigational.

We cannot be sure that reimbursement will be available for any product that we commercialize and, if coverage and reimbursement are available, what the level of reimbursement will be. Obtaining reimbursement for our products may be particularly difficult because of the higher prices often associated with branded therapeutics and therapeutics administered under the supervision of a physician. Our inability to promptly obtain coverage and adequate reimbursement rates from both government-funded and private payors for any approved products that we develop could have a material adverse effect on our operating results, our ability to raise capital needed to commercialize products and our overall financial condition.

Reimbursement may impact the demand for, and the price of, any product for which we obtain marketing approval. Even if we obtain coverage for a given product by a third-party payor, the resulting reimbursement payment rates may not be adequate or may require co-payments that patients find unacceptably high. Patients who are prescribed medications for the treatment of their conditions, and their prescribing physicians, generally rely on third-party payors to reimburse all or part of the costs associated with those medications. Patients are unlikely to use our products unless coverage is provided and reimbursement is adequate to cover all or a significant portion of the cost of our products. Therefore, coverage and adequate reimbursement are critical to a new product's acceptance. Coverage decisions may depend upon clinical and economic standards that disfavor new products when more established or lower cost therapeutic alternatives are already available or subsequently become available.

For products administered under the supervision of a physician, obtaining coverage and adequate reimbursement may be particularly difficult because of the higher prices often associated with such drugs. Additionally, separate reimbursement for the product itself may or may not be available. Instead, the hospital or administering physician may be reimbursed only for providing the treatment or procedure in which our product is used. Further, from time to time, in the US the Centers for Medicare & Medicaid Services (CMS) revises the reimbursement systems used to reimburse health care providers, including the Medicare Physician Fee Schedule and Hospital Outpatient Prospective Payment System, which may result in reduced Medicare payments.

We expect to experience pricing pressures in connection with the sale of any of our product candidates due to the trend toward managed healthcare, the increasing influence of health maintenance organizations, and additional legislative changes. The downward pressure on healthcare costs in general, particularly prescription medicines, medical devices and surgical procedures and other treatments, has become very intense. As a result, increasingly high barriers are being erected to the successful commercialization of new products. Further, the adoption and implementation of any future governmental cost containment or other health reform initiative may result in additional downward pressure on the price that we may receive for any approved product.

Outside of the United States, many countries require approval of the sale price of a product before it can be marketed, and the pricing review period only begins after marketing or product licensing approval is granted. To obtain reimbursement or pricing approval in some of these countries, including in some EEA countries, we may be required to conduct a clinical trial that compares the cost-effectiveness of our product candidate to other available therapies. In the EU, this Health Technology Assessment (HTA) process, which is currently governed by the national laws of the individual EU Member States, is the procedure to assess therapeutic, economic and societal impact of a given medicinal product in the national healthcare systems of the individual country. HTA of medicinal products is becoming an increasingly common part of the pricing and reimbursement procedures in some EU Member States, including those representing the larger markets. The outcome of an HTA will often influence the pricing and reimbursement status granted to these medicinal products by the competent authorities of individual EU Member States. The extent to which pricing and reimbursement decisions are influenced by the HTA of the specific medicinal product currently varies between EU Member States. Moreover, EU Member States may choose to restrict the range of products for which their national health insurance systems provide reimbursement and to control the prices of medicinal products for human use. EU Member States may approve a specific price for a product or it may instead adopt a system of direct or indirect controls on the profitability of the company placing the product on the market. Other EU Member States allow companies to fix their own prices for products but monitor and control prescription volumes and issue guidance to physicians to limit. If we are unable to maintain favorable pricing and reimbursement status in EU Member States for our products, any anticipated revenue from and growth prospects for those products in the EU could be negatively affected.

In some other foreign markets, prescription pharmaceutical pricing remains subject to continuing governmental control even after initial approval is granted. As a result, we might obtain marketing approval for a product candidate in a particular country, but then be subject to price regulations that delay our commercial launch of the product, possibly for lengthy time periods, and negatively impact the revenue, if any, we are able to generate from the sale of the product in that country. Adverse pricing limitations may hinder our ability to recoup our investment in one or more product candidates, even if such product candidates obtain marketing approval.

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

The Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act of 2010 (the Affordable Care Act) signed into law on March 23, 2010, includes a subtitle called the Biologics Price Competition and Innovation Act of 2009 (BPCIA) which created an abbreviated approval pathway for biological products that are biosimilar to or interchangeable with an FDA-licensed reference biological product. Under the BPCIA, an application for a biosimilar product may not be submitted to the FDA until four years following the date that the reference product was first licensed by the FDA. In addition, the approval of a biosimilar product may not be made effective by the FDA until 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 full BLA for the competing product containing the sponsor's own

preclinical data and data from adequate and well-controlled clinical trials to demonstrate the safety, purity and potency of their product. Equivalent laws and procedures apply in foreign countries.

We believe that any of our product candidates approved as a biological 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, court decisions or otherwise, or that the FDA will not consider our product candidates to be reference products for competing products, potentially creating the opportunity for generic competition sooner than anticipated. Other aspects of the BPCIA, some of which may impact the BPCIA exclusivity provisions, have also been the subject of recent litigation. Moreover, the extent to which a biosimilar, once approved, will be substituted for any one of our reference products in a way that is similar to traditional generic substitution for non-biological products is not yet clear, and will depend on a number of marketplace and regulatory factors that are still developing.

If any approved products are subject to biosimilar competition sooner than we expect, we will face significant pricing pressure and our commercial opportunity will be limited.

Relevant regulatory exclusivities may not be granted or, if granted, may be limited.

The EU provides opportunities for data and market exclusivity related to Marketing Authorizations (MAs). Upon receiving an MA, innovative medicinal products are generally entitled to receive eight years of data exclusivity and 10 years of market exclusivity. Data exclusivity, if granted, prevents regulatory authorities in the EU from referencing the innovator's data to assess an application for authorization of a generic product or of a biosimilar for eight years from the date of authorization of the innovative product, after which an application for authorization of a generic or biosimilar may be submitted, and the innovator's data may be referenced. The market exclusivity period prevents a successful applicant for authorization of a generic or biosimilar from commercializing its product in the EU until 10 years have elapsed from the initial MA of the reference product in the EU. The overall ten year period may, occasionally, be extended for a further year to a maximum of 11 years if, during the first eight years of those ten years, the MA holder obtains an authorization for one or more new therapeutic indications which, during the scientific evaluation prior to their authorization, are held to bring a significant clinical benefit in comparison with existing therapies. However, there is no guarantee that a product will be considered by the EU's regulatory authorities to be a new chemical/biological entity, and products may not qualify for data exclusivity.

The market opportunity for our product candidates may be relatively small as it will be limited to those patients who are ineligible for or have failed prior treatments and our estimates of the prevalence of our target patient populations may be inaccurate.

Cancer therapies are sometimes characterized as first line, second line, or third line, and the FDA customarily approves new therapies only for a second line or later lines of use. When cancer is detected early enough, first line therapy is sometimes adequate to cure the cancer or prolong life without a cure. Whenever first line therapies, usually chemotherapy, antibody drugs, tumor-targeted small molecules, hormone therapy, radiation therapy, surgery or a combination of these, proves unsuccessful, second line therapy may be administered. Second line therapies often consist of more chemotherapy, radiation, antibody drugs, tumor-targeted small molecules or a combination of these. Third line therapies can include chemotherapy, antibody drugs and small molecule tumor-targeted therapies, more invasive forms of surgery and new technologies. We expect to initially seek approval of our product candidates in most instances at least as a second line therapy. Subsequently, depending on the nature of the clinical data and experience with any approved products or product candidates, if any, we may pursue approval as an earlier line therapy and potentially as a first line therapy. But there is no guarantee that our product candidates, even if approved as a second or subsequent line of therapy, would be approved for an earlier line of therapy, and, prior to any such approvals, we may have to conduct additional clinical trials.

Our projections of the number of people who have PSMA, EGFR or other specific anti-tumor target expression are based on our assumptions and estimates. These estimates have been derived from a variety of sources, including scientific literature, surveys of clinics, patient foundations or market research, and may prove to be incorrect. Further, new therapies may change the estimated incidence or prevalence of the cancers that we are targeting. Consequently, even if our product candidates are approved for a second or third line of therapy, the number of patients who may be eligible for treatment with our product candidates may turn out to be much lower than

expected. In addition, we have not yet conducted market research to determine how treating physicians would expect to prescribe a product that is approved for multiple tumor types if there are different lines of approved therapies for each such tumor type.

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

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

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

If any of our product candidates are approved for marketing and commercialization and we are unable to establish sales and marketing capabilities or enter into agreements with third parties to sell and market our product candidates, we will be unable to successfully commercialize our product candidates if and when they are approved.

We have no sales, marketing or distribution capabilities or experience. To achieve commercial success for any approved product for which we retain sales and marketing responsibilities, we must either develop a sales and marketing organization, which would be expensive and time consuming, or outsource these functions to other third parties. In the future, we may choose to build a focused sales and marketing infrastructure to sell, or participate in sales activities with our collaborators for, some of our product candidates if and when they are approved.

There are risks involved with both establishing our own sales and marketing capabilities and entering into arrangements with third parties to perform these services. For example, recruiting and training a sales force is expensive and time consuming and could delay any product launch. If the commercial launch of a product candidate for which we recruit a sales force and establish marketing capabilities is delayed or does not occur for any reason, we would have prematurely or unnecessarily incurred these commercialization expenses. This may be costly, and our investment would be lost if we cannot retain or reposition our sales and marketing personnel.

Factors that may inhibit our efforts to commercialize future products on our own include:

- our inability to recruit and retain adequate numbers of effective sales and marketing personnel;
- the inability of sales personnel to obtain access to physicians or educate adequate numbers of physicians on the benefits of prescribing any future products;
- the lack of complementary products to be offered by sales personnel, which may put us at a competitive disadvantage relative to companies with more extensive product portfolios; and

- unforeseen costs and expenses associated with creating an independent sales and marketing organization.

If we enter into arrangements with third parties to perform sales, marketing and distribution services, our product revenue or the profitability of these product revenue to us are likely to be lower than if we were to market and sell any products that we develop ourselves. In addition, we may not be successful in entering into arrangements with third parties to sell and market our product candidates or may be unable to do so on terms that are favorable to us. In entering into third-party marketing or distribution arrangements, any revenue we receive will depend upon the efforts of the third parties and we cannot assure you that such third parties will establish adequate sales and distribution capabilities or devote the necessary resources and attention to sell and market any future products effectively. If we do not establish sales and marketing capabilities successfully, either on our own or in collaboration with third parties, we will not be successful in commercializing our product candidates.

Even if we obtain FDA approval of any of our product candidates, we may never obtain approval or commercialize such products outside of the United States, which would limit our ability to realize their full market potential.

In order to market any products outside of the United States, we must establish and comply with numerous and varying regulatory requirements of other countries regarding safety and efficacy. Clinical trials conducted in one country may not be accepted by regulatory authorities in other countries, and regulatory approval in one country does not mean that regulatory approval will be obtained in any other country. Approval procedures vary among countries and can involve additional product testing and validation and additional administrative review periods. Seeking foreign regulatory approvals could result in significant delays, difficulties and costs for us and may require additional preclinical studies or clinical trials which would be costly and time consuming. Regulatory requirements can vary widely from country to country and could delay or prevent the introduction of our products in those countries. Satisfying these and other regulatory requirements is costly, time consuming, uncertain and subject to unanticipated delays. In addition, our failure to obtain regulatory approval in any country may delay or have negative effects on the process for regulatory approval in other countries. We do not have any product candidates approved for sale in any jurisdiction, including international markets, and we do not have experience in obtaining regulatory approval in international markets. If we fail to comply with regulatory requirements in international markets or to obtain and maintain required approvals, our ability to realize the full market potential of our products will be harmed.

Risks Related to Our Collaborations and Other Strategic Agreements

Our existing collaboration with Merck is important to our business. If Merck ceases development efforts under our existing or future collaboration agreements, or if any of those agreements are terminated, these collaborations may fail to lead to commercial products and we may never receive milestone payments or future royalties under these agreements.

We have entered into collaboration with Merck to develop certain specified product candidates. All of our revenue to date has been derived from our existing collaboration agreement with Merck, and a significant portion of our near-term future revenue is expected to be derived from this agreement or other similar agreements into which we may enter in the future. Revenue from research and development collaborations depends upon continuation of the collaborations, payments for research and development services and product supply, and the achievement of milestones, contingent payments and royalties, if any, derived from future products developed from our research. If we are unable to successfully advance the development of our product candidates or achieve milestones, revenue and cash resources from milestone payments under our collaboration agreement will be substantially less than expected.

We are unable to predict the success of our collaborations and we may not realize the anticipated benefits of our strategic collaborations. Our collaborators have discretion in determining and directing the efforts and resources, including the ability to discontinue all efforts and resources, they apply to the development and, if approval is obtained, commercialization and marketing of the product candidates covered by such collaborations. As a result, our collaborators may elect to de-prioritize our programs, change their strategic focus or pursue alternative

technologies in a manner that results in reduced, delayed or no revenue to us. Our collaborators may have other marketed products and product candidates under collaboration with other companies, including some of our competitors, and their corporate objectives may not be consistent with our best interests. Our collaborators may also be unsuccessful in developing or commercializing our products. If our collaborations are unsuccessful, our business, financial condition, results of operations and prospects could be adversely affected. In addition, any dispute or litigation proceedings we may have with our collaborators in the future could delay development programs, create uncertainty as to ownership of intellectual property rights, distract management from other business activities and generate substantial expense.

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

We may not realize the benefits of any acquisitions, collaborations, in-license or strategic alliances that we enter into.

We have entered into a research collaboration and exclusive license agreement with Merck and in the future may seek and form strategic alliances, create joint ventures or additional collaborations, or enter into acquisitions or licensing arrangements with third parties that we believe will complement or augment our existing technologies and product candidates.

These transactions can entail numerous operational and financial risks, including exposure to unknown liabilities, disruption of our business and diversion of our management's time and attention in order to manage a collaboration or develop acquired products, product candidates or technologies, incurrence of substantial debt or dilutive issuances of equity securities to pay transaction consideration or costs, higher than expected collaboration, acquisition or integration costs, write-downs of assets or goodwill or impairment charges, increased amortization expenses, difficulty and cost in facilitating the collaboration or combining the operations and personnel of any acquired business, impairment of relationships with key suppliers, manufacturers or customers of any acquired business due to changes in management and ownership and the inability to retain key employees of any acquired business. As a result, if we enter into acquisition or in-license agreements or strategic partnerships, we may not be able to realize the benefit of such transactions if we are unable to successfully integrate them with our existing operations and company culture, which could delay our timelines or otherwise adversely affect our business. We also cannot be certain that, following a strategic transaction or license, we will achieve the revenue or specific net income that justifies such transaction or such other benefits that led us to enter into the arrangement.

We may wish to form additional collaborations in the future with respect to our product candidates, but may not be able to do so or to realize the potential benefits of such transactions, which may cause us to alter or delay our development and commercialization plans.

We may, in the future, decide to collaborate with other biopharmaceutical companies for the development and potential commercialization of those product candidates, including in territories outside the United States or for certain indications. 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 our 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 our product candidates as having the requisite potential to demonstrate safety and efficacy. If and when we collaborate with a third-party for development and commercialization of a product candidate, we can expect to relinquish some or all of the control over the future success of that product candidate to the third-party. Our ability to reach a definitive agreement for a collaboration will depend, among other things, upon our assessment of the collaborator's resources and expertise, the terms and conditions of the proposed collaboration and the proposed collaborator's evaluation of our technologies, product candidates and market opportunities. The collaborator may also consider alternative product candidates or technologies for similar indications that may be available to collaborate on and whether such a collaboration could be more attractive than the one with us for our product candidate. We may also be restricted under any license agreements from entering into agreements on certain terms or at all with potential collaborators.

Collaborations are complex and time-consuming to negotiate and document. In addition, there have been a significant number of recent business combinations among large pharmaceutical companies that have resulted in a reduced number of potential future collaborators and changes to the strategies of the combined company. As a result, we may not be able to negotiate collaborations on a timely basis, on acceptable terms, or at all. If we are unable to do so, we may have to curtail the development of such product candidate, reduce or delay one or more of our other development programs, delay the potential commercialization or reduce the scope of any planned sales or marketing activities for such product candidate, or increase our expenditures and undertake development, manufacturing or commercialization activities at our own expense. If we elect to increase our expenditures to fund development, manufacturing or commercialization activities on our own, we may need to obtain additional capital, which may not be available to us on acceptable terms or at all. If we do not have sufficient funds, we may not be able to further develop our product candidates or bring them to market and generate product revenue.

Our product candidates may also require specific components to work effectively and efficiently, and rights to those components may be held by others. We may be unable to in-license any compositions, methods of use, processes or other third-party intellectual property rights from third parties that we identify. We may fail to obtain any of these licenses at a reasonable cost or on reasonable terms, which would harm our business. 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.

Risks Related to Our Industry and Business Operations

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

We are exposed to the risk of fraud or other misconduct by our employees, principal investigators, consultants and commercial partners. Misconduct by these parties could include intentional failures to comply with the regulations of the FDA and foreign regulatory authorities, provide accurate information to the FDA and foreign 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 may restrict or prohibit a wide range of pricing, discounting, marketing and promotion, sales commission, customer incentive programs and other business arrangements. Such misconduct could also involve the improper use of information obtained in the course of clinical trials, which could result in regulatory sanctions and cause serious harm to our reputation. It is not always possible to identify and deter employee misconduct, and the precautions we take to detect and prevent this activity may not be effective in controlling unknown or unmanaged risks or losses or in protecting us from governmental investigations or other actions or lawsuits stemming from a failure to comply with these laws or regulations. If any such actions are instituted against us those actions could have a significant impact on our business, including the imposition of significant civil, criminal and administrative penalties, damages, fines, disgorgement, imprisonment, exclusion from government funded healthcare programs, such as Medicare and Medicaid or comparable foreign healthcare programs, contractual damages, reputational harm, diminished profits and future earnings, additional reporting obligations and oversight if subject to a corporate integrity agreement or other agreement to resolve allegations of non-compliance with these laws, and the curtailment or restructuring of our operations.

We face potential product liability, and, if successful claims are brought against us, we may incur substantial liability and costs. If the use of our product candidates harms patients or is perceived to harm patients even when such harm is unrelated to our product candidates, our regulatory approvals could be revoked or otherwise negatively impacted and we could be subject to costly and damaging product liability claims.

The use of our product candidates in clinical trials and the sale of any products for which we obtain marketing approval exposes us to the risk of product liability claims. Product liability claims might be brought against us by consumers, healthcare providers, pharmaceutical companies or others selling or otherwise coming into contact with our products. There is a risk that our product candidates may induce adverse events. If we cannot successfully

defend against product liability claims, we could incur substantial liability and costs. In addition, regardless of merit or eventual outcome, product liability claims may result in:

- impairment of our business reputation;
- withdrawal of clinical trial participants;
- costs due to related litigation;
- distraction of management's attention from our primary business;
- substantial monetary awards to patients or other claimants;
- the inability to commercialize our product candidates; and
- decreased demand for our product candidates, if approved for commercial sale.

We may not be able to maintain product liability insurance coverage at a reasonable cost or in sufficient amounts to protect us against losses due to liability. If and when we obtain marketing approval for product candidates, we intend to expand our insurance coverage to include the sale of commercial products; however, we may be unable to obtain product liability insurance on commercially reasonable terms or in adequate amounts. On occasion, large judgments have been awarded in class action lawsuits based on drugs or medical treatments that had unanticipated adverse effects. A successful product liability claims, or series of claims brought against us could cause our stock price to decline and, if judgments exceed our insurance coverage, could adversely affect our results of operations and business.

Patients with cancer and other diseases targeted by our product candidates are often already in severe and advanced stages of disease and have both known and unknown significant pre-existing and potentially life-threatening health risks. During the course of treatment, patients may suffer adverse events, including death, for reasons that may be related to our product candidates. Such events could subject us to costly litigation, require us to pay substantial amounts of money to injured patients, delay, negatively impact or end our opportunity to receive or maintain regulatory approval to market our products, or require us to suspend or abandon our commercialization efforts. Even in a circumstance in which we do not believe that an adverse event is related to our products, the investigation into the circumstance may be time-consuming or inconclusive. These investigations may interrupt our sales efforts, delay our regulatory approval process in other countries, or impact and limit the type of regulatory approvals our product candidates could receive or maintain. As a result of these factors, a product liability claim, even if successfully defended, could have a material adverse effect on our business, financial condition or results of operations.

We are highly dependent on our key personnel, and if we are not successful in attracting and retaining highly qualified personnel, we may not be able to successfully implement our business strategy.

Our ability to compete in the highly competitive biotechnology and pharmaceutical industries depends upon our ability to attract and retain highly qualified managerial, scientific and medical personnel. We are highly dependent on our management, scientific and medical personnel. The loss of the services of any of our executive officers, other key employees, and other scientific and medical advisors, and our inability to find suitable replacements could result in delays in product development and harm our business.

We conduct substantially all of our operations remotely and at our facilities in San Diego, California. This region is headquarters to many other biopharmaceutical companies and many academic and research institutions. Competition for skilled personnel in our market is intense and may limit our ability to hire and retain highly qualified personnel on acceptable terms or at all.

To induce valuable employees to remain at our company, in addition to salary and cash incentives, we have provided stock options that vest over time. The value to employees of stock options that vest over time may be

significantly affected by movements in our stock price that are beyond our control and may at any time be insufficient to counteract more lucrative offers from other companies. There also may be shortages of skilled labor due to public health crises, macroeconomic conditions, or other factors that may make it more difficult for us to attract and retain qualified personnel and lead to increased labor costs. Despite our efforts to retain valuable employees, members of our management, scientific and development teams may terminate their employment with us on short notice. Although we have employment agreements with certain of our key employees, these employment agreements provide for at-will employment, which means that any of our employees could leave our employment at any time, with or without notice. We do not maintain "key person" insurance policies on the lives of these individuals or the lives of any of our employees. Our success also depends on our ability to continue to attract, retain and motivate highly skilled junior, mid-level and senior managers as well as junior, mid-level and senior scientific and medical personnel.

We expect to expand our development, regulatory and operational capabilities and, as a result, we may encounter difficulties in managing our growth, which could disrupt our operations.

As of December 31, 2023, we had 64 employees. As we advance our research and development programs, we will be required to further increase the number of our employees and the scope of our operations, particularly in the areas of research and clinical development, medical affairs, general and administrative matters relating to being a public company, regulatory affairs and, if any of our product candidates receives marketing approval, sales, marketing and distribution. To manage any future growth, we must:

- identify, recruit integrate, maintain and motivate additional qualified personnel;
- manage our development efforts effectively, including the initiation and conduct of clinical trials for our product candidates, both as monotherapy and in combination with other therapeutics; and
- improve our operational, financial and management controls, reporting systems and procedures.

Our future financial performance and our ability to develop, manufacture and commercialize our product candidates, if approved, will depend, in part, on our ability to effectively manage any future growth, and our management may also have to divert financial and other resources, and a disproportionate amount of its attention away from day-to-day activities in order to devote a substantial amount of time, to managing these growth activities.

If we are not able to effectively expand our organization by hiring new employees and expanding our groups of consultants and contractors, we may not be able to successfully implement the tasks necessary to further develop and commercialize our product candidates and, accordingly, may not achieve our research, development and commercialization goals.

We face substantial competition, which may result in others discovering, developing or commercializing products more quickly or marketing them more successfully than us.

The development and commercialization of new products is highly competitive. We largely compete in the segments of the pharmaceutical, biotechnology and other related markets that develop immunotherapies for the treatment of cancer. Our commercial opportunity 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 any products that we may develop. Our competitors also may obtain FDA, European Commission, or other regulatory approval for their products more rapidly than we may obtain approval for ours, if ever, 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. Moreover, with the proliferation of new drugs and therapies into oncology, we expect to face increasingly intense competition as new technologies become available. If we fail to stay at the forefront of technological change, we may be unable to compete effectively. Any product candidates that we successfully develop and commercialize will compete with existing therapies and new therapies that may become available in the future. The highly competitive nature of and rapid technological changes in the biotechnology and pharmaceutical industries could render our product candidates or our technology obsolete, less competitive or uneconomical.

Other products that are similar to our product candidates have already been approved and other products in the same class are further along in development. As more product candidates within a particular class of biopharmaceutical products proceed through clinical development to regulatory review and approval, the amount and type of clinical data that may be required by regulatory authorities may increase or change. Consequently, the results of our clinical trials for product candidates in those classes will likely need to show a risk benefit profile that is competitive with or more favorable than those products and product candidates in order to obtain marketing approval or, if approved, a product label that is favorable for commercialization. If the risk benefit profile is not competitive with those products or product candidates, we may have developed a product that is not commercially viable, that we are not able to sell profitably or that is unable to achieve favorable pricing or reimbursement. In such circumstances, our future product revenue and financial condition would be materially and adversely affected.

Specifically, there are many companies pursuing a variety of approaches to immuno-oncology treatments, including large pharmaceutical and biotechnology companies, such as AbbVie, Amgen, AstraZeneca, Bristol Myers Squibb, Gilead, Johnson & Johnson, Merck & Co., Novartis, Pfizer, Regeneron Pharmaceuticals and Roche/Genentech. Other companies using PSMA-targeting therapeutics for the treatment of cancer include Amgen, Crescendo Biologics, Johnson and Johnson, Lava Therapeutics, Poseida Therapeutics, Regeneron, Tmunity Therapeutic, Novartis and Bayer. We also face competition from biologic prodrug developers such as Adagene, Sanofi, BioAtla, Chugai Pharmaceutical Co./Roche Holding AG, CytomX Therapeutics, Harpoon Therapeutics, Merck & Co., and Xilio Therapeutics.

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.

The key competitive factors affecting the success of all of our programs are likely to be efficacy, safety, and convenience. If we are not successful in developing, commercializing and achieving higher levels of reimbursement than our competitors, we will not be able to compete against them and our business would be materially harmed.

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

We have incurred substantial losses during our history and do not expect to become profitable in the near future, and we may never achieve profitability. Under current law, U.S. federal net operating losses (NOLs) incurred in taxable years beginning after December 31, 2017, can be carried forward indefinitely to offset future taxable income, but the deductibility of such U.S. federal NOL carryforwards in a taxable year is limited to 80% of taxable income in such year.

As of December 31, 2023, we had $49.9 million of U.S. federal NOLs and $117.6 million of state NOLs. Of the total federal NOLs, $49.4 million have an indefinite carryforward period. The remaining federal and total state NOLs have a 20-year carryforward period, and will begin to expire in 2037 unless previously utilized. Our NOL carryforwards are subject to review and possible adjustment by the U.S. and state tax authorities.

In addition, under Sections 382 and 383 of the Internal Revenue Code of 1986, as amended (the Code), and corresponding provisions of state law, if a corporation undergoes an “ownership change,” which is generally defined as a greater than 50 percentage point change (by value) in its equity ownership over a rolling three-year period, the corporation’s ability to use its pre-change NOL carryforwards and certain other tax attributes to offset its post-change income or taxes may be limited. This could limit the amount of NOLs or other applicable tax attributes that we can utilize annually to offset future taxable income or tax liabilities. Subsequent ownership changes and changes to the U.S. tax rules in respect of the utilization of NOLs and other applicable tax attributes carried forward may further affect the limitation in future years. We have not undertaken a Section 382 study, and it is possible that we have previously undergone one or more ownership changes so that our use of net operating losses is subject to limitation. We may experience ownership changes in the future as a result of subsequent shifts in our stock

ownership. As a result, if we earn net taxable income, our ability to use our pre-change NOLs to offset U.S. federal taxable income may be subject to limitations, which could potentially result in increased future tax liability to us. In addition, at the state level, there may be periods during which the use of NOLs is suspended or otherwise limited, which could accelerate or permanently increase state taxes owed. As a result, we may be unable to use all or a material portion of our NOL carryforwards and other tax attributes, which could adversely affect our future cash flows.

Epidemic diseases could adversely impact our business, including our ongoing and planned clinical trials, supply chain and business development activities.

A health epidemic or pandemic may cause, significant disruptions that could severely impact our business and clinical trials, including:

- interruption or delays in our operations, which may impact our ability to conduct and produce preclinical results required for submission of an IND in the United States or equivalent marketing authorization applications in foreign jurisdictions;
- delays in receiving approval from regulatory authorities to initiate our planned clinical trials;
- delays or difficulties in enrolling patients in our ongoing and planned clinical trials;
- delays or difficulties in clinical site initiation, including difficulties in recruiting clinical site investigators and clinical site staff;
- delays in clinical sites receiving the supplies and materials needed to conduct our ongoing and planned clinical trials, including interruption in global shipping that may affect the transport of clinical trial materials;
- changes in local regulations which may require us to change the ways in which our ongoing and planned clinical trials are conducted, which may result in unexpected costs, or to discontinue the clinical trials altogether;
- diversion of healthcare resources away from the conduct of clinical trials, including the diversion of hospitals serving as our clinical trial sites and hospital staff supporting the conduct of our clinical trials;
- interruption of key clinical trial activities, such as clinical trial site monitoring, due to limitations on travel imposed or recommended by federal or state governments, employers and others, or interruption of clinical trial subject visits and study procedures, the occurrence of which could affect the integrity of clinical trial data;
- interruption or delays in the operations of the FDA, the EMA or the European Commission, or other comparable foreign regulatory authorities, which may impact review and approval timelines;
- risk that participants enrolled in our clinical trials will acquire an epidemic disease while the clinical trial is ongoing, which could impact the results of the clinical trial, including by increasing the number of observed adverse events; and
- refusal of the FDA, the EMA or comparable foreign regulatory authorities to accept data from clinical trials in affected geographies.

These and other disruptions in our operations and the global economy could negatively impact our business, operating results and financial condition.

A resurgence of COVID-19 or another health epidemic or pandemic may also materially affect us economically. While the potential economic impact brought by, and the duration of, a resurgence of COVID-19 or other health crises may be difficult to assess or predict, there could be a significant disruption of global financial markets, reducing our ability to access capital, which could in the future negatively affect our liquidity and financial position.

The extent to which a resurgence of a health epidemic or pandemic or other health crises may impede the development of our product candidates, reduce the productivity of our employees, disrupt our supply chains, delay

our clinical trials, reduce our access to capital or limit our business development activities, will depend on future developments, which are highly uncertain and cannot be predicted with confidence and may also have the effect of heightening many of the other risks described in this “Risk Factors” section.

Risks Related to Government Regulation

Our business operations and current and future relationships with investigators, health care professionals, consultants, third-party payors and customers are subject, directly or indirectly, to U.S. federal and state, EU, or foreign jurisdictions' healthcare fraud and abuse laws, transparency laws and other healthcare laws and regulations. If we are unable to comply, or have not fully complied, with such laws, we could face substantial penalties.

Our current and future operations may be, directly or indirectly through our prescribers, customers and third-party payors, subject to various U.S. federal and state healthcare laws and regulations, including, without limitation, the U.S. federal Anti-Kickback Statute, the U.S. federal civil and criminal false claims laws and the Physician Payments Sunshine Act and regulations. Healthcare providers and others play a primary role in the recommendation and prescription of any products for which we obtain marketing approval. These laws may impact, among other things, our current business operations, including our clinical research activities, and proposed sales, marketing and education programs and constrain the business or financial arrangements and relationships with healthcare providers and other parties through which we may market, sell and distribute our products for which we obtain marketing approval. In addition, we may be subject to additional healthcare, statutory and regulatory requirements and enforcement by foreign regulatory authorities in jurisdictions in which we conduct our business. The laws that may affect our ability to operate include:

- the U.S. federal Anti-Kickback Statute, which prohibits, among other things, persons or entities from knowingly and willfully soliciting, offering, receiving or paying any remuneration (including any kickback, bribe or certain rebates), directly or indirectly, overtly or covertly, in cash or in kind, to induce or reward either the referral of an individual for, or the purchase, lease, order or recommendation of, any good, facility, item or service, for which payment may be made, in whole or in part, under U.S. federal and state healthcare programs such as Medicare and Medicaid. A person or entity does not need to have actual knowledge of the statute or specific intent to violate it in order to have committed a violation;
- the U.S. federal false claims laws, including the False Claims Act, which can be enforced through whistleblower actions, and civil monetary penalties laws, which, among other things, impose criminal and civil penalties against individuals or entities for knowingly presenting, or causing to be presented, to the U.S. federal government, claims for payment or approval that are false or fraudulent, knowingly making, using or causing to be made or used, a false record or statement material to a false or fraudulent claim, or from knowingly making a false statement to avoid, decrease or conceal an obligation to pay money to the U.S. federal government. In addition, the government may assert that a claim including items and services resulting from a violation of the U.S. federal Anti-Kickback Statute constitutes a false or fraudulent claim for purposes of the False Claims Act;
- the U.S. federal Health Insurance Portability and Accountability Act of 1996 (HIPAA) which imposes criminal and civil liability for, among other things, knowingly and willfully executing, or attempting to execute, a scheme to defraud any healthcare benefit program, or knowingly and willfully falsifying, concealing or covering up a material fact or making any materially false statement, in connection with the delivery of, or payment for, healthcare benefits, items or services; similar to the U.S. federal Anti-Kickback Statute, a person or entity does not need to have actual knowledge of the statute or specific intent to violate it in order to have committed a violation;
- In addition, HIPAA, as amended by Health Information Technology for Economic and Clinical Health Act of 2009 (HITECH), imposes certain requirements on covered entities, which include certain healthcare providers, health plans and healthcare clearinghouses, and their business associates and covered subcontractors that receive or obtain protected health information in connection with providing a service on behalf of a covered entity relating to the privacy, security and transmission of individually identifiable health information.

- the U.S. Federal Food, Drug and Cosmetic Act, which prohibits, among other things, the adulteration or misbranding of drugs, biologics and medical devices;
- the U.S. federal legislation commonly referred to as Physician Payments Sunshine Act, enacted as part of the Affordable Care Act, and its implementing regulations, which requires certain manufacturers of drugs, devices, biologics and medical supplies that are reimbursable under Medicare, Medicaid or the Children's Health Insurance Program to report annually to the CMS information related to certain payments and other transfers of value to physicians (defined to include doctors, dentists, optometrists, podiatrists and chiropractors), other healthcare professionals (such as physicians assistants and nurse practitioners), and teaching hospitals, as well as ownership and investment interests held by the physicians described above and their immediate family members;
- analogous state laws and regulations, including: state anti-kickback and false claims laws, which may apply to our business practices, including, but not limited to, research, distribution, sales and marketing arrangements and claims involving healthcare items or services reimbursed by any third-party payor, including private insurers; state laws that require pharmaceutical companies to comply with the pharmaceutical industry's voluntary compliance guidelines and the relevant compliance guidance promulgated by the U.S. federal government, or otherwise restrict payments that may be made to healthcare providers and other potential referral sources; state laws and regulations that require drug manufacturers to file reports relating to pricing and marketing information, which requires tracking gifts and other remuneration and items of value provided to healthcare professionals and entities; and state and local laws requiring the registration of pharmaceutical sales representatives; and
- European Union and other foreign law equivalents of each of the laws, including reporting requirements detailing interactions with and payments to healthcare providers.

Ensuring that our internal operations and future business arrangements with third parties comply with applicable healthcare laws and regulations will involve substantial costs. It is possible that governmental authorities will conclude that our business practices do not comply with current or future statutes, regulations, agency guidance or case law involving applicable fraud and abuse or other healthcare laws and regulations. If our operations are found to be in violation of any of the laws described above or any other governmental laws and regulations that may apply to us, we may be subject to significant penalties, including civil, criminal and administrative penalties, damages, fines, exclusion from U.S. government funded healthcare programs, such as Medicare and Medicaid, or similar programs in other countries or jurisdictions, disgorgement, imprisonment, contractual damages, reputational harm, diminished profits, additional reporting requirements and oversight if we become subject to a corporate integrity agreement or similar agreement to resolve allegations of non-compliance with these laws and the delay, reduction, termination or restructuring of our operations. Further, defending against any such actions can be costly and time-consuming, and may require significant financial and personnel resources. Therefore, even if we are successful in defending against any such actions that may be brought against us, our business may be impaired. If any of the physicians or other providers or entities with whom we expect to do business is found to not be in compliance with applicable laws, they may be subject to significant criminal, civil or administrative sanctions, including exclusions from government funded healthcare programs and imprisonment. If any of the above occur, it could adversely affect our ability to operate our business and our results of operations.

Enacted and future legislation may increase the difficulty and cost for us to obtain marketing approval of and commercialize our product candidates and affect the prices we may charge for such product candidates.

The United States and many foreign jurisdictions have enacted or proposed legislative and regulatory changes affecting 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 for which we obtain marketing approval.

In March 2010, the Affordable Care Act was enacted, which includes measures that have significantly changed the way health care is financed by both governmental and private insurers. There have been executive, judicial and congressional challenges to certain aspects of the Affordable Care Act. For example, on June 17, 2021, the U.S. Supreme Court dismissed a challenge on procedural grounds that argued the Affordable Care Act is unconstitutional in its entirety because the "individual mandate" was repealed by Congress. Further, prior to the U.S. Supreme Court

ruling, on January 28, 2021, President Biden issued an executive order that initiated a special enrollment period for purposes of obtaining health insurance coverage through the Affordable Care Act marketplace. The executive order also instructed certain governmental agencies to review and reconsider their existing policies and rules that limit access to healthcare, including among others, reexamining Medicaid demonstration projects and waiver programs that include work requirements, and policies that create unnecessary barriers to obtaining access to health insurance coverage through Medicaid or the Affordable Care Act. It is possible that the Affordable Care Act will be subject to judicial or congressional challenges in the future. Further, on August 16, 2022, President Biden signed the Inflation Reduction Act of 2022 (IRA) into law, which among other things, extends enhanced subsidies for individuals purchasing health insurance coverage in Affordable Care Act marketplaces through plan year 2025. The IRA also eliminates the "donut hole" under the Medicare Part D program beginning in 2025 by significantly lowering the beneficiary maximum out-of-pocket cost and through a newly established manufacturer discount program. It is also unclear how any additional healthcare reform measures of the Biden administration will impact the Affordable Care Act or our business.

In addition, other legislative changes have been proposed and adopted since the Affordable Care Act was enacted. For example, in August 2011, the Budget Control Act of 2011 was signed into law, which, among other things, included aggregate reductions to Medicare payments to providers of, on average, 2% per fiscal year until 2032. Additionally, on March 11, 2021, President Biden signed the American Rescue Plan Act of 2021 into law, which eliminates the statutory Medicaid drug rebate cap, currently set at 100% of a drug's average manufacturer price, for single source and innovator multiple source drugs, effective January 1, 2024.

Recently, there has been increasing legislative and enforcement interest in the United States with respect to specialty drug pricing practices. Specifically, there have been several U.S. presidential executive orders, congressional inquiries and legislation designed to, among other things, bring more transparency to drug pricing, reduce the cost of prescription drugs under Medicare, review the relationship between pricing and manufacturer patient programs and reform government program reimbursement methodologies for drugs. For example, in July 2021, the Biden administration expressed its intent to pursue certain policy initiatives to reduce drug prices released an executive order that included multiple provisions aimed at prescription drugs. In response to Biden's executive order, on September 9, 2021, the U.S. Department of Health and Human Services (HHS) released a Comprehensive Plan for Addressing High Drug Prices that outlines principles for drug pricing reform. The plan sets out a variety of potential legislative policies that Congress could pursue as well as potential administrative actions HHS can take to advance these principles. In addition, the IRA, among other things, (1) directs HHS to negotiate the price of certain single-source drugs and biologics covered under Medicare and (2) imposes rebates under Medicare Part B and Medicare Part D to penalize price increases that outpace inflation. These provisions take effect progressively starting in fiscal year 2023. On August 29, 2023, HHS announced the list of the first ten drugs that will be subject to price negotiations, although the Medicare drug price negotiation program is currently subject to legal challenges. HHS has and will continue to issue and update guidance as these programs are implemented. It is currently unclear how the IRA will be implemented but is likely to have a significant impact on the pharmaceutical industry. In response to the Biden administration's October 2022 executive order, on February 14, 2023, HHS released a report outlining three new models for testing by the CMS Innovation Center which will be evaluated on their ability to lower the cost of drugs, promote accessibility, and improve quality of care. It is unclear whether the models will be utilized in any health reform measures in the future. Further, on December 7, 2023, the Biden administration announced an initiative to control the price of prescription drugs through the use of march-in rights under the Bayh-Dole Act. On December 8, 2023, the National Institute of Standards and Technology published for comment a Draft Interagency Guidance Framework for Considering the Exercise of March-In Rights which for the first time includes the price of a product as one factor an agency can use when deciding to exercise march-in rights. While march-in rights have not previously been exercised, it is uncertain if that will continue under the new framework. At the state level, legislatures have increasingly passed legislation and implemented regulations designed to control costs pharmaceutical and biological products. Moreover, regional healthcare 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 healthcare programs.

In the European Union, many EU Member States periodically review their reimbursement procedures for medicinal products, which could have an adverse impact on reimbursement status. We expect that legislators, policymakers and healthcare insurance funds in the EU Member States will continue to propose and implement cost-containing measures, such as lower maximum prices, lower or lack of reimbursement coverage and incentives to use

cheaper, usually generic, products as an alternative to branded products, and/or branded products available through parallel import to keep healthcare costs down. Moreover, in order to obtain reimbursement for our products in some European countries, including some EU Member States, we may be required to compile additional data comparing the cost-effectiveness of our products to other available therapies through HTA processes. The HTA process is currently governed by national laws in each EU Member State. In December 2021 the European Union Parliament adopted the HTA regulation which, when it enters into application in 2025, will be intended to harmonize the clinical benefit assessment of HTA across the European Union. Further, an increasing number of European Union and other foreign countries use prices for medicinal products established in other countries as "reference prices" to help determine the price of the product in their own territory. Consequently, a downward trend in prices of medicinal products in some countries could contribute to similar downward trends elsewhere.

In addition, on April 26, 2023, the European Commission adopted a proposal for a new Directive and Regulation to revise the existing pharmaceutical legislation. If adopted in the form proposed, the recent European Commission proposals to revise the existing EU laws governing authorization of medicinal products may result in a decrease in data and market exclusivity opportunities for our product candidates in the EU.

We expect that the healthcare reform measures that have been adopted, and that may be adopted in the future, may result in more rigorous coverage criteria and in additional downward pressure on the price that we receive for any approved product and could seriously harm our future revenues. Any reduction in reimbursement from Medicare or other comparable government programs may result in a similar reduction in payments from private payors. The implementation of cost containment measures or other healthcare reforms may prevent us from being able to generate revenue, attain profitability or commercialize our products.

The United Kingdom's withdrawal from the European Union may have a negative effect on global economic conditions, financial markets and our business, which could reduce the price of our common stock.

The United Kingdom's, or UK, withdrawal from the EU on January 31, 2020, commonly referred to as Brexit, has changed the regulatory relationship between the UK and the EU. The Medicines and Healthcare products Regulatory Agency, or MHRA, is now the UK's standalone regulator for medicinal products and medical devices. Great Britain (England, Scotland and Wales) is now a third country to the EU. Northern Ireland will, with regard to EU regulations, continue to follow the EU regulatory rules for now.

The UK regulatory framework in relation to clinical trials is governed by the Medicines for Human Use (Clinical Trials) Regulations 2004, as amended, which is derived from the CTD, as implemented into UK national law through secondary legislation. On January 17, 2022, the MHRA launched an eight-week consultation on reframing the UK legislation for clinical trials,and which aimed to streamline clinical trials approvals, enable innovation, enhance clinical trials transparency, enable greater risk proportionality, and promote patient and public involvement in clinical trials.The UK Government published its response to the consultation on March 21, 2023 confirming that it would bring forward changes to the legislation. These resulting legislative amendments will determine how closely the UK regulations will align with the CTR. In October 2023, the MHRA announced a new Notification Scheme for clinical trials which enables a more streamlined and risk-proportionate approach to initial clinical trial applications for Phase 4 and low-risk Phase 3 clinical trial applications.

Marketing authorizations in the UK are governed by the Human Medicines Regulations (SI 2012/1916), as amended. Since January 1, 2021, an applicant for the EU centralized procedure marketing authorization can no longer be established in the UK. As a result, since this date, companies established in the UK cannot use the EU centralized procedure and instead must follow one of the UK national authorization procedures or one of the remaining post-Brexit international cooperation procedures to obtain a marketing authorization to market products in the UK. All existing EU marketing authorizations for centrally authorized products were automatically converted or grandfathered into UK marketing authorization, effective in Great Britain only, free of charge on January 1, 2021, unless the marketing authorization holder opted-out of this possibility. Northern Ireland currently remains within the scope of EU authorizations in relation to centrally authorized medicinal products. Accordingly, until the Windsor Framework is implemented in Northern Ireland on January 1, 2025, products falling within the scope of the EU centralized procedure can only be authorized through UK national authorization procedures in Great Britain.

The MHRA has also introduced changes to national marketing authorization procedures. This includes introduction of procedures to prioritize access to new medicines that will benefit patients, including a 150-day assessment route, a rolling review procedure and the International Recognition Procedure. Since January 1, 2024, the MHRA may rely on the International Recognition Procedure, or IRP, when reviewing certain types of marketing authorization applications. This procedure is available for applicants for marketing authorization who have already received an authorization for the same product from a reference regulator. These include the FDA, the EMA, and national competent authorities of individual EEA countries. A positive opinion from the EMA and CHMP, or a positive end of procedure outcome from the mutual recognition or decentralized procedures are considered to be authorizations for the purposes of the IRP.

There is no pre-marketing authorization orphan designation for medicinal products in the UK. Instead, the MHRA reviews applications for orphan designation in parallel to the corresponding marketing authorization application. The criteria are essentially the same as those in the EU, but have been tailored for the market. This includes the criterion that prevalence of the condition in Great Britain, rather than the EU, must not be more than five in 10,000. Upon the grant of a marketing authorization with orphan status, the medicinal product will benefit from up to 10 years of market exclusivity from similar products in the approved orphan indication. The start of this market exclusivity period will be set from the date of first approval of the product in Great Britain.

We are subject to stringent and evolving U.S. and foreign laws, regulations, rules, contractual obligations, industry standards, policies and other obligations related to data privacy and security. Our actual or perceived failure to comply with such obligations could lead to regulatory investigations or actions; litigation (including class claims) and mass arbitration demands; fines and penalties; disruptions of our business operations; reputational harm; loss of revenue or profits; and other adverse business consequences.

In the ordinary course of business, we Process personal information and other sensitive information, including proprietary and confidential business data, trade secrets, intellectual property, data we collect about trial participants in connection with clinical trials, and sensitive third-party data. Our data processing activities subject us to numerous data privacy and security obligations, such as various laws, regulations, guidance, industry standards, external and internal privacy and security policies, contractual requirements, and other obligations relating to data privacy and security.

In the United States, federal, state, and local governments have enacted numerous data privacy and security laws, including health information privacy laws, data breach notification laws, personal information privacy laws, consumer protection laws (e.g., Section 5 of the Federal Trade Commission Act), and other similar laws (e.g., wiretapping laws). For example, we may obtain health information from third parties (including research institutions from which we obtain clinical trial data) that are subject to privacy and security requirements under the HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act of 2009 (HITECH), and their respective implementing regulations. HIPAA imposes specific requirements relating to the privacy, security, and transmission of individually identifiable health information. Additionally, in the past few years, numerous U.S. states—including California, Virginia, Colorado, Connecticut, and Utah—have enacted comprehensive privacy laws that impose certain obligations on covered businesses, including providing specific disclosures in privacy notices and affording residents with certain rights concerning their personal information. As applicable, such rights may include the right to access, correct, or delete certain personal information, and to opt-out of certain data processing activities, such as targeted advertising, profiling, and automated decision-making. The exercise of these rights may impact our business and ability to provide our products and services. Certain states also impose stricter requirements for processing certain personal information, including sensitive information, such as conducting data privacy impact assessments. These state laws allow for statutory fines for noncompliance. For example, the CCPA applies to personal information of consumers, business representatives, and employees who are California residents, and requires businesses to provide specific disclosures in privacy notices and honor request of California residents to exercise certain privacy rights with respect to their personal information, such as those noted below. The CCPA provides for civil penalties for violations (up to $7,500 per intentional violation) and allows private litigants affected by certain data breaches to recover significant statutory damages. Although the CCPA (like other U.S. comprehensive privacy laws) exempts some data processed in the context of clinical trials, the CCPA increases compliance costs and potential liability with respect to other personal information we maintain about California residents. Similar laws are being considered in several other states, as well as at the federal and local levels, and we expect more jurisdictions to pass similar laws in the future. Additionally, under various privacy laws and other

obligations, we may be required to obtain certain consents to process personal information. Our inability or failure to do so could result in material adverse consequences, including interrupting our clinical trial activities. In many jurisdictions, enforcement actions and consequences for noncompliance are rising. In the United States, these include enforcement actions in response to rules and regulations promulgated under the authority of federal agencies, state attorneys general, legislatures and consumer protection agencies.

Outside the United States, an increasing number of laws, regulations, and industry standards may govern to data privacy and security. For example, the European Union's General Data Protection Regulation (EU GDPR), the United Kingdom's GDPR (UK GDPR) and Australia's Privacy Act impose strict requirements for processing personal data and violators of these laws face significant penalties. For example, under the EU GDPR and UK GDPR, government regulators may impose temporary or definitive bans on data processing, as well as fines of up to 20 million euros (£17.5 million for the UK GDPR) or 4% of annual global revenue, whichever is greater; or - private litigation related to the processing of personal data, brought by classes of data subjects or consumer protection organizations authorized by law to represent their interests.

We are also bound by contractual obligations related to data privacy and security, and our efforts to comply with such obligations may not be successful. For example, certain privacy laws, such as the GDPR and the CCPA, require us to impose specific contractual restrictions on our service providers. Moreover, clinical trial subjects about whom we or our potential collaborators obtain information, as well as the providers who share this information with us, may contractually limit our ability to use and disclose such information. We also publish privacy policies, marketing materials and other statements regarding data privacy and security. If these policies, materials or statements are found to be deficient, lacking in transparency, deceptive, unfair, or misrepresentative of our practices, we may be subject to investigation, enforcement actions by regulators or other adverse consequences. In addition, privacy advocates and industry groups have regularly proposed, and may propose in the future, self-regulatory standards with which we are legally or contractually bound to comply, or may become subject to in the future.

Our obligations related to data privacy and security (and consumers' data privacy expectations) are quickly changing in an increasingly stringent fashion, creating some uncertainty as to the effective future legal framework. Additionally, these obligations may be subject to differing applications and interpretations, which may be inconsistent or conflict among jurisdictions. Preparing for and complying with these obligations requires significant resources, which may necessitate changes to our information technologies, systems, and practices and to those of any third parties that process personal information on our behalf. Although we endeavor to comply with all applicable data privacy and security obligations, we may at times fail (or be perceived to have failed) to do so. Moreover, despite our efforts, our personnel or third parties upon whom we rely may fail to comply with such obligations, which could negatively impact our business operations and compliance posture.

If we or the third parties on which we rely fail, or are perceived to have failed, to address or comply with applicable data privacy and security obligations, we could face significant consequences, including but not limited to: government enforcement actions (e.g., investigations, fines, penalties, audits, inspections, and similar); litigation (including class-action claims) and mass arbitration demands; additional reporting requirements and/or oversight; bans on processing personal information; orders to destroy or not use personal information; and imprisonment of company officials. In particular, plaintiffs have become increasingly more active in bringing privacy-related claims against companies, including class claims and mass arbitration demands. Some of these claims allow for the recovery of statutory damages on a per violation basis, and, if viable, carry the potential for monumental statutory damages, depending on the volume of data and the number of violations. Any of these events could have a material adverse effect on our reputation, business, or financial condition, including but not limited to, interruptions or stoppages in our business operations (including, as relevant, clinical trials), inability to process personal information or to operate in certain jurisdictions, limited ability to develop or commercialize our products, expenditure of time and resources to defend any claim or inquiry, adverse publicity, or substantial changes to our operations.

In addition, we may be unable to transfer personal data from Europe and other jurisdictions to the United States or other countries due to data localization requirements or limitations on cross-border data flows. Although there are various mechanisms that may be used in some cases to lawfully transfer personal data to the United States or other countries, these mechanisms are subject to legal challenges and may not be available to us. An inability or material limitation on our ability to transfer personal data to the United States or other countries could materially impact our business operations.

In the ordinary course of business, we may transfer personal data from Europe and other jurisdictions to the United States or other countries. Europe and other jurisdictions have enacted laws requiring data to be localized or limiting the transfer of personal data to other countries. In particular, the EEA and the UK have significantly restricted the transfer of personal data to the United States and other countries whose privacy laws it generally believes are inadequate. Other jurisdictions may adopt similarly stringent interpretations of their data localization and cross-border data transfer laws.

Although there are currently various mechanisms that may be used to transfer personal data from the EEA and UK to the United States in compliance with law, such as the EEA and UK's standard contractual clauses, the UK's International Data Transfer Agreement / Addendum, and the EU-U.S. Data Privacy Framework (Framework) and the UK extension thereto (which allows for transfers for relevant U.S.-based organizations who self-certify compliance and participate in the Framework), these mechanisms are subject to legal challenges, and there is no assurance that we can satisfy or rely on these measures to lawfully transfer personal data to the United States.

If there is no lawful manner for us to transfer personal data from the EEA, the UK or other jurisdictions to the United States, or if the requirements for a legally-compliant transfer are too onerous, we could face significant adverse consequences, including the interruption or degradation of our operations, the need to relocate part of or all of our business or data processing activities to other jurisdictions (such as Europe) at significant expense, increased exposure to regulatory actions, substantial fines and penalties, the inability to transfer data and work with partners, vendors and other third parties, and injunctions against our processing or transferring of personal data necessary to operate our business. Additionally, companies that transfer personal data out of the EEA and UK to other jurisdictions, particularly to the United States, are subject to increased scrutiny from regulators, individual litigants, and activist groups. Some European regulators have ordered certain companies to suspend or permanently cease certain transfers out of Europe for allegedly violating the GDPR's cross-border data transfer limitations.

Risks Related to Our Intellectual Property

If we are unable to obtain and maintain sufficient intellectual property protection for our platform technologies and product candidates, or if the scope of the intellectual property protection is not sufficiently broad, our competitors could develop and commercialize products similar or identical to ours, and our ability to successfully commercialize our products may be adversely affected.

We rely upon a combination of patents, know-how and confidentiality agreements to protect the intellectual property related to our products and technologies and to prevent third parties from copying and surpassing our achievements, thus eroding our competitive position in our market.

Our success depends in large part on our ability to obtain and maintain patent protection for our platform technologies, product candidates and their uses, as well as our ability to operate without infringing the proprietary rights of others. We seek to protect our proprietary position by filing patent applications in the United States and abroad related to our novel discoveries and technologies that are important to our business. Our pending and future patent applications may not result in patents being issued or that issued patents will afford sufficient protection of our product candidates or their intended uses against competitors, nor can there be any assurance that the patents issued will not be infringed, designed around, invalidated by third parties, or effectively prevent others from commercializing competitive technologies, products or product candidates.

Obtaining and enforcing patents is expensive and time-consuming, and we may not be able to file and prosecute all necessary or desirable patent applications or maintain and/or enforce patents that may issue based on our patent applications, at a reasonable cost or in a timely manner. It is also possible that we will fail to identify patentable aspects of our research and development results before it is too late to obtain patent protection. Although we enter into non-disclosure and confidentiality agreements with parties who have access to patentable aspects of our research and development output, such as our employees, corporate collaborators, outside scientific collaborators, contract research organizations, contract manufacturers, consultants, advisors and other third parties, any of these parties may breach these agreements and disclose such results before a patent application is filed, thereby jeopardizing our ability to seek patent protection.

Composition of matter patents for biological and pharmaceutical product candidates often provide a strong form of intellectual property protection for those types of products, as such patents provide protection without regard to any method of use. We cannot be certain that the claims in our pending patent applications directed to composition of matter of our product candidates will be considered patentable by the United States Patent and Trademark Office (USPTO) or by patent offices in foreign countries, or that any claims that issue from our patent applications will be considered valid and enforceable by courts in the United States or foreign countries. Method of use patents protect the use of a product for the specified method. This type of patent does not prevent a competitor from making and marketing a product that is identical to our product for an indication that is outside the scope of the patented method. Moreover, even if competitors do not actively promote their product for our targeted indications, physicians may prescribe these products "off-label." Although off-label prescriptions may infringe or contribute to the infringement of method of use patents, the practice is common and such infringement is difficult to prevent or prosecute.

The patent position of biopharmaceutical companies generally is highly uncertain, involves complex legal and factual questions and has in recent years been the subject of much litigation, resulting in court decisions, including Supreme Court decisions, which have increased uncertainties as to the ability to enforce patent rights in the future. In addition, the laws of foreign countries may not protect our rights to the same extent as the laws of the United States, or vice versa. No earlier than October 1, 2022, European applications will have the option, upon grant of a patent, of becoming a Unitary Patent which will be subject to the jurisdiction of the Unitary Patent Court (UPC). This will be a significant change in European patent practice. As the UPC is a new court system, there is no precedent for the court, increasing the uncertainty of any litigation.

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

The patent application process is subject to numerous risks and uncertainties, and there can be no assurance that we or any of our potential future collaborators will be successful in protecting our product candidates by obtaining and defending patents. For example, we may not be aware of all third-party intellectual property rights potentially relating to our product candidates or their intended uses, and as a result the impact of such third-party intellectual property rights upon the patentability of our own patents and patent applications, as well as the impact of such third-party intellectual property upon our freedom to operate, is highly uncertain. Patent applications in the United States and other jurisdictions are typically not published until 18 months after filing or, in some cases, not at all. Therefore, we cannot know with certainty whether we were the first to make the inventions claimed in our patents or pending patent applications, or that we were the first to file for patent protection of such inventions. As a result, the issuance, inventorship, scope, validity, enforceability and commercial value of our patent rights are highly uncertain. Our pending patent applications may be challenged in patent offices in the United States and abroad. Even issued patents may later be found invalid or unenforceable or may be modified or revoked in proceedings instituted by third parties before various patent offices or in courts. For example, our pending patent applications may be subject to third-party pre-issuance submissions of prior art to the USPTO or our issued patents may be subject to post-grant review (PGR) proceedings, oppositions, derivations, reexaminations, or *inter partes* review proceedings, in the United States or elsewhere, challenging our patent rights or the patent rights of others. An adverse determination in any such challenges may result in loss of exclusivity or in patent claims being narrowed, invalidated, or held unenforceable, in whole or in part, which could limit our ability to stop others from using or commercializing similar or identical technology and products, or limit the duration of the patent protection of our technology and

products. 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. The degree of future protection for our proprietary rights is uncertain. Only limited protection may be available and may not adequately protect our rights or permit us to gain or keep any competitive advantage. Any failure to obtain or maintain patent protection with respect to our product candidates or their uses could have a material adverse effect on our business, financial condition, results of operations and prospects.

In addition to the protection afforded by patents, we rely on trade secret protection and confidentiality agreements to protect proprietary know-how that is not patentable, processes for which patents are difficult to enforce and any other elements of our discovery and development processes that involve proprietary know-how, information or technology that is not covered by patents. We may also rely on trade secret protection as temporary protection for concepts that may be included in a future patent filing. However, trade secret protection will not protect us from innovations that a competitor develops independently of our proprietary know how. If a competitor independently develops a technology that we protect as a trade secret and files a patent application on that technology, then we may not be able to patent that technology in the future, may require a license from the competitor to use our own know-how, and if the license is not available on commercially-viable terms, then we may not be able to launch our product. Although we require all of our employees to assign their inventions to us, and require all of our employees, consultants, advisors and any third parties who have access to our proprietary know-how, information or technology to enter into confidentiality agreements, 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, and this scenario could materially adversely affect our business, financial condition and results of operations.

We cannot ensure that patent rights relating to inventions described and claimed in our pending patent applications will issue or that patents based on our patent applications will not be challenged and rendered invalid and/or unenforceable.

The patent application process is subject to numerous risks and uncertainties, and there can be no assurance that we or any of our potential future collaborators will be successful in protecting our product candidates by obtaining and defending patents. We have pending U.S. Patent Cooperation Treaty, and foreign patent applications in our portfolio; however, we cannot predict:

- if and when patents may issue based on our patent applications;
- the scope of protection of any patent issuing based on our patent applications;
- whether the claims of any patent issuing based on our patent applications will provide protection against competitors;
- whether or not third parties will find ways to invalidate or circumvent our patent rights;
- whether or not others will obtain patents claiming aspects similar to those covered by our patents and patent applications;
- whether we will need to initiate litigation or administrative proceedings to enforce and/or defend our patent rights which will be costly whether we win or lose; and/or
- whether the patent applications that we own or in-license will result in issued patents with claims that cover our product candidates or uses thereof in the United States or in other foreign countries.

We cannot be certain that the claims in our pending patent applications directed to our product candidates and/or technologies will be considered patentable by the USPTO or by patent offices in foreign countries. There can be no assurance that any such patent applications will issue as granted patents. One aspect of the determination of patentability of our inventions depends on the scope and content of the “prior art,” information that was or is

deemed available to a person of skill in the relevant art prior to the priority date of the claimed invention. There may be prior art of which we are not aware that may affect the patentability of our patent claims or, if issued, affect the validity or enforceability of a patent claim. Even if the patents do issue based on our patent applications, 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, patents in our portfolio may not adequately exclude third parties from practicing relevant technology or prevent others from designing around our claims. If the breadth or strength of our intellectual property position with respect to our product candidates is threatened, it could dissuade companies from collaborating with us to develop and threaten our ability to commercialize our product candidates. In the event of litigation or administrative proceedings, we cannot be certain that the claims in any of our issued patents will be considered valid by courts in the United States or foreign countries.

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

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

- others may be able to make product candidates that are similar to ours but that are not covered by the claims of the patents that we own or may exclusively license;
- we or licensors or collaborators might not have been the first to make the inventions covered by the issued patent or pending patent application that we own or have exclusively licensed;
- we or licensors or collaborators might not have been the first to file patent applications covering certain of our inventions;
- others may independently develop similar or alternative technologies or duplicate any of our technologies without infringing our intellectual property rights;
- it is possible that noncompliance with the USPTO and foreign governmental patent agencies requirement for a number of procedural, documentary, fee payment and other provisions during the patent process can result in abandonment or lapse of a patent or patent application, and partial or complete loss of patent rights in the relevant jurisdiction;
- it is possible that our pending patent applications will not lead to issued patents;
- issued patents that we own or have exclusively licensed may be revoked, modified, or held invalid or unenforceable, as a result of legal challenges by our competitors;
- our competitors might conduct research and development activities in countries where we do not have patent rights and then use the information learned from such activities to develop competitive products for sale in our major commercial markets;
- we may not develop additional proprietary technologies that are patentable;
- we cannot predict the scope of protection of any patent issuing based on our patent applications, including whether the patent applications that we own or in-license will result in issued patents with claims that directed to our product candidates or uses thereof in the United States or in other foreign countries;
- there may be significant pressure on the U.S. government and international governmental bodies to limit the scope of patent protection both inside and outside the United States for disease treatments that prove successful, as a matter of public policy regarding worldwide health concerns;
- countries other than the United States may have patent laws less favorable to patentees than those upheld by U.S. courts, allowing foreign competitors a better opportunity to create, develop and market competing product candidates;
- the claims of any patent issuing based on our patent applications may not provide protection against competitors or any competitive advantages, or may be challenged by third parties;
- if enforced, a court may not hold that our patents are valid, enforceable and infringed;

- we may need to initiate litigation or administrative proceedings to enforce and/or defend our patent rights which will be costly whether we win or lose;
- we may choose not to file a patent application in order to maintain certain trade secrets or know-how, and a third-party may subsequently file a patent application covering such intellectual property;
- we may fail to adequately protect and police our trademarks and trade secrets; and
- the patents of others may have an adverse effect on our business, including if others obtain patents claiming subject matter similar to or improving that covered by our patents and patent applications.

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

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

We cannot guarantee that any of our patent searches or analyses, including the identification of relevant patents, the scope of patent claims or the expiration of relevant patents, are complete or thorough, nor can we be certain that we have identified each and every third-party patent and pending application in the United States and abroad that is relevant to or necessary for the commercialization of our product candidates in any jurisdiction.

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

We are currently party to an in-license agreement under which we were granted rights to manufacture certain components of our product candidates. If we breach our obligations under this and future license agreements, we may be required to pay damages, lose our rights to these technologies or both, which would adversely affect our business and prospects.

We rely, in part, on license and other strategic agreements, which subject us to various obligations, including payment obligations for achievement of certain milestones on product sales. For example, we have licensed a cell line to manufacture these products under an agreement with WuXi Biologics. If we fail to comply with the obligations under our license agreements or use the intellectual property licensed to us in an unauthorized manner, we may be required to pay damages and our licensors may have the right to terminate the license. If our license agreements are terminated, we may experience significant delays, difficulties, and costs in developing new cell lines and identifying an alternative source to manufacture components of our candidate products covered by our agreements and those being tested or approved in combination with such products. Such an occurrence could materially adversely affect the value of the product candidates being developed under any such agreement.

In addition, the agreements under which we license intellectual property or technology to or from third parties are complex, and certain provisions in such agreements may be susceptible to multiple interpretations. The resolution of any contract interpretation disagreement that may arise could narrow what we believe to be the scope of our rights to the relevant intellectual property or technology or increase what we believe to be our financial or other obligations under the relevant agreement, either of which could have a material adverse effect on our business, financial condition, results of operations or prospects.

In the event we breach any of our obligations related to such prosecution, we may incur significant liability to our licensing partners. Licensing intellectual property involves complex legal, business and scientific issues and is complicated by the rapid pace of scientific discovery in our industry. Disputes may arise regarding intellectual property subject to a licensing agreement, including:

- the scope of rights granted under the license agreement and other interpretation-related issues;

- the extent to which our technology and processes infringe on intellectual property of the licensor that is not subject to the licensing agreement;
- the sublicensing of patent and other rights;
- our diligence obligations under the license agreement and what activities satisfy those diligence obligations;
- the ownership of inventions and know-how resulting from the creation or use of licensed intellectual property by us alone or with our licensors and partners;
- the right to control prosecution, maintenance, enforcement, and defense of the licensed patents and improvements thereof;
- the scope and duration of our payment obligations; and
- the priority of invention of patented technology.

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

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 we are unable to successfully obtain rights to required third-party intellectual property rights or maintain the existing intellectual property rights we have, we may have to abandon development of the relevant research programs or product candidates and our business, financial condition, results of operations and prospects could suffer.

In the future, we may need to obtain licenses of third-party technology that may not be available to us or are available only on commercially unreasonable terms, and which may cause us to operate our business in a more costly or otherwise adverse manner that was not anticipated.

We currently own intellectual property directed to our product candidates and other proprietary technologies. Other pharmaceutical companies and academic institutions may also have filed or are planning to file patent applications potentially relevant to our business. From time to time, in order to avoid infringing these third-party patents, we may be required to license technology from additional third parties to further develop or commercialize our product candidates. Should we be required to obtain licenses to any third-party technology, including any such patents required to manufacture, use or sell our product candidates, such licenses may not be available to us on commercially reasonable terms, or at all. The inability to obtain any third-party license required to develop or commercialize any of our product candidates could cause us to abandon any related efforts, which could seriously harm our business and operations.

The licensing or acquisition of third-party intellectual property rights is a competitive area, and several more established companies may pursue strategies to license or acquire third-party intellectual property rights we may consider attractive or necessary. These established companies may have a competitive advantage over us due to their size, capital 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.

Moreover, some of our owned patent applications and patents may 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 may need the cooperation of any such co-owners of our patents in order to enforce such patents against third parties, and such cooperation may not be provided to us. Furthermore, our owned patents may be subject to a reservation of rights by one or more third parties. Any of the foregoing could have a material adverse effect on our competitive position, business, financial conditions, results of operations and prospects.

If we are sued for infringing intellectual property rights of third parties, such litigation could be costly and time consuming and could prevent or delay us from developing or commercializing our product candidates.

Our commercial success depends, in part, on our ability to develop, manufacture, market and sell our product candidates without infringing the intellectual property and other proprietary rights of third parties. Third parties may allege that we have infringed or misappropriated their intellectual property. Litigation or other legal proceedings relating to intellectual property claims, with or without merit, is unpredictable and generally expensive and time consuming and, even if resolved in our favor, is likely to divert significant resources from our core business, including distracting our technical and management personnel from their normal responsibilities. In addition, there could be public announcements of the results of hearings, motions or other interim proceedings or developments and if securities analysts or investors perceive these results to be negative, it could have a substantial adverse effect on the market price of our common stock. Such litigation or proceedings could substantially increase our operating losses and reduce the resources available for development activities or any future sales, marketing or distribution activities. We may not have sufficient financial or other resources to adequately conduct such litigation or proceedings. Some of our competitors may be able to sustain the costs of such litigation or proceedings more effectively than we can because of their greater financial resources and more mature and developed intellectual property portfolios. Uncertainties resulting from the initiation and continuation of patent litigation or other proceedings could have a material adverse effect on our ability to compete in the marketplace.

There is a substantial amount of intellectual property litigation in the biotechnology and pharmaceutical industries, and we may become party to, or threatened with, litigation or other adversarial proceedings regarding intellectual property rights with respect to our products candidates. We cannot be certain that our product candidates and other proprietary technologies we may develop will not infringe existing or future patents owned by third parties. We are currently aware of a third-party European patent that may cover our products. However, we do not plan to launch any product in the European Union before the expiration of such patent. Third parties may assert infringement claims against us based on existing or future intellectual property rights. Proving invalidity may be difficult. For example, in the United States, proving invalidity in court requires a showing of clear and convincing evidence to overcome the presumption of validity enjoyed by issued patents. If we are found to infringe a third-party's intellectual property rights, we could be forced, including by court order, to cease developing, manufacturing or commercializing the infringing candidate product or product. Alternatively, we may be required to obtain a license from such third-party in order to use the infringing technology and continue developing, manufacturing or marketing the infringing candidate product or product. However, we may not be able to obtain any required license on commercially reasonable terms or at all. Even if we were able to obtain a license, it could be non-exclusive, thereby giving our competitors access to the same technologies licensed to us. In addition, we could be found liable for monetary damages, including treble damages and attorneys' fees if we are found to have willfully infringed a patent. A finding of infringement could prevent us from commercializing our investigational products or force us to cease some of our business operations, which could materially harm our business.

We may not be aware of patents that have already been issued and that a third-party, for example, a competitor in the fields in which we are developing our product candidates, might assert are infringed by our current or future product candidates, including claims to compositions, formulations, methods of manufacture or methods of use or treatment that cover our product candidates. It is also possible that patents owned by third parties of which we are aware, but which we do not believe are relevant to our product candidates and other proprietary technologies we may develop, could be found to be infringed by our product candidates. In addition, because patent applications can take many years to issue, there may be currently pending patent applications that may later result in issued patents that our product candidates may infringe. Our competitors in both the United States and abroad, many of which have substantially greater resources and have made substantial investments in patent portfolios and competing technologies, may have applied for or obtained or may in the future apply for and obtain, patents that will prevent, limit or otherwise interfere with our ability to make, use and sell our product candidates. The pharmaceutical and biotechnology industries have produced a considerable number of patents, and it may not always be clear to industry

participants, including us, which patents cover various types of products or methods of use. The coverage of patents is subject to interpretation by the courts, and the interpretation is not always uniform. If we were sued for patent infringement, we would need to demonstrate that our product candidates, products or methods either do not infringe the patent claims of the relevant patent or that the patent claims are invalid or unenforceable, and we may not be able to do this. Proving invalidity may be difficult and there is no assurance that a court of competent jurisdiction would invalidate the claims of any such U.S. patent. Even if we are successful in these proceedings, we may incur substantial costs and the time and attention of our management and scientific personnel could be diverted in pursuing these proceedings, which could have a material adverse effect on our business and operations. 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 litigation. In addition, we may not have sufficient resources to bring these actions to a successful conclusion.

We may choose to challenge the enforceability or validity of claims in a third-party's U.S. patent by requesting that the USPTO review the patent claims in an *ex-parte* re-exam, *inter partes* review or post-grant review proceedings. These proceedings are expensive and may consume our time or other resources. We may choose to challenge a third-party's patent in patent opposition proceedings in the European Patent Office (EPO), or other foreign patent office. The costs of these opposition proceedings could be substantial, and may consume our time or other resources. If we fail to obtain a favorable result at the USPTO, EPO or other patent office then we may be exposed to litigation by a third-party alleging that the patent may be infringed by our product candidates or proprietary technologies.

If we are found to infringe a third-party's intellectual property rights, we could be forced, including by court order, to cease developing, manufacturing or commercializing the infringing product candidate or product. Alternatively, we may be required to obtain a license from such third-party in order to use the infringing technology and continue developing, manufacturing or marketing the infringing product candidate. However, we may not be able to obtain any required license on commercially reasonable terms or at all. Even if we were able to obtain a license, it could be non-exclusive, thereby giving our competitors access to the same technologies licensed to us. In addition, we could be found liable for monetary damages, including treble damages and attorneys' fees if we are found to have willfully infringed a patent. A finding of infringement could prevent us from commercializing our product candidates or force us to cease some of our business operations, and could divert the time and attention of our technical personnel and management, cause development delays, and/or require us to develop non-infringing technology, which may not be possible on a cost-effective basis, any of which could materially harm our business. In the event of a successful claim of infringement against us, we may have to pay substantial monetary damages, including treble damages and attorneys' fees for willful infringement, pay royalties and other fees, redesign our infringing drug or obtain one or more licenses from third parties, which may be impossible or require substantial time and monetary expenditure. Claims that we have misappropriated the confidential information or trade secrets of third parties could have a similar negative impact on our business.

We may become involved in lawsuits to protect or enforce our patents or other intellectual property, which could be expensive, time consuming and unsuccessful.

Competitors or other third parties may infringe our patents, trademarks or other intellectual property. To counter infringement or unauthorized use, we may be required to file infringement claims, which can be expensive and time consuming and divert the time and attention of our management and scientific personnel. Our pending patent applications cannot be enforced against third parties practicing the technology claimed in such applications unless and until a patent issues from such applications. Any claims we assert against perceived infringers could provoke these parties to assert counterclaims against us alleging that we infringe their patents, in addition to counterclaims asserting that our patents are invalid or unenforceable, or both. In patent litigation in the United States, defendant counterclaims alleging invalidity and/or unenforceability are commonplace. Grounds for a validity challenge could be an alleged failure to meet any of several statutory requirements, including lack of novelty, obviousness, non-enablement or insufficient written description. Grounds for an unenforceability assertion could be an allegation that someone connected with prosecution of the patent withheld relevant information from the USPTO or made a misleading statement during prosecution. The outcome following legal assertions of invalidity and unenforceability is unpredictable. In any patent infringement proceeding, there is a risk that a court will decide that a patent of ours is invalid or unenforceable, in whole or in part, and that we do not have the right to stop the other party from using the invention at issue. There is also a risk that, even if the validity of such patents is upheld, the court will construe the

patent's claims narrowly or decide that we do not have the right to stop the other party from using the invention at issue on the grounds that our patent claims do not cover the invention, or decide that the other party's use of our patented technology falls under the safe harbor to patent infringement under 35 U.S.C. §271(e)(1). An adverse outcome in a litigation or proceeding involving our patents could limit our ability to assert our patents against those parties or other competitors and may curtail or preclude our ability to exclude third parties from making and selling similar or competitive products. Any of these occurrences could adversely affect our competitive business position, business prospects and financial condition. Similarly, if we assert trademark infringement claims, a court may determine that the marks we have asserted are invalid or unenforceable, or that the party against whom we have asserted trademark infringement has superior rights to the marks in question. In this case, we could ultimately be forced to cease use of such trademarks.

Even if we establish infringement, the court may decide not to grant an injunction against further infringing activity and instead award only monetary damages, which may or may not be an adequate remedy. 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 litigation. There could also be public announcements of the results of hearings, motions or other interim proceedings or developments. If securities analysts or investors perceive these results to be negative, it could have a material adverse effect on the price of shares of our common stock. Moreover, we cannot assure you that we will have sufficient financial or other resources to file and pursue such infringement claims, which typically last for years before they are concluded. Even if we ultimately prevail in such claims, the monetary cost of such litigation and the diversion of the attention of our management and scientific personnel could outweigh any benefit we receive as a result of the proceedings.

Because of the expense and uncertainty of litigation, we may not be in a position to enforce our intellectual property rights against third parties.

Because of the expense and uncertainty of litigation, we may conclude that even if a third-party is infringing our patents that may be issued as a result of our pending or future patent applications or other intellectual property rights, the risk-adjusted cost of bringing and enforcing such a claim or action may be too high or not in the best interest of our company or our stockholders, or it may be otherwise impractical or undesirable to enforce our intellectual property against some third parties. Our competitors or other third parties may be able to sustain the costs of complex patent litigation or proceedings more effectively than we can because of their greater financial resources and more mature and developed intellectual property portfolios. In such cases, we may decide that the more prudent course of action is to simply monitor the situation or initiate or seek some other non-litigious action or solution. In addition, the uncertainties associated with litigation could compromise our ability to raise the funds necessary to continue our preclinical studies, initiate and continue clinical trials, continue our internal research programs, in-license needed technology or other product candidates, or enter into development partnerships that would help us bring our product candidates to market.

We may be subject to claims that we have wrongfully hired an employee from a competitor or that our employees, consultants or independent contractors have wrongfully used or disclosed confidential information of third parties.

As is common in the pharmaceutical industry, in addition to our employees, in the future we may engage the services of consultants to assist us in the development of our product candidates. Many of these potential consultants, and many of our employees, were previously employed at, or may have previously provided or may be currently providing consulting services to, other pharmaceutical companies including our competitors or potential competitors. We could in the future be subject to claims that we or our employees have inadvertently or otherwise used or disclosed alleged trade secrets or other confidential information of former employers or competitors. Although we try to ensure that our employees and consultants do not use the intellectual property, proprietary information, know-how or trade secrets of others in their work for us, we may become subject to claims that we caused an employee to breach the terms of his or her non-competition or non-solicitation agreement, or that we or these individuals have, inadvertently or otherwise, used or disclosed the alleged trade secrets or other proprietary information of a former employer or competitor.

While we may litigate to defend ourselves against these claims, even if we are successful, litigation could result in substantial costs and could be a distraction to management. If our defenses to these claims fail, in addition to

requiring us to pay monetary damages, a court could prohibit us from using technologies or features that are essential to our product candidates, if such technologies or features are found to incorporate or be derived from the trade secrets or other proprietary information of the former employers. Moreover, any such litigation or the threat thereof may adversely affect our reputation, our ability to form strategic alliances or sublicense our rights to collaborators, engage with scientific advisors or hire employees or consultants, each of which would have an adverse effect on our business, results of operations and financial condition. Even if we are successful in defending against such claims, litigation could result in substantial costs and be a distraction to management.

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

As is the case with other biopharmaceutical companies, our success is heavily dependent on intellectual property, particularly patents. Obtaining and enforcing patents in the biopharmaceutical industry involves both technological and legal complexity and is therefore costly, time consuming and inherently uncertain. Changes in either the patent laws or interpretation of the patent laws in the United States could increase the uncertainties and costs, and may diminish our ability to protect our inventions, obtain, maintain, and enforce our intellectual property rights and, more generally, could affect the value of our intellectual property or narrow the scope of our owned patents that issue in the future. Patent reform legislation in the United States and other countries, including the Leahy-Smith America Invents Act (the Leahy-Smith Act), signed into law on September 16, 2011, could increase those uncertainties and costs surrounding the prosecution of our patent applications and the enforcement or defense of our issued patents. The Leahy-Smith Act includes a number of significant changes to U.S. patent law. These include provisions that affect the way patent applications are prosecuted, redefine prior art and provide more efficient and cost-effective avenues for competitors to challenge the validity of patents. These include allowing third-party submission of prior art to the USPTO during patent prosecution and additional procedures to attack the validity of a patent by USPTO administered post-grant proceedings, including post-grant review, *inter partes* review, and derivation proceedings. Further, because of a lower evidentiary standard in these USPTO post-grant proceedings compared to the evidentiary standard in United States federal courts necessary to invalidate a patent claim, a third-party could potentially provide evidence in a USPTO proceeding sufficient for the USPTO to hold a claim invalid even though the same evidence would be insufficient to invalidate the claim if first presented in a district court action. Accordingly, a third-party may attempt to use the USPTO procedures to invalidate our patent claims that would not have been invalidated if first challenged by the third-party as a defendant in a district court action. Thus, the Leahy-Smith 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, financial condition, results of operations and prospects.

After March 2013, under the Leahy-Smith Act, the United States transitioned to a first inventor to file system in which, assuming that the other statutory requirements are met, the first inventor to file a patent application will be entitled to the patent on an invention regardless of whether a third-party was the first to invent the claimed invention. A third-party that files a patent application in the USPTO after March 2013, but before we file an application covering the same invention, could therefore be awarded a patent covering an invention of ours even if we had made the invention before it was made by such third-party. This will require us to be cognizant going forward of the time from invention to filing of a patent application. Since patent applications in the United States and most other countries are confidential for a period of time after filing or until issuance, we cannot be certain that we or our licensors were the first to either (i) file any patent application related to our product candidates and other proprietary technologies we may develop or (ii) invent any of the inventions claimed in our or our licensor's patents or patent applications. Even where we have a valid and enforceable patent, we may not be able to exclude others from practicing the claimed invention where the other party can show that they used the invention in commerce before our filing date or the other party benefits from a compulsory license. However, the Leahy-Smith 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, financial condition, results of operations and prospects.

In addition, the patent positions of companies in the development and commercialization of pharmaceuticals are particularly uncertain. The U.S. Supreme Court has ruled on several patent cases in recent years, either narrowing the scope of patent protection available in certain circumstances or weakening the rights of patent owners in certain situations. We cannot predict how decisions by the federal courts, the U.S. Congress or the USPTO may impact the

value of our patent rights. For example, the Supreme Court of the United States held in Amgen v. Sanofi (2023) that a functionally claimed genus was invalid for failing to comply with the enablement requirement of the Patent Act. In addition, the Federal circuit recently issued a decision involving the interaction of patent term adjustment (PTA), terminal disclaimers, and obvious-type double patenting. Depending on future actions by the U.S. Congress, the U.S. courts, the USPTO and the relevant law-making bodies in other countries, the laws and regulations governing patents could change in unpredictable ways that would weaken our ability to obtain new patents or to enforce our existing patents and patents that we might obtain in the future. For example, in the 2013 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, the U.S. Congress or the USPTO may impact the value of our patents.

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

Periodic maintenance fees, renewal fees, annuities fees and various other governmental fees on patents and/or patent applications are due to be paid to the USPTO and foreign patent agencies in several stages over the lifetime of the patent and/or patent application. The USPTO and various foreign governmental patent agencies also require compliance with a number of procedural, documentary, fee payment and other similar provisions during the patent application process. 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. Non-compliance 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. If we fail to maintain the patents and patent applications covering our product candidates, our competitive position would be adversely affected.

We may rely on trade secret and proprietary know-how which can be difficult to trace and enforce and, if we are unable to protect the confidentiality of our trade secrets, our business and competitive position would be harmed.

In addition to seeking patents for some of our technology and product candidates, we may also rely on trade secrets, including unpatented know-how, technology and other proprietary information, to maintain our competitive position. Elements of our product candidates, including processes for their preparation and manufacture, may involve proprietary know-how, information, or technology that is not covered by patents, and thus for these aspects we may consider trade secrets and know-how to be our primary intellectual property. Any disclosure, either intentional or unintentional, by our employees, the employees of third parties with whom we share our facilities or third-party consultants and vendors that we engage to perform research, clinical trials or manufacturing activities, or misappropriation by third parties (such as through a cybersecurity breach) of our trade secrets or proprietary information could enable competitors to duplicate or surpass our technological achievements, thus eroding our competitive position in our market. Because we expect to rely on third parties in the development and manufacture of our product candidates, we must, at times, share trade secrets with them. Our reliance on third parties requires us to share our trade secrets, which increases the possibility that a competitor will discover them or that our trade secrets will be misappropriated or disclosed.

Trade secrets and know-how can be difficult to protect. We require our employees to enter into written employment agreements containing provisions of confidentiality and obligations to assign to us any inventions generated in the course of their employment. We and any third parties with whom we share facilities enter into written agreements that include confidentiality and intellectual property obligations to protect each party's property, potential trade secrets, proprietary know-how, and information. We further seek to protect our potential trade secrets, proprietary know-how, and information in part, by entering into non-disclosure and confidentiality agreements with parties who are given access to them, such as our corporate collaborators, outside scientific collaborators, contract research organizations, contract manufacturers, consultants, advisors and other third parties. With our consultants, contractors, and outside scientific collaborators, these agreements typically include invention assignment obligations. We cannot guarantee that we have entered into such agreements with each party that may have or has had access to our trade secrets or proprietary technology and processes. 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. Despite these efforts, any of these parties may breach the agreements and disclose our proprietary information, including our trade secrets, and we may not be able to obtain adequate remedies for such breaches. Enforcing a claim that a party illegally disclosed or misappropriated a trade secret is difficult, expensive and time-consuming, and the outcome is unpredictable. In addition, some courts inside and outside the United States are less willing or unwilling to protect trade secrets. We may need to share our proprietary information, including trade secrets, with future business partners, collaborators, contractors and others located in countries at heightened risk of theft of trade secrets, including through direct intrusion by private parties or foreign actors, and those affiliated with or controlled by state actors. Further, if any of our trade secrets were to be lawfully obtained or independently developed by a competitor or other third-party, we would have no right to prevent them from using that technology or information to compete with us. If any of our trade secrets were to be disclosed to or independently developed by a competitor or other third-party, our competitive position would be harmed.

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

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

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

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

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

Patent rights are of limited duration. In the United States, if all maintenance fees are paid timely, the natural expiration of a patent is generally 20 years after its first effective filing date excluding U.S. provisional patent applications. 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 product candidates are commercialized. Even if patents covering our product candidates are obtained, once the patent life has expired for a product, we may be open to competition from biosimilar or generic products. As a result, our patent portfolio may

not provide us with sufficient rights to exclude others from commercializing product candidates similar or identical to ours. Upon issuance in the United States, the term of a patent can be increased by patent term adjustment, which is based on certain delays caused by the USPTO, but this increase can be reduced or eliminated based on certain delays caused by the patent applicant during patent prosecution. The term of a United States patent may also be shortened if the patent is terminally disclaimed over an earlier-filed patent. A patent term extension (PTE) based on regulatory delay may be available in the United States. However, only a single patent can be extended for each marketing approval, and any patent can be extended only once, for a single product. Moreover, the scope of protection during the period of the PTE does not extend to the full scope of the claim, but instead only to the scope of the product as approved. Laws governing analogous PTEs in foreign jurisdictions vary widely, as do laws governing the ability to obtain multiple patents from a single patent family. Additionally, we may not receive an extension if we fail to exercise due diligence during the testing phase or regulatory review process, apply within applicable deadlines, fail to apply prior to expiration of relevant patents or otherwise fail to satisfy applicable requirements. If we are unable to obtain PTE or restoration, or the term of any such extension is less than we request, the period during which we will have the right to exclusively market our product will be shortened and our competitors may obtain approval of competing products following our patent expiration and may take advantage of our investment in development and clinical trials by referencing our clinical and preclinical data to launch their product earlier than might otherwise be the case, and our revenue could be reduced, possibly materially.

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

Our current or future trademarks or trade names may be challenged, infringed, circumvented or declared generic or descriptive or determined to be infringing on other marks. We may not be able to protect our rights to these trademarks and trade names or may be forced to stop using these names, which we need for name recognition by potential partners or customers in our markets of interest. During trademark registration proceedings, we may receive rejections of our applications by the USPTO or in other foreign jurisdictions. Although we would be given an opportunity to respond to those rejections, 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 to seek to cancel 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. We may license our trademarks and trade names to third parties, such as distributors. Although these license agreements may provide guidelines for how our trademarks and trade names may be used, a breach of these agreements or misuse of our trademarks and tradenames by our licensees may jeopardize our rights in or diminish the goodwill associated with our trademarks and trade names.

Moreover, any name we have proposed to use with our product candidate in the United States must be approved by the FDA, regardless of whether we have registered it, or applied to register it, as a trademark. Similar requirements exist in Europe. The FDA typically conducts a review of proposed product names, including an evaluation of potential for confusion with other product names. If the FDA (or an equivalent administrative body in a foreign jurisdiction) objects to any of our proposed proprietary product names, it may be required to expend significant additional resources in an effort to identify a suitable substitute name that would qualify under applicable trademark laws, not infringe the existing rights of third parties and be acceptable to the FDA. Furthermore, in many countries, owning and maintaining a trademark registration may not provide an adequate defense against a subsequent infringement claim asserted by the owner of a senior trademark. At times, competitors or other third parties may adopt trade names or trademarks similar to ours, thereby impeding our ability to build brand identity and possibly leading to market confusion. In addition, there could be potential trade name or trademark infringement claims brought by owners of other registered trademarks or trademarks that incorporate variations of our registered or unregistered trademarks or trade names. If we assert trademark infringement claims, a court may determine that the marks we have asserted are invalid or unenforceable, or that the party against whom we have asserted trademark infringement has superior rights to the marks in question. In this case, we could ultimately be forced to cease use of such trademarks.

Risks Related to the Securities Market and Ownership of Our Common Stock

An active trading market for our common stock may not continue to be developed or be sustained, which may make it more difficult for you to sell your shares.

Prior to our IPO in June 2021, there had been no public market for our common stock. The trading market for our common stock on the Nasdaq Global Market has been limited and an active trading market for our shares may not be sustained. If an active market for our common stock is not sustained, it may be difficult for you to sell your shares at a price that is attractive to you, or at all.

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

Our stock price may be volatile. 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, you may not be able to sell your shares at a price that is attractive to you, or at all. The market price for our common stock may be influenced by numerous factors, many of which are beyond our control, including:

- adverse results or delays in preclinical studies or clinical trials;
- results from our future clinical trials with our future product candidates or of our competitors;
- failure to commercialize our product candidates;
- unanticipated serious safety concerns related to immuno-oncology or related to the use of our product candidates;
- changes in our projected operating results that we provide to the public, our failure to meet these projections or changes in recommendations by securities analysts that elect to follow our common stock;
- 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;
- regulatory or legal developments in the United States and other countries;
- the level of expenses related to future product candidates or clinical development programs;
- our failure to achieve product development goals in the timeframe we announce;
- announcements of acquisitions, strategic alliances or significant agreements by us or by our competitors;
- recruitment or departure of key personnel;
- developments with respect to our intellectual property rights;
- overall performance of the equity markets;
- the economy as a whole and market conditions in our industry;
- trading activity by a limited number of stockholders who together beneficially own a majority of our outstanding common stock;
- the published opinions and third-party valuations by banking and market analysts;
- political uncertainty and/or instability in the United States;
- the future impact of a resurgence of COVID-19 or other health epidemic or pandemic; and
- any other factors discussed in this Annual Report.

In addition, the stock markets have experienced extreme price and volume fluctuations that have affected and continue to affect the market prices of equity securities of many immuno-oncology companies. Stock prices of many immuno-oncology companies have fluctuated in a manner unrelated or disproportionate to the operating performance of those companies.

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

Certain of our executive officers, directors and large stockholders own a significant percentage of our outstanding capital stock. As a result of their share ownership, these stockholders will have the ability to influence us through their ownership positions. These stockholders may be able to determine all matters requiring stockholder approval. For example, these stockholders, acting together, may be able to control elections of directors, amendments of our organizational documents, or approval of any merger, sale of assets, or other major corporate transaction. This may prevent or discourage unsolicited acquisition proposals or offers for our common stock that you may believe are in your best interest as one of our stockholders.

If there are substantial sales of shares of our common stock, the market price of our common stock could decline.

The price of our common stock could decline if there are substantial sales of our common stock, particularly sales by our directors, executive officers and significant stockholders, or if there is a large number of shares of our common stock available for sale and the market perceives that sales will occur. As of December 31, 2023, we had 46,262,759 outstanding shares of common stock.

Future sales and issuances of our common stock or rights to purchase common stock, including pursuant to our equity incentive plans, could result in additional dilution of the percentage ownership of our stockholders and could cause our stock price to fall.

Additional capital will be needed in the future to continue our planned operations. To the extent we raise additional capital by issuing equity securities, our stockholders may experience substantial dilution. We may sell common stock, convertible securities or other equity securities in one or more transactions at prices and in a manner, we determine from time to time. If we sell common stock, convertible securities or other equity securities, investors may be materially diluted. These sales may also result in material dilution to our existing stockholders, and new investors could gain rights superior to our existing stockholders.

Pursuant to our 2021 Equity Incentive Plan (2021 Plan), we are authorized to grant stock options and other equity-based awards to our employees, directors and consultants. The number of shares of our common stock reserved for issuance under our 2021 Plan automatically increases on January 1 of each calendar year, through January 1, 2031, in an amount equal to the lesser of (i) 5% of the total number of shares of our common stock outstanding on the last day of the calendar month before the date of each automatic increase; or (ii) a lesser number of shares determined by our board of directors prior to the applicable January 1st. In addition, pursuant to our 2021 Employee Stock Purchase Plan, the number of shares of our common stock reserved for issuance automatically increases on January 1 of each calendar year, through January 1, 2031, by the lesser of (i) 1% of the total number of shares of our common stock outstanding on the last day of the calendar month before the date of each automatic increase, and (ii) 932,000 shares; provided that before the date of any such increase, our board of directors may determine that such increase will be less than the amount set forth in clauses (i) and (ii). Unless our board of directors elects not to increase the number of shares available for future grant each year, our stockholders may experience additional dilution, which could cause our stock price to fall.

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. Any return to stockholders will therefore be limited to the appreciation of their stock.

Delaware law and provisions in our amended and restated certificate of incorporation and amended and restated bylaws could make a merger, tender offer or proxy contest difficult, thereby depressing the trading price of our common stock.

Our status as a Delaware corporation and the anti-takeover provisions of the Delaware General Corporation Law may discourage, delay or prevent a change in control by prohibiting us from engaging in a business

combination with an interested stockholder for a period of three years after the person becomes an interested stockholder, even if a change of control would be beneficial to our existing stockholders. Our amended and restated certificate of incorporation and amended and restated bylaws contain provisions that may make the acquisition of our company more difficult, including the following:

- a classified board of directors with three-year staggered terms, which could delay the ability of stockholders to change the membership of a majority of our board of directors;
- the ability of our board of directors to issue shares of preferred stock and to determine the price and other terms of those shares, including preferences and voting rights, without stockholder approval, which could be used to significantly dilute the ownership of a hostile acquirer;
- the exclusive right of our board of directors to elect a director to fill a vacancy created by the expansion of our board of directors or the resignation, death or removal of a director, which prevents stockholders from being able to fill vacancies on our board of directors;
- a prohibition on stockholder action by written consent, which forces stockholder action to be taken at an annual or special meeting of our stockholders;
- the requirement that a special meeting of stockholders may be called only by a majority vote of our entire board of directors, the chairman of our board of directors or our chief executive officer, which could delay the ability of our stockholders to force consideration of a proposal or to take action, including the removal of directors;
- the requirement for the affirmative vote of holders of at least 66-2/3% of the voting power of all of the then-outstanding shares of the voting stock, voting together as a single class, to amend the provisions of our amended and restated certificate of incorporation relating to the management of our business or our amended and restated bylaws, which may inhibit the ability of an acquirer to affect such amendments to facilitate an unsolicited takeover attempt; and
- advance notice procedures with which stockholders must comply to nominate candidates to our board of directors or to propose matters to be acted upon at a stockholders' meeting, which may discourage or deter a potential acquirer from conducting a solicitation of proxies to elect the acquirer's own slate of directors or otherwise attempting to obtain control of us.

In addition, as a Delaware corporation, we are subject to Section 203 of the Delaware General Corporation Law. These provisions may prohibit large stockholders, in particular those owning 15% or more of our outstanding voting stock, from merging or combining with us for a certain period of time. A Delaware corporation may opt out of this provision by express provision in its original certificate of incorporation or by amendment to its certificate of incorporation or bylaws approved by its stockholders. However, we have not opted out of this provision.

These and other provisions in our amended and restated certificate of incorporation, amended and restated bylaws and Delaware law could make it more difficult for stockholders or potential acquirors to obtain control of our board of directors or initiate actions that are opposed by our then-current board of directors, including delay or impede a merger, tender offer or proxy contest involving our company. The existence of these provisions could negatively affect the price of our common stock and limit opportunities for you to realize value in a corporate transaction.

Our amended and restated certificate of incorporation and our amended and restated bylaws provide that the Court of Chancery of the State of Delaware will be the exclusive forum for substantially all disputes between us and our stockholders and that the federal district courts shall be the exclusive forum for the resolution of any complaint asserting a cause of action arising under the Securities Act, which could limit our stockholders' ability to obtain a favorable judicial forum for disputes with us or our directors, officers or employees or the underwriters or any offering giving rise to such claim.

Our amended and restated certificate of incorporation and amended and restated bylaws provide that the Court of Chancery of the State of Delaware will be the sole and exclusive forum for the following types of actions or proceedings under Delaware statutory or common law: (i) any derivative action or proceeding brought on our behalf; (ii) any action or proceeding asserting a claim of breach of a fiduciary duty owed by any of our current or

former directors, officers, or other employees to us or our stockholders; (iii) any action or proceeding asserting a claim against us or any of our current or former directors, officers, or other employees, arising out of or pursuant to any provision of the Delaware General Corporation Law, our amended and restated certificate of incorporation or our amended and restated bylaws; (iv) any action or proceeding to interpret, apply, enforce, or determine the validity of our amended and restated certificate of incorporation or our amended and restated bylaws; (v) any action or proceeding as to which the Delaware General Corporation Law confers jurisdiction to the Court of Chancery of the State of Delaware; and (vi) any action asserting a claim against us or any of our directors, officers, or other employees governed by the internal affairs doctrine, in all cases to the fullest extent permitted by law and subject to the court's having personal jurisdiction over the indispensable parties named as defendants. These provisions would 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. 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 amended and restated certificate of incorporation and our amended and restated bylaws provide that the federal district courts of the United States of America will be the exclusive forum for resolving any complaint asserting a cause of action arising under the Securities Act, including any complaint against the underwriters of any offering giving rise to such claim. 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 amended and restated certificate of incorporation and our amended and restated bylaws. This may require significant additional costs associated with resolving such action in other jurisdictions and the provisions may not be enforced by a court in those other jurisdictions.

These exclusive forum provisions may limit a stockholder's ability to bring a claim in a judicial forum that it finds favorable for disputes with us or our directors, officers, or other employees and may discourage these types of lawsuits and result in increased costs for investors to bring a claim. Furthermore, the enforceability of similar choice of forum provisions in other companies' certificates of incorporation or bylaws has been challenged in legal proceedings, and it is possible that a court could find these types of provisions to be inapplicable or unenforceable. If a court were to find the exclusive forum provision contained in our amended and restated certificate of incorporation or amended and restated bylaws 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 seriously harm our business.

General Risk Factors

We incur significantly increased costs as a result of operating as a public company, and our management is required to devote substantial time to public company reporting and compliance initiatives.

As a public company listed on the Nasdaq Global Market, we incur significant legal, accounting, and other expenses that we did not incur as a private company. We are subject to the reporting requirements of the Exchange Act, which require, among other things, that we file with the SEC annual, quarterly, and current reports with respect to our business and financial condition. In addition, the Sarbanes-Oxley Act, as well as rules subsequently adopted by the SEC and Nasdaq to implement provisions of the Sarbanes-Oxley Act, impose significant requirements on public companies, including requiring establishment and maintenance of effective disclosure and financial controls and changes in corporate governance practices. Further, in July 2010, the Dodd-Frank Wall Street Reform and Consumer Protection Act (Dodd-Frank Act) was enacted. There are significant corporate governance and executive compensation related provisions in the Dodd-Frank Act that require the SEC to adopt additional rules and regulations in these areas such as "say on pay" and proxy access. Emerging growth companies and smaller reporting companies are exempted from certain of these requirements, but we may be required to implement these requirements sooner than budgeted or planned and thereby incur unexpected expenses. Stockholder activism, the current political environment and the current high level of government intervention and regulatory reform may lead to substantial new regulations and disclosure obligations, which may lead to additional compliance costs and impact the manner in which we operate our business in ways we cannot currently anticipate.

The rules and regulations applicable to public companies substantially increase our legal and financial compliance costs and make some activities more time-consuming and costly. If these requirements divert the

attention of our management and personnel from other business concerns, they could have a material adverse effect on our business, financial condition, results of operations and prospects. The increased costs decrease our net income or increase our net loss, and may require us to reduce costs in other areas of our business or increase the prices of our products or services. For example, these rules and regulations make it more difficult and more expensive for us to obtain director and officer liability insurance and we may be required to incur substantial costs to maintain the same or similar coverage. We cannot predict or estimate the amount or timing of additional costs we may incur to respond to these requirements. The impact of these requirements could also make it more difficult for us to attract and retain qualified persons to serve on our board of directors, our board committees or as executive officers.

If we fail to maintain an effective system of disclosure controls and internal control over financial reporting, our ability to produce timely and accurate financial statements or comply with applicable regulations could be impaired.

As a public company, we are subject to requirements of the Sarbanes-Oxley Act, the regulations of the Nasdaq Global Market, the rules and regulations of the SEC, expanded disclosure requirements, accelerated reporting requirements and more complex accounting rules. We expect that the requirements of these rules and regulations will continue to increase our legal, accounting and financial compliance costs, make some activities more difficult, time-consuming and costly and place significant strain on our personnel, systems and resources. Company responsibilities required by the Sarbanes-Oxley Act include, among other things, that we maintain corporate oversight and adequate internal control over financial reporting and disclosure controls and procedures. We are continuing to develop and refine our disclosure controls and other procedures that are designed to ensure that information required to be disclosed by us in the reports that we file with the SEC is recorded, processed, summarized and reported within the time periods specified in SEC rules and forms and that information required to be disclosed in reports under the Exchange Act is accumulated and communicated to our principal executive and financial officers. We are also continuing to improve our internal control over financial reporting. In order to develop, maintain, and improve the effectiveness of our internal controls and procedures, and internal control over financial reporting, we have expended, and anticipate that we will continue to expend, significant resources, including accounting-related costs and significant management oversight.

Our current controls and any new controls that we develop may become inadequate because of changes in conditions in our business. Further, weaknesses in our disclosure controls and internal control over financial reporting may be discovered in the future. Any failure to develop or maintain effective controls or any difficulties encountered in their implementation or improvement could harm our results of operations or cause us to fail to meet our reporting obligations and may result in a restatement of our financial statements for prior periods. Any failure to implement and maintain effective internal control over financial reporting could also adversely affect the results of periodic management evaluations and annual independent registered public accounting firm attestation reports regarding the effectiveness of our internal control over financial reporting that we will eventually be required to include in our periodic reports that will be filed with the SEC. Ineffective disclosure controls and procedures and internal control over financial reporting could also cause investors to lose confidence in our reported financial and other information, which would likely have a negative effect on the trading price of our common stock. In addition, if we are unable to continue to meet these requirements, we may not be able to remain listed on the Nasdaq Global Market. We are not currently required to make a formal assessment of the effectiveness of our internal control over financial reporting under the SEC rules that implement Section 404 of the Sarbanes-Oxley Act. We are also required to provide an annual management report on the effectiveness of our disclosure controls and procedures over financial reporting.

If we cannot provide reliable financial reports or prevent fraud, our business and results of operations could be harmed, investors could lose confidence in our reported financial information and we could be subject to sanctions or investigations by Nasdaq, the SEC or other regulatory authorities. Any failure to maintain effective disclosure controls and internal control over financial reporting could have a material and adverse effect on our business, results of operations and financial condition and could cause a decline in the trading price of our common stock.

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

We are subject to the periodic reporting requirements of the Exchange Act. We designed our disclosure controls and procedures to reasonably assure that information we must disclose in reports we file or submit under the Exchange Act is accumulated and communicated to management, and 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 controls and procedures, 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. For example, our directors or executive officers could inadvertently fail to disclose a new relationship or arrangement causing us to fail to make any related party transaction disclosures. 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 due to error or fraud may occur and not be detected.

Future changes in financial accounting standards or practices may cause adverse and unexpected revenue fluctuations and adversely affect our reported results of operations.

Future changes in financial accounting standards may cause adverse, unexpected revenue fluctuations and affect our reported financial position or results of operations. Financial accounting standards in the United States are constantly under review and new pronouncements and varying interpretations of pronouncements have occurred with frequency in the past and are expected to occur again in the future. As a result, we may be required to make changes in our accounting policies. Those changes could affect our financial condition and results of operations or the way in which such financial condition and results of operations are reported. We intend to invest resources to comply with evolving standards, and this investment may result in increased general and administrative expenses and a diversion of management time and attention from business activities to compliance activities. See the section titled “Management’s Discussion and Analysis of Financial Condition and Results of Operations—Recent Accounting Pronouncements.”

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

New income, sales, use, or other tax laws, statutes, rules, regulations or ordinances could be enacted at any time, which could adversely affect our business operations and financial performance. Further, existing tax laws, statutes, rules, regulations, or ordinances could be interpreted, changed, modified, or applied adversely to us. For example, the Tax Act, the Coronavirus Aid, Relief, and Economic Security Act and the IRA enacted many significant changes to the U.S. tax laws. Effective January 1, 2022, the Tax Act eliminated the option to deduct research and development expenses for tax purposes in the year incurred and requires taxpayers to capitalize and subsequently amortize such expenses over five years for research activities conducted in the United States and over 15 years for research activities conducted outside the United States. Although there have been legislative proposals to repeal or defer the capitalization requirement to later years, there can be no assurance that the provision will be repealed or otherwise modified. Future guidance from the Internal Revenue Service and other tax authorities with respect to such legislation may affect us, and certain aspects of such legislation could be repealed or modified in future legislation. In addition, it is uncertain if and to what extent various states will conform to federal tax laws. Future tax reform legislation could have a material impact on the value of our deferred tax assets, could result in significant one-time charges, and could increase our future U.S. tax expense.

Unstable market and economic conditions may have serious adverse consequences on our business, financial condition and stock price.

As a result of disruptions and changes in the macro environment, including those resulting from COVID-19 and actions taken to slow its spread, bank failures, and geopolitical actions such as the United States and foreign government actions related to the military conflict in Ukraine and Russia and the war in the Middle East, the global credit and financial markets have experienced extreme volatility and disruptions, including severely diminished liquidity and credit availability, declines in consumer confidence, declines in economic growth, increases in unemployment rates and uncertainty about economic stability. There can be no assurance that further deterioration in credit and financial markets and confidence in economic conditions will not occur. Our general business strategy

may be adversely affected by any such economic downturn, volatile business environment or continued unpredictable and unstable market conditions. If the current equity and credit markets deteriorate, it may make any necessary debt or equity financing more difficult, more costly and more dilutive. Failure to secure any necessary financing in a timely manner and on favorable terms or failure to access to our liquidity within the U.S. banking system could have a material adverse effect on our growth strategy, financial performance and stock price and could require us to delay or abandon clinical development plans. In addition, there is a risk that one or more of our current service providers, manufacturers and other partners may not survive an economic downturn, which could directly affect our ability to attain our operating goals on schedule and on budget.

Inflation may adversely affect us by increasing our costs.

Recently, inflation has increased throughout the U.S. economy. Inflation can adversely affect us by increasing the costs of clinical trials and research, the development of our product candidates, administration and other costs of doing business. We may experience increases in the prices of labor and other costs of doing business. In an inflationary environment, cost increases may outpace our expectations, causing us to use our cash and other liquid assets faster than forecasted. If this happens, we may need to raise additional capital to fund our operations, which may not be available in sufficient amounts or on reasonable terms, if at all, sooner than expected.

If our internal information technology systems or sensitive information, or those of our third-party CROs or other contractors or consultants, are or were compromised, we could experience adverse consequences from such compromise, including but not limited to, a material disruption of our product candidates' development programs, regulatory investigations or actions, litigation, fines and penalties, reputational harm, loss of revenue or profits, and other adverse consequences.

We are increasingly dependent upon information technology systems, infrastructure and data to operate our business. In the ordinary course of business, we and the third parties upon which we rely on process proprietary, confidential, and sensitive information, including personal information (such as health-related data), intellectual property, and trade secrets (collectively, sensitive information).

Cyber-attacks, malicious internet-based activity, online and offline fraud, and other similar activities threaten the confidentiality, integrity, and availability of our sensitive information and information technology systems, and those of the third parties upon which we rely. Such threats are prevalent and continue to rise, are increasingly difficult to detect, and come from a variety of sources, including traditional computer "hackers," threat actors, "hacktivists," organized criminal threat actors, personnel (such as through theft or misuse), sophisticated nation states, and nation-state-supported actors. Some actors now engage and are expected to continue to engage in cyber-attacks, including, without limitation, nation-state actors for geopolitical reasons and in conjunction with military conflicts and defense activities. During times of war and other major conflicts, we and the third parties upon which we rely may be vulnerable to a heightened risk of these attacks, including cyber-attacks that could materially disrupt our systems and operations, supply chain, and ability to produce, sell and distribute our goods and services.

We and the third parties upon which we rely are subject to a variety of evolving threats, including, but not limited to social-engineering attacks (including through deep fakes, which may be increasingly more difficult to identify as fake, and phishing attacks), malicious code (such as viruses and worms), malware (including as a result of advanced persistent threat intrusions), denial-of-service attacks (such as credential stuffing), credential harvesting, personnel misconduct or error, ransomware attacks, supply-chain attacks, software bugs, server malfunctions, software or hardware failures, loss of data or other information technology assets, adware, telecommunications failures, attacks enhanced or facilitated by artificial intelligence, earthquakes, fires, floods, and other similar threats. Severe ransomware attacks are becoming increasingly prevalent and can lead to significant interruptions in our operations, loss of data and income, reputational harm, and diversion of funds. Extortion payments may alleviate the negative impact of a ransomware attack, but we may be unwilling or unable to make such payments due to, for example, applicable laws or regulations prohibiting such payments. Future or past business transactions (such as acquisitions or integrations) could also expose us to additional cybersecurity risks and vulnerabilities, as our systems could be negatively affected by vulnerabilities present in acquired or integrated entities' systems and technologies. Furthermore, we may discover security issues that were not found during due diligence of such acquired or integrated entities, and it may be difficult to integrate companies into our information technology environment and security program.

We rely on third-parties and technologies to operate critical business systems in a variety of contexts, including, without limitation, cloud-based infrastructure, encryption and authentication technology, employee email, and other functions. Our ability to monitor these third parties' information security practices is limited, and these third parties may not have adequate information security measures in place. If the third-parties upon which we rely experience a security incident or other interruption, we could experience adverse consequences. While we may be entitled to damages if the third-parties upon which we rely fail to satisfy their privacy or security-related obligations to us, any award may be insufficient to cover our damages, or we may be unable to recover such award. In addition, supply-chain attacks have increased in frequency and severity, and we cannot guarantee that third parties' infrastructure in our supply chain or our third-party partners' supply chains have not been compromised.

While we have implemented security measures designed to protect against security incidents, there can be no assurance that these measures will be effective. We take steps designed to detect, mitigate and remediate vulnerabilities in our information security systems (such as our hardware and/or software, including that of third parties upon which we rely), but we may not be able to detect, mitigate, and remediate all such vulnerabilities including on a timely basis, Further, we may experience delays in developing and deploying remedial measures designed to address any such identified vulnerabilities.

Any of the previously identified or similar threats could cause a security incident or other interruption that could result in unauthorized, unlawful, or accidental acquisition, modification, destruction, loss, alteration, encryption, disclosure of, or access to our sensitive information or our information technology systems, or those of the third parties upon whom we rely. A security incident or other interruption could disrupt our ability (and that of third parties upon whom we rely) to conduct our business operations. For example, a security incident could result in a material disruption of our programs and the development of our product candidates could be delayed. In addition, the loss of preclinical study data or clinical trial data for our product candidates could result in delays in our marketing approval efforts and significantly increase our costs to recover or reproduce the data. We may expend significant resources or modify our business activities (including our clinical trial activities) to try to protect against security incidents. Certain data privacy and security obligations may require us to implement and maintain specific security measures, industry-standard or reasonable security measures to protect our information technology systems and sensitive information.

Applicable data privacy and security obligations may require us to notify relevant stakeholders of security incidents, including individuals and data protection authorities. Such disclosures are costly, and the disclosures or the failure to comply with such requirements could lead to adverse consequences. If we (or a third-party upon whom we rely) experience a security incident or are perceived to have experienced a security incident, we may experience adverse consequences, such as government enforcement actions (for example, investigations, fines, penalties, audits, and inspections); additional reporting requirements and/or oversight; restrictions on processing sensitive information (including personal information); litigation (including class claims); indemnification obligations; negative publicity; reputational harm; monetary fund diversions; diversion of management attention; interruptions in our operations (including availability of data); financial loss; and other similar harms. Security incidents and attendant consequences may cause interruptions in our operations and could result in a material disruption of our programs. For example, the loss of clinical trial data for our product candidates could result in delays in our regulatory approval efforts and significantly increase our costs to recover or reproduce the data.

Our contracts may not contain limitations of liability, and even where they do, there can be no assurance that limitations of liability in our contracts are sufficient to protect us from liabilities, damages, or claims related to our data privacy and security obligations. We cannot be sure that our insurance coverage will be adequate or sufficient to protect us from or to mitigate liabilities arising out of our privacy and security practices, that such coverage will continue to be available on commercially reasonable terms or at all, or that such coverage will pay future claims. In addition, third parties may gather, collect, or infer sensitive information about us from public sources, data brokers, or other means that reveals competitively sensitive details about our organization and could be used to undermine our competitive advantage or market position. Sensitive information of the company could also be leaked, disclosed, or revealed as a result of or in connection with our employees', personnel's, or vendors' use of generative AI technologies.

We or the third parties upon whom we depend on may be adversely affected by earthquakes, fires or other natural disasters and our business continuity and disaster recovery plans may not adequately protect us from a serious disaster.

Our corporate headquarters and main research facility are located in the county of San Diego, California, which in the past has experienced severe earthquakes and fires. If these earthquakes, fires, other natural disasters, terrorism and similar unforeseen events beyond our control prevented us from using all or a significant portion of our headquarters or research facility, it may be difficult or, in certain cases, impossible for us to continue our business for a substantial period of time. We do not have a disaster recovery or business continuity plan in place and may incur substantial expenses as a result of the absence or limited nature of our internal or third-party service provider disaster recovery and business continuity plans, which, particularly when taken together with our lack of earthquake insurance, could have a material adverse effect on our business. Furthermore, integral parties in our supply chain are operating from single sites, increasing their vulnerability to natural disasters or other sudden, unforeseen and severe adverse events. If such an event were to affect our supply chain, it could have a material adverse effect on our ability to conduct our clinical trials, our development plans and business.

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

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

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 have a material adverse effect on the success of our business.

We, and the third parties with whom we share our facilities, 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. Each of our operations involve the use of hazardous and flammable materials, including chemicals and biological materials. Each of our operations also produce hazardous waste products. We generally contract with third parties for the disposal of these materials and wastes. We cannot eliminate the risk of contamination or injury from these materials. We could be held liable for any resulting damages in the event of contamination or injury resulting from the use of hazardous materials by us or the third parties with whom we share our facilities, and any liability could exceed our resources. We also could incur significant costs associated with civil or criminal fines and penalties.

Although we maintain workers' compensation insurance to cover us for costs and expenses we may incur due to injuries to our employees resulting from the use of hazardous materials, 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 connection with our storage or disposal of biological or hazardous materials.

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

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

Patent protection is available on a national or regional level. Filing, prosecuting and defending patents throughout the world and on all of our product candidates would be prohibitively expensive. As such, our intellectual property rights outside the United States may not extend to all other possible countries outside the United States and we may not be able to prevent third parties from practicing our inventions in countries outside the United States where we do not have patent protection, or from selling in and importing products into other jurisdictions made using our inventions in such countries outside the United States. Competitors may use our technologies in jurisdictions where we have not obtained patent protection to develop their own products or technology and may export otherwise infringing products or technology to territories where we have patent protection, but enforcement rights are not as strong as those 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. Further, the legal systems of certain countries particularly certain developing countries, do not favor the enforcement of patents and other intellectual property protection, particularly those relating to pharmaceuticals or biologics, 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 such lawsuits that we initiate and the damages and other remedies awarded, if any, may not be commercially meaningful.

Similarly, if our trade secrets are disclosed in a foreign jurisdiction, competitors worldwide could have access to our proprietary information and we may be without satisfactory recourse. Such disclosure could have a material adverse effect on our business. Moreover, our ability to protect and enforce our intellectual property rights may be adversely affected by unforeseen changes in foreign intellectual property laws. We plan to enter into contract research and manufacturing relationships with organizations that operate in certain countries that are at heightened risk of theft of technology, data and intellectual property, including through direct intrusion by private parties or foreign actors, and those affiliated with or controlled by state actors. In addition, certain developing countries, including China and India, have compulsory licensing laws under which a patent owner may be compelled under certain circumstances to grant licenses to third parties at nominal or no consideration. In those countries, we and our licensors may have limited remedies if patents are infringed or if we or our licensors are compelled to grant a license to a third-party, which could materially diminish the value of those patents. In addition, many countries limit the enforceability of patents against government agencies or government contractors. This could limit our potential revenue opportunities. 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.

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

The trading market for our common stock will depend in part on the research and reports that securities or industry analysts publish about us or our business. Securities and industry analysts do not currently, and may never, publish research on our company. If no or only very few securities analysts commence coverage of us, or if industry analysts cease coverage of us, the trading price for our common stock would be negatively affected. If one or more of the analysts who cover us downgrade our common stock or publish inaccurate or unfavorable research about our business, our common stock price would likely decline. If one or more of these analysts cease coverage of us or fail to publish reports on us regularly, demand for our common stock could decrease, which might cause our common stock price and trading volume to decline.

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

We may seek additional capital through a combination of public and private equity offerings, debt financings, strategic partnerships and alliances and licensing arrangements. To the extent that we raise additional capital through the sale of equity or convertible debt securities, your ownership interest will be diluted, and the terms may include liquidation or other preferences that adversely affect your rights as a stockholder. The incurrence of indebtedness would result in increased fixed payment obligations and could involve certain restrictive covenants, such as

limitations on our ability to incur additional debt, 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. If we raise additional funds through strategic partnerships and alliances and licensing arrangements with third parties, we may have to relinquish valuable rights to our technologies or product candidates, or grant licenses on terms unfavorable to us.

We could be subject to securities class action litigation.

In the past, securities class action litigation has often been brought against a company following a decline in the market price of its securities. This risk is especially relevant for us because pharmaceutical companies have experienced significant stock price volatility in recent years. If we face such litigation, it could result in substantial costs and a diversion of management's attention and resources, which could harm our business.

We are an "emerging growth company" and a "smaller reporting company" and we cannot be certain if the reduced reporting requirements applicable to emerging growth companies and smaller reporting companies will make our common stock less attractive to investors.

We are an "emerging growth company" as defined in the JOBS Act, and we intend to take advantage of some of the exemptions from reporting requirements that are applicable to other public companies that are not emerging growth companies, including:

- being permitted to provide only two years of audited financial statements, in addition to any required unaudited interim financial statements, with correspondingly reduced "Management's Discussion and Analysis of Financial Condition and Results of Operations" disclosure;
- not being required to comply with the auditor attestation requirements in the assessment of our internal control over financial reporting;
- not being required to comply with any requirement that may be adopted by the Public Company Accounting Oversight Board regarding mandatory audit firm rotation or a supplement to the auditor's report providing additional information about the audit and the financial statements;
- reduced disclosure obligations regarding executive compensation; and
- not being required to hold a non-binding advisory vote on executive compensation or obtain stockholder approval of any golden parachute payments not previously approved.

In addition, as an "emerging growth company" the JOBS Act allows us to delay adoption of new or revised accounting pronouncements applicable to public companies until such pronouncements are made applicable to private companies, unless we later irrevocably elect not to avail ourselves of this exemption. We have irrevocably elected not to avail ourselves of this exemption from new or revised accounting standards and, therefore, will be subject to the same new or revised accounting standards as other public companies that are not emerging growth companies.

We cannot predict if investors will find our common stock less attractive because we will rely on these exemptions. If some investors find our common stock less attractive as a result, there may be a less active trading market for our common stock and our stock price may be more volatile. We may take advantage of these reporting exemptions until we are no longer an emerging growth company. We will remain an emerging growth company until the earlier of (i) December 31, 2026 (the last day of the fiscal year following the fifth anniversary of the closing of our IPO), (ii) the last day of the fiscal year in which we have total annual gross revenue of at least $1.235 billion, (iii) the date upon which we are deemed to be a "large accelerated filer", which means the market value of our common stock that is held by non-affiliates exceeds $700 million as of the prior June 30th and (iv) the date on which we have issued more than $1.0 billion in non-convertible debt during the prior three-year period.

We are also a smaller reporting company as defined in the Exchange Act. We may continue to be a smaller reporting company even after we are no longer an emerging growth company, which would allow us to take advantage of many of the same exemptions available to emerging growth companies, including not being required to comply with the auditor attestation requirements of Section 404 of the Sarbanes-Oxley Act and reduced disclosure

obligations regarding executive compensation. We will be able to take advantage of these scaled disclosures for so long as our voting and non-voting common stock held by non-affiliates is less than $250.0 million measured on the last business day of our second fiscal quarter, or our annual revenue is less than $100.0 million during the most recently completed fiscal year and our voting and non-voting common stock held by non-affiliates is less than $700.0 million measured on the last business day of our second fiscal quarter. If some investors find our common stock less attractive as a result, there may be a less active trading market for our common stock and our stock price may be more volatile.

Item 1B. Unresolved Staff Comments.

Not applicable.

Item 1C. Cybersecurity.

Risk management and strategy

We have implemented and maintain various information security processes designed to identify, assess and manage material risks from cybersecurity threats to our critical computer networks, third party hosted services, communications systems, hardware and software, and our critical data, including intellectual property, confidential information that is proprietary, strategic or competitive in nature, and data related to our development programs and clinical trials (Information Systems and Data).

Our Information Technology (IT) department and IT Director, with the assistance of our legal department and CFO, help identify, assess and manage our cybersecurity threats and risks. This group identifies and assesses risks from cybersecurity threats by monitoring and evaluating our threat environment and our risk profile using various methods including, for example manual and automated tools, subscribing to reports and services that identify cybersecurity threats, evaluating our and our industry's risk profile, evaluating threats reported to us and coordinating with law enforcement about such threats as may be appropriate, conducting internal and external audits, conducting internal threat assessments to evaluate for both internal and external threats, having third parties conduct threat assessments, and conducting vulnerability assessments designed to identify vulnerabilities.

Depending on the environment, we implement and maintain various technical, physical, and organizational measures, processes, standards and policies designed to manage and mitigate material risks from cybersecurity threats to our Information Systems and Data, including, for example, our incident response policy; incident detection and response processes; a vulnerability management policy; a disaster recovery plans; risk assessments; encrypting certain data; network security controls; segregating certain of our data; maintaining access and physical controls; asset management, tracking and disposal; systems monitoring; employee training; penetration testing conducted by third parties; maintaining cybersecurity insurance; and having dedicated cybersecurity staff.

Our assessment and management of material risks from cybersecurity threats are integrated into our overall risk management processes. For example, (1) cybersecurity risk is addressed as a component of our enterprise risk management program; (2) the IT department and IT Director discuss cybersecurity risk with management, including our CFO and legal department to prioritize our risk management processes and mitigate cybersecurity threats that are more likely to lead to a material impact to our business; (3) our senior management evaluates material risks from cybersecurity threats against our overall business objectives and reports certain risks to the audit committee of the board of directors, which evaluates our overall enterprise risk.

We use third-party service providers to assist us from time to time to identify, assess, and manage material risks from cybersecurity threats, including for example, professional services firms (including legal counsel), cybersecurity consultants, cybersecurity software providers, and penetration testing firms.

We use third-party service providers to perform a variety of functions throughout our business, such as hosting companies, contract research organizations (CROs), and contract manufacturing organizations (CMOs). We have processes to manage cybersecurity risks associated with our use of certain of these providers. These processes include reviewing certain vendors' written security program and security assessments, and imposing certain

contractual obligations related to cybersecurity on the vendor. Depending on the nature of the services provided, the sensitivity of the Information Systems and Data at issue, and the identity of the provider, our vendor management processes may involve different levels of assessment designed to help identify cybersecurity risks associated with a provider.

For a description of the risks from cybersecurity threats that may materially affect us and how they may do so, see the section of this Annual Report on Form 10-K titled “Risk Factors”, including, but not limited to, the risk factor titled “If our internal information technology systems or sensitive information, or those of our third-party CROs or other contractors or consultants, are or were compromised, we could experience adverse consequences from such compromise, including but not limited to, a material disruption of our product candidates’ development programs, regulatory investigations or actions, litigation, fines and penalties, reputational harm, loss of revenue or profits, and other adverse consequences.”

Governance

Our board of directors addresses our cybersecurity risk management as part of its general oversight function. The audit committee of the board of directors is responsible for overseeing our cybersecurity risk management processes, including oversight and mitigation of risks from cybersecurity threats.

Our cybersecurity risk assessment and management processes are implemented and maintained by certain of our personnel, including our IT Director, who has 20 years of experience in IT and cybersecurity and is a member of the Information Systems Audit and Control Association (ISACA).

Our IT Director is responsible for hiring appropriate personnel, helping to integrate cybersecurity risk considerations into our overall risk management strategy, and communicating key priorities to relevant personnel. Our CFO is responsible for approving budgets and, along with our IT Director and our legal department, helping prepare for cybersecurity incidents, approving cybersecurity processes, and reviewing security assessments and other security-related reports.

Our cybersecurity incident response and vulnerability and patch management policies are designed to escalate certain cybersecurity incidents to members of management depending on the circumstances, including our CEO, CFO and General Counsel. Such management members work with our incident response team to help us mitigate and remediate cybersecurity incidents of which they are notified. In addition, our incident response policy includes reporting to the audit committee of the board of directors for certain cybersecurity incidents.

The audit committee receives periodic reports from our IT Director concerning our significant cybersecurity threats and risk and the processes we have implemented to address them. The audit committee also has access to various reports, summaries or presentations related to cybersecurity threats, risk and mitigation.

Item 2. Properties.

Our corporate headquarters is located in San Diego, California, where we lease office and laboratory space pursuant to a lease agreement which commenced in July, 2022 and expires in January, 2033. We believe that our existing facilities are adequate for the foreseeable future. As we expand, we believe that suitable additional alternative spaces will be available in the future on commercially reasonable terms, if required.

Item 3. Legal Proceedings.

From time to time, we may become involved in legal proceedings or be subject to claims arising in the ordinary course of our business. We are not currently a party to any material legal proceedings. Regardless of outcome, such proceedings or claims can have an adverse impact on us because of defense and settlement costs, diversion of resources and other factors, and there can be no assurances that favorable outcomes will be obtained.

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.

Our common stock has been publicly traded on the Nasdaq Global Market under the symbol "JANX" since our initial public offering on June 11, 2021. Prior to that date, there was no public market for our common stock.

Holders of Common Stock

As of February 29, 2024, there were 46,262,759 shares of common stock issued and held by approximately 24 stockholders of record. The actual number of stockholders is greater than this number of record holders and includes stockholders who are beneficial owners but whose shares are held in street name by brokers and other nominees.

Securities Authorized for Issuance Under Equity Compensation Plans

Information about securities authorized for issuance under our equity compensation plans is incorporated herein by reference to Item 12 of Part III of this Annual Report on Form 10-K.

Dividend Policy

We have never declared or paid any cash dividends on our capital stock. We currently intend to retain all available funds and any future earnings to support our operations and finance the growth and development of our business. We do not intend to pay cash dividends on our common stock for the foreseeable future. Any future determination related to our dividend policy will be made at the discretion of our board of directors and will depend upon, among other factors, our results of operations, financial condition, capital requirements, contractual restrictions, business prospects and other factors our board of directors may deem relevant.

Stock Performance Graph

Not applicable to a smaller reporting company.

Recent Sales of Unregistered Securities

None.

Use of Proceeds

On June 10, 2021, the SEC declared effective our registration statement on Form S-1 (File No. 333-256297), as amended, filed in connection with our initial public offering (IPO). At the closing of the offering on June 15, 2021, we issued and sold 13,110,000 shares of our common stock at the initial public offering price to the public of $17.00 per share, which included the exercise in full of the underwriters' option to purchase additional shares. We received gross proceeds from the IPO of $222.9 million, before deducting underwriting discounts and commissions of approximately $15.6 million and offering costs of approximately $3.1 million. BofA Securities, Inc., Cowen and Company, LLC and Evercore Group L.L.C. acted as joint book-running managers for the offering. H.C. Wainwright & Co., LLC acted as lead manager for the offering. No offering expenses were paid or are payable, directly or indirectly, to our directors or officers, to persons owning 10% or more of any class of our equity securities or to any of our affiliates.

Upon receipt, the net proceeds from our IPO were held in cash and cash equivalents, primarily in money market funds invested in U.S. government agency securities. As of December 31, 2023, we have not used any of the proceeds from our IPO and there has been no material change in the planned use of such proceeds from that described in the final prospectus filed by us with the SEC on June 11, 2021. Pursuant to our investment policy we have invested these funds in high-quality marketable security types with contractual maturity dates of up to three years until needed to fund our operations.

Issuer Purchases of Equity Securities

Not applicable.

Item 6. [Reserved]

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

You should read the following discussion and analysis together with our financial statements and related notes included in "Item 8. Financial Statements and Supplementary Data" in this Annual Report on Form 10-K. The following discussion contains forward-looking statements that involve risks and uncertainties. For a complete discussion of forward-looking statements, see the section above entitled "Special Note Regarding Forward Looking Statements." Our actual results could differ materially from those expressed or implied in any forward-looking statements as a result of various factors, including those set forth under the caption "Item 1A. Risk Factors."

Overview

We are an innovative clinical-stage biopharmaceutical company developing tumor-activated immunotherapies for cancer. Our proprietary technology has enabled the development of two distinct bispecific platforms: TRACTr and TRACIr. The TRACTr platform produces TCEs with a tumor antigen-binding domain and a CD3 T cell binding domain, while the TRACIr platform produces bispecifics with a tumor antigen-binding domain and a costimulatory CD28 binding domain. The goal of both platforms is to provide cancer patients with safe and effective therapeutics that direct and guide their immune system to eradicate tumors while minimizing safety concerns. Our initial focus is on developing a novel class of TRACTr therapeutics designed to target clinically validated TCE drug targets, but overcome liabilities associated with prior generations of TCEs. While TCE therapeutics have displayed potent anti-tumor activity in hematological cancers, developing TCEs to treat solid tumors has faced challenges due to the limitations of prior TCE technologies, namely (i) on-target healthy tissue immune activation that contributes to CRS and healthy tissue toxicity and (ii) poor PK leading to short half-life. Our first clinical candidate, JANX007, is a prostate-specific membrane antigen or PSMA-TRACTr and is being investigated in a Phase 1 clinical trial in adult subjects with mCRPC. In February 2024 we announced updated interim clinical data for JANX007 which displayed meaningful PSA drops, and a favorable safety profile, low-grade CRS, and PK, consistent with the TRACTr mechanism-of-action. Our second clinical candidate, JANX008, is an epidermal growth factor receptor or EGFR-TRACTr and is being studied in a Phase 1 clinical trial for the treatment of multiple solid cancers including colorectal cancer, squamous cell carcinoma of the head and neck, non-small cell lung cancer, and renal cell carcinoma. The first patient for this trial was dosed in April 2023 and in February 2024 we announced positive early data JANX008 that displayed anti-tumor activity in multiple tumor types with low-grade CRS and predominantly low-grade TRAEs. We are also generating a number of unnamed TRACTr and TRACIr programs for potential future development, some of which are at development candidate stage or later. We are currently assessing priorities in our preclinical pipeline.

We were incorporated in June 2017. To date, we have devoted substantially all of our resources to organizing and staffing our company, business planning, business development, raising capital, developing and optimizing our technology platform, identifying potential product candidates, undertaking research and development for our lead programs, establishing and enhancing our intellectual property portfolio and providing general and administrative support for these operations. All of our product candidates and research programs other than JANX007 and JANX008 are in preclinical development, and none have been approved for commercial sale. We have never generated any revenue from product sales and have incurred net losses each year since we commenced operations. We have funded our operations primarily with the net proceeds from the issuance of convertible promissory notes, the issuance of convertible preferred stock, the exercise of common stock options, proceeds from our initial public offering (IPO), the issuance of common stock and pre-funded common stock warrants in public and/or underwritten offerings and amounts received under a collaboration agreement with Merck Sharp & Dohme Corp. (Merck).

We have incurred operating losses since our inception and have not yet generated any product revenue. Our net losses were $58.3 million and $63.1 million for the years ended December 31, 2023 and 2022, respectively. As of December 31, 2023, we had an accumulated deficit of $168.8 million.

Our net losses may fluctuate significantly from quarter-to-quarter and year-to-year, depending on a variety of factors including the timing and scope of our clinical and preclinical studies and our expenditures on other research and development activities and the timing of any revenue recognition under our collaboration agreement with Merck. We expect our expenses and operating losses will increase substantially and that we will continue to incur significant losses for the foreseeable future as we conduct our ongoing and planned research and development activities and conduct preclinical studies and clinical trials, hire additional personnel, protect our intellectual property and incur additional costs associated with being a public company.

We do not expect to generate any revenues from product sales unless and until we successfully complete development and obtain regulatory approval for one or more product candidates, which will not be for many years, if ever. Accordingly, until such time as we can generate significant revenue from sales of our product candidates, if ever, we expect to finance our cash needs through equity offerings, debt financings or other capital sources, including potentially grants, collaborations, licenses or other similar arrangements. However, we may be unable to raise additional funds or enter into such other arrangements when needed on favorable terms or at all. Our failure to raise capital or enter into such other arrangements when needed would have a negative impact on our financial condition and could force us to delay, limit, reduce or terminate our product development or future commercialization efforts or grant rights to develop and market product candidates or to our platform technologies that we would otherwise prefer to develop and market ourselves. Based on our current operating plan, we believe that our existing cash and cash equivalents and short-term investments, will be sufficient to meet our anticipated operating expenses and capital expenditure requirements through at least the next 12 months, following the date of this Annual Report.

Our Research Collaboration with Merck

In December 2020, we entered into a research collaboration and exclusive license agreement with Merck to develop TRACTr product candidates that are distinct from those in our internally developed pipeline (the Merck Agreement). Merck has the right to select up to two collaboration targets (each a Collaboration Target) related to next generation T cell engager immunotherapies for the treatment of cancer. Merck selected the first Collaboration Target upon execution of the agreement and selected the second Collaboration Target in May 2022. Merck received an exclusive worldwide license for each selected target and intellectual property from the collaboration. In return, we are eligible to receive up to $500.5 million per target in upfront and milestone payments, plus royalties on sales of the products derived from the collaboration. Merck provides research funding under the collaboration.

Risks and Uncertainties

Global economic and business activities continue to face widespread macroeconomic uncertainties, including those associated with COVID-19 and other public health crises, bank failures, inflation and monetary supply shifts, recession risks and potential disruptions from the Russia-Ukraine conflict, the war in the Middle East and related sanctions. For example, in 2023, the Federal Deposit Insurance Corporation took control and was appointed receiver of certain financial institutions. If other banks and financial institutions enter receivership or become insolvent in the future in response to financial conditions affecting the banking system and financial markets, our ability to access our existing cash, cash equivalents and investments may be threatened and could have a material adverse effect on our business and financial condition. Inflation generally affects us by increasing our salaries and fees paid to third-party contract service providers. We have considered potential impacts arising from the risks and uncertainties as described above and have not experienced any material disruption to our operations to date.

Support Services Agreement with Avalon BioVentures, Inc. (formerly COI Pharmaceuticals, Inc.)

In January 2021, we entered into a Support Services Agreement (the 2021 Support Services Agreement) with Avalon BioVentures, Inc. (Avalon) that outlines the terms of services provided by Avalon to the Company, as well as the fees charged for such services. Avalon is a shared service company that provides certain back-office and administrative and research and development support services, including facilities support, to the portfolio

companies of Avalon Ventures, an entity that beneficially owns greater than 5% of our outstanding capital stock. The amounts paid to Avalon include support service fees or mark-ups of up to 5%. The 2021 Support Services Agreement was most recently renewed in January 2024 and will continue to renew for additional one-year renewal periods until terminated by the parties. Either party may terminate the 2021 Support Services Agreement with 30 days written notice.

Financial Operations Overview

Revenues

To date, we have not generated any revenues from the commercial sale of any products, and we do not expect to generate revenues from the commercial sale of any products for the foreseeable future, if ever. We recognized $8.1 million and $8.6 million of revenue under the Merck Agreement for the years ended December 31, 2023 and 2022, respectively.

Research and Development

To date, our research and development expenses have related primarily to direct and indirect expenses in connection with the development of our TRACTr and TRACIr platforms, discovery efforts and preclinical and clinical development of our product candidates. Research and development expenses are recognized as incurred and payments made prior to the receipt of goods or services to be used in research and development are capitalized until the goods or services are received.

Our direct research and development expenses include:

- external research and development expenses incurred under agreements with CROs and consultants to conduct our preclinical and clinical studies;
- license fees; and
- laboratory equipment, materials and supplies.

Our indirect research and development expenses include:

- salaries and employee-related costs, including recruiting fees and stock-based compensation for those individuals involved in research and development efforts;
- maintenance of facilities and equipment, software license fees, depreciation; and
- allocated facilities and equipment-related expenses, which include rent, utilities, insurance, and office supplies.

Certain research and development expenses as listed above include amounts paid to Avalon pursuant to the 2021 Support Services Agreement.

We anticipate that our research and development expenses will substantially increase for the foreseeable future as we continue the development of our TRACTr and TRACIr platforms and the discovery and development of product candidates under our TRACTr and TRACIr platforms.

We cannot determine with certainty the timing of initiation, the duration or the completion costs of clinical trials and preclinical studies of product candidates due to the inherently unpredictable nature of preclinical and clinical development. Preclinical and clinical development timelines, the probability of success and development costs can differ materially from expectations. We anticipate that we will make determinations as to which product candidates and development programs to pursue and how much funding to direct to each product candidate or program on an ongoing basis in response to the results of ongoing and future preclinical studies and clinical trials, regulatory developments and our ongoing assessments as to each product candidate's commercial potential. We will need to raise substantial additional capital in the future. In addition, we cannot forecast which product candidates may be

subject to future collaborations, when such arrangements will be secured, if at all, and to what degree such arrangements would affect our development plans and capital requirements.

General and Administrative

General and administrative expenses consist primarily of salaries and employee-related costs, including stock-based compensation, for personnel in executive, finance and other administrative functions. Other significant general and administrative expenses include facility-related costs, which include direct depreciation costs and allocated expenses for rent and maintenance of facilities; legal fees relating to intellectual property and corporate matters; professional fees for accounting, tax and consulting services; insurance costs; and other operating costs. Our general and administrative expenses include amounts paid to Avalon pursuant to the 2021 Support Services Agreement for certain back-office and administrative support services, including facilities support. We anticipate that our general and administrative expenses will increase for the foreseeable future as we continue to increase our general and administrative headcount to support our continued research and development activities and, if any of our product candidates receive marketing approval, commercialization activities. We also anticipate increased expenses associated with operating as a public company, including expenses related to audit, legal, regulatory, and tax-related services associated with maintaining compliance with exchange listing and SEC requirements, director and officer insurance premiums and investor relations costs.

Other Income

Other income consists of interest income on our cash and cash equivalents and short-term investments.

Results of Operations

Comparison of the Years Ended December 31, 2023 and 2022

	Year Ended December 31,		
	2023	2022	Change
	(in thousands)		
Collaboration revenue	$ 8,083	$ 8,612	$ (529)
Operating expenses:			
Research and development	54,922	53,441	1,481
General and administrative	26,140	22,262	3,878
Total operating expenses	81,062	75,703	5,359
Loss from operations	(72,979)	(67,091)	(5,888)
Other income	14,686	4,032	10,654
Net loss	$ (58,293)	$ (63,059)	$ 4,766

Collaboration Revenue

Collaboration revenues were $8.1 million and $8.6 million for the years ended December 31, 2023 and 2022, respectively. The decrease of $0.5 million was primarily due to a decrease in full-time equivalent hours incurred in the performance of research services required under the Merck Agreement.

Research and Development Expense

The following table summarizes our direct and indirect research and development expenses for the years ended December 31, 2023 and 2022:

	Year Ended December 31,		
	2023	2022	Change
	(in thousands)		
Direct costs:			
JANX007	$ 7,895	$ 5,462	$ 2,433
JANX008	5,401	7,629	(2,228)
Preclinical stage programs and other direct unallocated costs	13,950	18,233	(4,283)
Total direct costs	27,246	31,324	(4,078)
Indirect costs	27,676	22,117	5,559
Total research and development expenses	$ 54,922	$ 53,441	$ 1,481

IND applications for JANX007 and JANX008 were cleared by the U.S. Food and Drug Administration (FDA) in May 2022 and January 2023, respectively. As a result, we have separated direct costs for the development of JANX007 and JANX008 from preclinical stage programs and other direct unallocated costs for the years ended December 31, 2023 and 2022. We will further separate direct costs related to our other programs as future IND applications are cleared by the FDA. These changes in presentation had no effect on net loss, total research and development expenses, stockholders' equity, or cash flows as previously reported.

Research and development expenses were $54.9 million and $53.4 million for the years ended December 31, 2023 and 2022, respectively. The increase of $1.5 million was primarily due to increases in indirect costs of $5.6 million and direct costs related to the development of JANX007 of $2.4 million, offset by decreases in direct costs related to the development of JANX008 of $2.2 million and preclinical stage programs and other unallocated direct costs of $4.3 million. The increase in indirect costs was primarily due to increases in personnel costs of $2.8 million, facilities and other costs of $2.2 million and stock-based compensation expense of $0.6 million.

General and Administrative Expense

General and administrative expenses were $26.1 million and $22.3 million for the years ended December 31, 2023 and 2022, respectively. The increase of $3.8 million was primarily due to increases in stock-based compensation of $2.2 million, personnel and facilities related costs of $2.0 million, offset by a decrease in other general and administrative expenses of $0.4 million.

Other Income

Other income was $14.7 million and $4.0 million for the years ended December 31, 2023 and 2022, respectively. The increase of $10.7 million was due to the impact of increases in interest rates on our debt securities, resulting in increased interest income.

Liquidity and Capital Resources

We have incurred net losses and negative cash flows from operations since our inception and anticipate we will continue to incur net losses and negative cash flows for the foreseeable future. As of December 31, 2023, we had cash, cash equivalents, restricted cash and short-term investments of $344.8 million. Inclusive in this amount is $0.8 million of restricted cash that is not available for current use.

In August 2022, we filed a shelf registration statement (File No. 333-266720), which was declared effective in September 2022. The shelf registration statement provides us with the ability to offer up to $400.0 million of certain securities, including shares of our common stock, from time to time. The specific terms of any offering under the shelf registration statement are established at the time of such offering.

In August 2022, we entered into an Open Market Sale Agreement℠ (Sale Agreement) with Jefferies LLC (Jefferies) to sell shares of our common stock, from time to time, through an "at the market offering" program having an aggregate offering price of up to $100.0 million through which Jefferies would act as sales agent. In May 2023, we terminated the Sale Agreement.

In May 2023, we entered into an ATM Equity Offering℠ Sales Agreement (New Sale Agreement) with BofA Securities, Inc. (BofA) to sell shares of our common stock, from time to time, through an "at the market offering" program having an aggregate offering price of up to $150.0 million through which BofA would act as sales agent. As of December 31, 2023, $150.0 million of common stock remained available for sale under the New Sale Agreement. In February 2024, we delivered written notice to BofA that we were suspending and terminating the prospectus related to the shares of our common stock issuable pursuant to the terms of the New Sale Agreement. As a result, we will not make any sales of our securities pursuant to the New Sale Agreement, unless and until a new prospectus, prospectus supplement, or a new registration statement relating to the shares of our common stock is filed. Other than the termination of the prospectus, the New Sale Agreement remains in full force and effect.

In July 2023, we closed an underwritten offering of 4,153,717 shares of our common stock and pre-funded warrants to purchase 583,483 shares of common stock at an exercise price of $0.001 per share. The shares of common stock were sold at a price of $12.46 per share and the pre-funded common stock warrants were sold at a price of $12.459 per pre-funded common stock warrant, resulting in gross proceeds of $59.0 million. Fees related to the offering included underwriting discounts, commissions, and offering expenses in the aggregate amount of $2.5 million, resulting in net proceeds of $56.5 million.

In March 2024, we closed an underwritten offering of 5,397,301 shares of our common stock and pre-funded warrants to purchase 1,935,483 shares of common stock. The shares of common stock were sold at a price of $46.50 per share and the pre-funded common stock warrants were sold at a price of $46.499 per pre-funded common stock warrant, resulting in gross proceeds of $341.0 million. Fees related to the offering included underwriting discounts, commissions, and estimated offering expenses in the aggregate amount of $20.8 million, resulting in estimated net proceeds of $320.2 million.

The following summarizes our cash flows for the periods indicated:

	Year Ended December 31,	
	2023	2022
	(in thousands)	
Net cash provided by (used in):		
Operating activities	$ (50,575)	$ (42,922)
Investing activities	(41,194)	58,266
Financing activities	59,548	500
Net increase (decrease) in cash, cash equivalents and restricted cash	$ (32,221)	$ 15,844

Operating Activities

Net cash used in operating activities of $50.6 million for the year ended December 31, 2023 was primarily due to our net loss of $58.3 million and a change in operating assets and liabilities and other non-cash charges of $12.3 million, adjusted for $20.0 million of stock-based compensation expense. Net cash used in operating activities of $42.9 million for the year ended December 31, 2022 was primarily due to our net loss of $63.1 million, adjusted for $17.2 million of stock-based compensation expense and a decrease in operating assets and liabilities and other non-cash charges of $3.0 million.

Investing Activities

Net cash used in investing activities of $41.2 million for the year ended December 31, 2023 was primarily due to $39.3 million of net purchases of short-term investments and by our purchase of property and equipment, primarily consisting of laboratory equipment of $1.9 million. Net cash provided by investing activities of $58.3 million for the year ended December 31, 2022 was primarily due to $64.7 million of net maturities of short-term investments offset by our purchase of property and equipment, primarily consisting of laboratory equipment of $6.4 million.

Financing Activities

Net cash provided by financing activities of $59.5 million for the year ended December 31, 2023 was primarily due to proceeds from the issuance of common stock and pre-funded common stock warrants, net of issuance costs, of $56.5 million, and exercises of common stock options and from shares issued under our 2021 Employee Stock Purchase Plan (ESPP) of $3.0 million. Net cash provided by financing activities of $0.5 million for the year ended December 31, 2022 was primarily due to proceeds from shares issued under our ESPP.

Funding Requirements

Based on our current operating plan, we believe that our existing cash and cash equivalents and short-term investments, will be sufficient to meet our anticipated operating expenses and capital expenditure requirements through at least the next 12 months, following the date of this Annual Report. However, our forecast of the period of time through which our financial resources will be adequate to support our operations is a forward-looking statement that involves risks and uncertainties, and actual results could vary materially. We have based this estimate on assumptions that may prove to be wrong, and we could deplete our capital resources sooner than we expect. Additionally, the process of testing product candidates in clinical trials is costly, and the timing of progress and expenses in these trials is uncertain.

Our future capital requirements will depend on many factors, including:

- the initiation, trial design, progress, timing, costs and results of drug discovery, preclinical studies and clinical trials of our product candidates, and in particular the clinical trials for JANX007 and JANX008;
- the number and characteristics of clinical programs that we pursue;
- the outcome, timing and costs of seeking FDA, European Commission and any other comparable regulatory approvals for any future drug candidates;
- the costs of manufacturing our product candidates;
- the costs associated with hiring additional personnel and consultants as our preclinical, manufacturing and clinical activities increase;
- the receipt of marketing approval and revenue received from any commercial sales of any of our product candidates, if approved;
- the cost of commercialization activities for any of our product candidates, if approved, including marketing, sales and distribution costs;
- the ability to establish and maintain strategic collaboration, licensing or other arrangements and the financial terms of such agreements;
- the extent to which we in-license or acquire other products and technologies;
- the costs involved in preparing, filing, prosecuting, maintaining, expanding, defending and enforcing patent claims, including litigation costs and the outcome of such litigation;
- our implementation of additional internal systems and infrastructure, including operational, financial and management information systems;
- our costs associated with expanding our facilities or building out our laboratory space;
- the effects of the disruptions to and volatility in the credit and financial markets in the United States and worldwide from COVID-19 or other epidemics; and
- the costs of operating as a public company.

Until such time, if ever, as we can generate substantial product revenues to support our cost structure, we expect to finance our cash needs through a combination of equity offerings, debt financings or other capital sources, including potentially grants, collaborations, licenses or other similar arrangements. To the extent that we raise additional capital through the sale of equity or convertible debt securities, the ownership interest of our stockholders

will be or could be diluted, and the terms of these securities may include liquidation or other preferences that adversely affect the rights of our common stockholders. Debt financing and equity financing, if available, may involve agreements that include covenants limiting or restricting our ability to take specific actions, such as incurring additional debt, making capital expenditures or declaring dividends. If we raise funds through collaborations, or other similar 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 and/or may reduce the value of our common stock. If we are unable to raise additional funds through equity or debt financings when needed, we may be required to delay, limit, reduce or terminate our product development or future commercialization efforts or grant rights to develop and market our product candidates even if we would otherwise prefer to develop and market such product candidates ourselves.

Contractual Obligations and Commitments

In April 2021, we entered into a cell line license agreement (Cell Line License Agreement) with WuXi Biologics (Hong Kong) Limited (WuXi Biologics). According to the terms of the Cell Line License Agreement, if we do not engage WuXi Biologics or its affiliates to manufacture the therapeutic products produced through the use of the cell line licensed by WuXi Biologics under the Cell Line License Agreement (WuXi Biologics Licensed Products) for our commercial supplies, we are required to make royalty payments to WuXi Biologics in an amount equal to a low single-digit percentage of specified portions of net sales of WuXi Biologics Licensed Products manufactured by a third-party manufacturer. We have the right (but not the obligation) to buy out our remaining royalty obligations with respect to each WuXi Biologics Licensed Product by paying WuXi Biologics a one-time payment in an amount ranging from low single digit million dollars to a maximum of $15.0 million (Buyout Option). The royalty obligations will remain in effect during the term of the Cell Line License Agreement so long as we have not exercised the Buyout Option. See the section within Item 1 of Part I of this Annual Report on Form 10-K titled "License Agreement with WuXi Biologics (Hong Kong) Limited" for additional information.

In October 2021, we entered into a noncancelable agreement to lease office and laboratory space in San Diego, California (Torrey Plaza Lease) with aggregate payments of approximately $38.0 million over the 126-month term of the lease. The Torrey Plaza Lease commenced in July 2022. See Note 3 to our audited financial statements appearing in Part II, Item 8 of this Annual Report on Form 10-K for additional information.

We enter into contracts in the normal course of business with various third parties for preclinical and clinical research studies and testing, manufacturing and other services and products for operating purposes. These contracts provide for termination upon notice. Payments due upon cancellation consist only of payments for services provided or expenses incurred, including non-cancellable obligations of our service providers, up to the date of cancellation.

Critical Accounting Policies and Estimates

Our management’s discussion and analysis of our financial condition and results of operations are based on our financial statements, which have been prepared in accordance with U.S. generally accepted accounting principles (GAAP). The preparation of these financial statements requires us to make estimates and judgments that affect the reported amounts of assets, liabilities, revenues, and expenses and the disclosure of contingent assets and liabilities in our financial statements. On an ongoing basis, we evaluate our estimates and judgments, including those related to estimates to complete the performance obligations and the estimated transaction price for collaboration revenues, accruals for research and development expenses and estimates used in valuing our equity awards for stock-based compensation expense. We base our estimates on historical experience, known trends and events, and various other factors that are believed to be reasonable under the circumstances, the results of which form the basis for making judgments about the carrying values of assets and liabilities that are not readily apparent from other sources. Actual results may differ from these estimates under different assumptions or conditions.

While our significant accounting policies are described in more detail in Note 1 to our financial statements included elsewhere in this Annual Report, we believe the following accounting policies and estimates to be most critical to the preparation of our financial statements.

Collaboration Revenue

We determined that our collaboration with Merck is a contract with a customer. We recognize revenue in a manner that depicts the transfer of control of a product or a service to a customer and reflects the amount of the consideration we are entitled to receive in exchange for such product or service. To determine revenue recognition for our contracts with customers, we follow a five-step approach: (i) identify the contract with a customer, (ii) identify the performance obligations in the contract, (iii) determine the transaction price, (iv) allocate the transaction price to the performance obligations, and (v) recognize revenue when (or as) the customer obtains control of the product or service.

A customer is a party that has entered into a contract with us, where the purpose of the contract is to obtain a product or a service that is an output of our ordinary activities in exchange for consideration. To be considered a contract, (i) the contract must be approved (in writing, orally, or in accordance with other customary business practices), (ii) each party's rights regarding the product or the service to be transferred can be identified, (iii) the payment terms for the product or the service to be transferred can be identified, (iv) the contract must have commercial substance (that is, the risk, timing or amount of future cash flows is expected to change as a result of the contract), and (v) it is probable that we will collect substantially all of the consideration to which we are entitled to receive in exchange for the transfer of the product or the service.

A performance obligation is defined as a promise to transfer a product or a service to a customer. We identify each promise to transfer a product or a service (or a bundle of products or services, or a series of products and services that are substantially the same and have the same pattern of transfer) that is distinct. A product or a service is distinct if both (i) the customer can benefit from the product or the service either on its own or together with other resources that are readily available to the customer and (ii) our promise to transfer the product or the service to the customer is separately identifiable from other promises in the contract. Each distinct promise to transfer a product or a service is a unit of accounting for revenue recognition. If a promise to transfer a product or a service is not separately identifiable from other promises in the contract, such promises should be combined into a single performance obligation. When an entity grants a customer the option to acquire additional goods or services, that option is a separate performance obligation only if it provides a material right to the customer that the customer would not receive without entering into the contract. Under our existing collaboration agreement with Merck, due to the early stage of the licensed technology, the license of such technology was combined with the additional promises associated with each of the targets in the agreement as one combined performance obligation. Furthermore, as it relates to the option to select an additional collaboration target, we determined that the option did not represent a material right. The option instead represents a customer option to purchase additional goods or services and was therefore accounted for as a separate contract.

The transaction price is the amount of consideration we are entitled to receive in exchange for the transfer of control of a product or a service to a customer. To determine the transaction price, we consider the existence of any significant financing component, the effects of any variable elements, noncash considerations and consideration payable to the customer. If a significant financing component exists, the transaction price is adjusted for the time value of money. If an element of variability exists, we must estimate the consideration we expect to receive and use that amount as the basis for recognizing revenue as the product or the service is transferred to the customer. There are two methods for determining the amount of variable consideration: (i) the expected value method, which is the sum of probability-weighted amounts in a range of possible consideration amounts, and (ii) the mostly likely amount method, which identifies the single most likely amount in a range of possible consideration amounts.

With respect to variable consideration relating to development and regulatory milestone payments, if it is probable that a significant revenue reversal would not occur, the associated payment value is included in the transaction price. For development and regulatory milestones that are uncertain in nature and highly dependent on factors outside of our control, the aggregate consideration is determined to be fully constrained and is not included in the transaction price until the underlying events occur or the associated approvals are received. At the end of each reporting period, we re-evaluate the probability of achievement of each milestone and any related constraint, and if necessary, adjust our estimate of the overall transaction price. Any such adjustments are recorded on a cumulative catch-up basis, which would affect the reported amount of revenues in the period of adjustment.

For arrangements that include sales-based royalties, including milestone payments based on a level of sales, and the license is deemed to be the predominant item to which the royalties relate, we recognize 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).

If a contract has multiple performance obligations, we allocate the transaction price to each distinct performance obligation in an amount that reflects the consideration we are entitled to receive in exchange for satisfying each distinct performance obligation. For each distinct performance obligation, revenue is recognized when (or as) we transfer control of the product or the service applicable to such performance obligation. To date, for collaboration arrangements that represent a single performance obligation, the revenues are recognized over time based on actual Full Time Equivalent employees (FTEs) utilized as a percentage of total FTEs expected to be utilized over the expected term of the research services. We apply judgment in the total estimated FTEs anticipated over the contract. Estimates are based on input from key research personnel and expectations of FTEs necessary to complete the planned activities within the scope of the agreement and availability of internal FTEs to complete such activities.

In those instances where we first receive consideration in advance of satisfying its performance obligation, we classify such consideration as deferred revenue until (or as) we satisfy such performance obligation. In those instances where we first satisfy our performance obligation prior to our receipt of consideration, the consideration is recorded as accounts receivable.

We expense incremental costs of obtaining a contract as and when incurred if the expected amortization period of the asset that would be recognized is one year or less, or if the amount of the asset is immaterial. Otherwise, such costs are capitalized and amortized to research and development expense ratably in conjunction with the underlying revenue recognition. No incremental costs of obtaining a contract have been incurred to date.

Accrued Research and Development Expenses

As part of the process of preparing our financial statements, we are required to estimate our accrued expenses as of each balance sheet date. This process involves reviewing open contracts and purchase orders, communicating with our 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 make estimates of our accrued expenses as of each balance sheet date based on facts and circumstances known to us at that time. We periodically confirm the accuracy of our estimates with the service providers and make adjustments, if necessary. The significant estimates in our accrued research and development expenses include the costs incurred for services performed by our vendors in connection with research and development activities for which we have not yet been invoiced.

We base our expenses related to research and development activities on our estimates of the services received and efforts expended pursuant to quotes and contracts with vendors that conduct research and development on our behalf. The financial terms of these agreements are subject to negotiation, vary from contract to contract and may result in uneven payment flows. There may be instances in which payments made to our vendors will exceed the level of services provided and result in a prepayment of the research and development expense. 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. If the actual timing of the performance of services or the level of effort varies from our estimate, we adjust the accrual or prepaid expense accordingly. 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.

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. To date, there have been no material differences between our estimates of such expenses and the amounts actually incurred.

Stock-Based Compensation Expense

Stock-based compensation expense represents the grant date fair value of equity awards, consisting of stock options and employee stock purchase rights, recognized on a straight-line basis over the requisite service period for

stock options and over the respective offering period for employee stock purchase plan rights. The grant date fair value of the equity awards is estimated using the Black-Scholes option pricing model. The Black-Scholes option pricing model utilizes inputs which are highly subjective assumptions and generally require significant judgment. See Note 5 to our financial statements included elsewhere in this Annual Report for information concerning certain of the specific assumptions we used in applying the Black-Scholes option pricing model to determine the estimated fair value of our stock option grants. Equity award forfeitures are recognized as they occur.

Recent Accounting Pronouncements

See Note 1 to our audited financial statements appearing in Part II, Item 8 of this Annual Report on Form 10-K for additional information.

Emerging Growth Company Status

We are an emerging growth company, as defined in the JOBS Act. For so long as we remain an emerging growth company, we are permitted and intend to rely on certain exemptions from various public company reporting requirements, including not being required to have our internal control over financial reporting audited by our independent registered public accounting firm pursuant to Section 404 of the Sarbanes-Oxley Act, reduced disclosure obligations regarding executive compensation in our periodic reports and proxy statements, and exemptions from the requirements of holding a nonbinding advisory vote on executive compensation and any golden parachute payments not previously approved.

Under the JOBS Act, emerging growth companies can delay adopting new or revised accounting standards issued subsequent to the enactment of the JOBS Act until such time as those standards apply to private companies. We have not elected to use this extended transition period.

We will remain an emerging growth company until the earliest to occur of: (i) the last day of the fiscal year in which we have at least $1.235 billion in annual revenue; (ii) the last day of the fiscal year in which we are deemed to be a “large accelerated filer,” as defined in Rule 12b-2 under the Exchange Act; (iii) the date on which we have issued more than $1.0 billion in nonconvertible debt securities during the prior three-year period; and (iv) December 31, 2026.

Item 7A. Quantitative and Qualitative Disclosures About Market Risk.

Not applicable to a smaller reporting company.

Item 8. Financial Statements and Supplementary Data.

REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

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

Opinion on the Financial Statements

We have audited the accompanying balance sheets of Janux Therapeutics, Inc. (the Company) as of December 31, 2023 and 2022, the related statements of operations and comprehensive loss, stockholders' equity and cash flows for each of the two years in the period ended December 31, 2023, and the related notes (collectively referred to as the "financial statements"). In our opinion, the financial statements present fairly, in all material respects, the financial position of the Company at December 31, 2023 and 2022, and the results of its operations and its cash flows for each of the two years in the period ended December 31, 2023, 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 2021.

San Diego, California
March 8, 2024

Janux Therapeutics, Inc.
Balance Sheets
(in thousands, except share and par value data)

	December 31,	
Assets	**2023**	**2022**
Current assets:		
Cash and cash equivalents	$ 19,205	$ 51,426
Short-term investments	324,823	275,590
Prepaid expenses and other current assets	5,213	5,423
Total current assets	349,241	332,439
Restricted cash	816	816
Property and equipment, net	7,003	7,086
Operating lease right-of-use assets	20,838	22,279
Other long-term assets	2,509	1,390
Total assets	$ 380,407	$ 364,010
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable	$ 2,424	$ 2,159
Accrued expenses	7,387	8,179
Current portion of deferred revenue	1,705	5,406
Current portion of operating lease liabilities	1,517	763
Total current liabilities	13,033	16,507
Deferred revenue, net of current portion	—	2,221
Operating lease liabilities, net of current portion	23,025	24,542

Total liabilities	36,058	43,270
Commitments and contingencies (Note 3)		
Stockholders' equity:		
Preferred stock, $0.001 par value; authorized shares – 10,000,000 at December 31, 2023 and 2022, respectively; no shares issued and outstanding at December 31, 2023 and 2022	—	—
Common stock, $0.001 par value; authorized shares – 200,000,000 at December 31, 2023 and 2022, respectively; issued shares – 46,262,759 and 41,684,666 at December 31, 2023 and 2022, respectively; outstanding shares – 46,252,440 and 41,616,260 at December 31, 2023 and 2022, respectively	46	42
Additional paid-in capital	512,401	432,703
Accumulated other comprehensive income (loss)	665	(1,535)
Accumulated deficit	(168,763)	(110,470)
Total stockholders' equity	344,349	320,740
Total liabilities and stockholders' equity	$ 380,407	$ 364,010

See accompanying notes.

Janux Therapeutics, Inc.
Statements of Operations and Comprehensive Loss
(in thousands, except share and per share data)

	Year Ended December 31,	
	2023	2022
Collaboration revenue	$ 8,083	$ 8,612
Operating expenses:		
Research and development	54,922	53,441
General and administrative	26,140	22,262
Total operating expenses	81,062	75,703
Loss from operations	(72,979)	(67,091)
Other income:		
Interest income	14,686	4,032
Total other income	14,686	4,032
Net loss	(58,293)	(63,059)
	$	$
Other comprehensive gain (loss):		
Unrealized gain (loss) on available-for-sale securities, net	2,200	(1,265)
Comprehensive loss	(56,093)	(64,324)
	$	$
Net loss per common share, basic and diluted	(1.32)	(1.52)
	$	$
Weighted-average shares of common stock outstanding, basic and diluted	44,016,283	41,469,631

See accompanying notes.

Janux Therapeutics, Inc.
Statements of Stockholders' Equity
(in thousands, except share data)

	Common Stock		Additional Paid-in Capital	Accumulated Other Comprehensive Income (Loss)	Accumulated Deficit	Total Stockholders' Equity
	Shares	Amount				
Balance at December 31, 2021	41,243,137	$ 41	$ 413,967	$ (270)	$ (47,411)	366,327
Exercise of common stock options	7,405	—	1	—	—	1
Shares issued under employee stock purchase plan	54,299	—	499	—	—	499
Vesting of restricted shares	311,419	1	1,033	—	—	1,034
Stock-based compensation	—	—	17,203	—	—	17,203
Unrealized loss on available-for-sale securities, net	—	—	—	(1,265)	—	(1,265)
Net loss	—	—	—	—	(63,059)	(63,059)
Balance at December 31, 2022	41,616,260	$ 42	$ 432,703	$ (1,535)	$ (110,470)	$ 320,740
Issuance of common stock and pre-funded common stock warrants, net of issuance costs	4,153,717	4	56,526	—	—	56,530
Exercise of pre-funded common stock warrants	80,257	—	—	—	—	—
Exercise of common stock options	253,545	—	2,246	—	—	2,246
Shares issued under employee stock purchase plan	90,574	—	772	—	—	772
Vesting of restricted shares	58,087	—	149	—	—	149
Stock-based compensation	—	—	20,005	—	—	20,005
Unrealized gain on available-for-sale securities, net	—	—	—	2,200	—	2,200
Net loss	—	—	—	—	(58,293)	(58,293)
Balance at December 31, 2023	46,252,440	$ 46	$ 512,401	$ 665	$ (168,763)	$ 344,349

See accompanying notes.

Janux Therapeutics, Inc.
Statements of Cash Flows
(in thousands)

	Year Ended December 31,	
	2023	**2022**
Cash flows from operating activities		
Net loss	$ (58,293)	$ (63,059)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation	1,955	841
Stock-based compensation	20,005	17,203
Accretion of discounts on investments, net	(7,688)	(2,183)
Changes in operating assets and liabilities:		
Prepaid expenses and other current assets	210	(3,369)
Other long-term assets	(1,119)	(1,270)
Accounts payable	277	(294)
Accrued expenses	(678)	4,156
Deferred revenue	(5,922)	1,764
Operating lease right-of-use assets and liabilities, net	678	3,289
Net cash used in operating activities	(50,575)	(42,922)
Cash flows from investing activities		
Purchases of property and equipment	(1,850)	(6,445)
Purchases of short-term investments	(317,344)	(294,389)
Maturities of short-term investments	278,000	359,100
Net cash provided by (used in) investing activities	(41,194)	58,266
Cash flows from financing activities		
Proceeds from exercise of common stock options and employee stock purchase plan	3,018	500

Proceeds from the issuance of common stock and pre-funded common stock warrants, net of issuance costs	56,530	—
Net cash provided by financing activities	59,548	500
Net increase (decrease) in cash, cash equivalents and restricted cash	(32,221)	15,844
Cash, cash equivalents and restricted cash – beginning of year	52,242	36,398
Cash, cash equivalents and restricted cash – end of period	$ 20,021	$ 52,242
Supplemental disclosure of noncash investing and financing activities		
Unpaid property and equipment	$ 132	$ 109
Vesting of restricted common stock	$ 149	$ 1,034
Unrealized gain (loss) on available-for-sale securities, net	$ 2,200	$ (1,265)
Operating lease liabilities arising from right-of-use assets	$ —	$ 23,422

See accompanying notes.

Janux Therapeutics, Inc.
Notes to Financial Statements

1. Organization and Summary of Significant Accounting Policies

Organization

Janux Therapeutics, Inc. (the “Company”) was incorporated in the State of Delaware in June 2017 and is based in San Diego, California. The Company is a clinical-stage biopharmaceutical company developing a broad pipeline of novel immunotherapies by applying its proprietary technology to its Tumor Activated T Cell Engager (“TRACTr”) and Tumor Activated Immunomodulator (“TRACIr”) platforms to better treat patients suffering from cancer.

Liquidity and Capital Resources

From its inception through December 31, 2023, the Company has devoted substantially all its efforts to organizing and staffing, business planning, raising capital and developing its TRACTr and TRACIr therapeutic platforms and assets. The Company has incurred net losses and negative cash flows from operations since inception and had an accumulated deficit of $

168.8

million as of December 31, 2023. The Company has a limited operating history, has not generated any product revenue, and the sales and income potential of its business is unproven. To date the Company has funded its operations primarily with the net proceeds from the issuance of convertible promissory notes, the issuance of convertible preferred stock, the issuance of common stock in its initial public offering (“IPO”), the issuance of common stock and pre-funded common stock warrants in an underwritten offering, the exercise of common stock options, and amounts received under a collaboration agreement. The Company expects to incur substantial operating losses for the next several years and will need to obtain additional financing in order to continue its research and development activities, initiate and complete clinical trials and launch and commercialize any product candidates for which it receives regulatory approval. The Company plans to continue to fund its losses from operations and capital funding needs through public or private equity or debt financings or other sources. If the Company is not able to secure adequate additional funding, the Company may be forced to make reductions in spending, extend payment terms with suppliers, liquidate assets where possible, or suspend or curtail planned programs. Any of these actions could materially harm the Company’s business, results of operations and future prospects. There can be no assurance that such financing will be available or will be at terms acceptable to the Company, especially in light of COVID-19 and other public health crises, current financial conditions within the banking industry, including the effects of recent failures of financial institutions and liquidity levels, as well as recent or anticipated changes in interest rates and the inflationary macro environment.

The accompanying financial statements have been prepared assuming the Company will continue as a going concern, which contemplates the realization of assets and the satisfaction of liabilities in the normal course of business, and do not include any adjustments to reflect the possible future effects on the recoverability and classification of assets or amounts and classification of liabilities that may result from the outcome of this uncertainty. Management is required to perform an analysis over its ability to continue as a going concern. Management must first evaluate whether there are conditions and events that raise substantial doubt about the Company’s ability to continue as a going concern (step 1). If management concludes that substantial doubt is raised, management is also required to consider whether its plans alleviate that doubt (step 2). Management’s assessment included the preparation of cash flow forecasts resulting in management’s conclusion that the Company has sufficient capital to fund operations for at least 12 months from the date the financial statements for the year ended December 31, 2023 are issued.

Use of Estimates

The Company’s financial statements are prepared in accordance with U.S. generally accepted accounting principles ("GAAP"). The preparation of the Company’s financial statements requires it to make estimates and assumptions that impact the reported amounts of assets, liabilities, revenues and expenses and the disclosure of contingent assets and liabilities in the Company’s financial statements and accompanying notes. The most significant estimates in the Company’s financial statements relate to estimates to complete the performance obligations and the estimated transaction price for collaboration revenue, accruals for research and development expenses, stock-based compensation and fair value measurements. These estimates and assumptions are based on current facts, historical experience and various other factors believed to be reasonable under the circumstances, the results of which form the basis for making judgments about the carrying values of assets and liabilities and the recording of revenues and expenses that are not readily apparent from other sources. The Company continues to use the best information available to update its accounting estimates. Actual results may differ materially and adversely from these estimates.

Fair Value Measurements

The accounting guidance defines fair value, establishes a consistent framework for measuring fair value and expands disclosure for each major asset and liability category measured at fair value on either a recurring or non-recurring basis. Fair value is defined as

an 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 such, fair value is a market-based measurement that should be determined based on assumptions that market participants would use in pricing an asset or liability. As a basis for considering such assumptions, the accounting guidance establishes a three-tier fair value hierarchy, which prioritizes the inputs used in measuring fair value as follows:

Level 1: Observable inputs such as quoted prices in active markets.

Level 2: Inputs, other than the quoted prices in active markets that are observable either directly or indirectly.

Level 3: Unobservable inputs in which there is little or no market data, which require the reporting entity to develop its own assumptions.

The carrying amounts of the Company's financial instruments, including cash and cash equivalents, restricted cash, accounts receivable, prepaid and other current assets, accounts payable, and accrued expenses, approximate fair value due to the short-term nature of those instruments. The fair value of assets classified within Level 1 is based on quoted prices in active markets as provided by the Company's investment managers. The fair value of short-term investments classified within Level 2 is based on standard observable inputs, including reported trades, broker/dealer quotes, and bids and/or offers. The Company validates the quoted market prices provided by its investment managers by comparing the investment managers' assessment of the fair values of the Company's investment portfolio balance against the fair values of the Company's investment portfolio balance obtained from an independent source. The Company has no financial liabilities recorded at fair value on a recurring basis. None of the Company's non-financial assets or liabilities are recorded at fair value on a non-recurring basis. No transfers between levels have occurred during the periods presented.

The following tables summarize the Company's financial instruments measured at fair value on a recurring basis (in thousands):

		Fair Value Measurements at Reporting Date Using		
	Total	Quoted Prices in Active Markets for Identical Assets (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)
As of December 31, 2023:				
Assets:				
Cash equivalents:				
Money market funds	$ 14,751	$ 14,751	$ —	$ —
Total cash equivalents	14,751	14,751	—	—
Short-term investments:				
U.S. Treasury securities	71,300	71,300	—	—
U.S. agency bonds	167,103	—	167,103	—
Asset-backed securities	5,055	—	5,055	—
Corporate debt securities	1,999	—	1,999	—
Commercial paper	79,366	—	79,366	—
Total short-term investments	324,823	71,300	253,523	—
Restricted cash:				
Money market account	816	816	—	—
Total restricted cash	816	816	—	—
Total assets measured at fair value on a recurring basis	$ 340,390	$ 86,867	$ 253,523	$ —

Janux Therapeutics, Inc.
Notes to Financial Statements - (Continued)

	Total	Fair Value Measurements at Reporting Date Using: Quoted Prices in Active Markets for Identical Assets (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)
As of December 31, 2022:				
Assets:				
Cash equivalents:				
Money market funds	$ 12,697	$ 12,697	$ —	$ —
Total cash equivalents	12,697	12,697	—	—
Short-term investments:				
U.S. Treasury securities	63,016	63,016	—	—
U.S. agency bonds	67,020	—	67,020	—
U.S. agency discount notes	4,334	—	4,334	—
Corporate debt securities	1,970	—	1,970	—
Commercial paper	139,250	—	139,250	—
Total short-term investments	275,590	63,016	212,574	—
Restricted cash:				
Money market account	816	816	—	—
Total restricted cash	816	816	—	—
Total assets measured at fair value on a recurring basis	$ 289,103	$ 76,529	$ 212,574	$ —

Cash and Cash Equivalents

The Company considers all highly liquid investments with original maturities of three months or less when purchased to be cash equivalents. Cash and cash equivalents include cash in readily available checking accounts and money market funds.

Restricted Cash

Restricted cash consists of a money market account securing a standby letter of credit issued in connection with the Company's Torrey Plaza operating lease (as defined and described in Note 3).

The following table provides a reconciliation of cash and cash equivalents and restricted cash reported within the accompanying balance sheets that sum to the amounts shown in the statements of cash flows (in thousands):

	December 31,	
	2023	2022
Cash and cash equivalents	$ 19,205	$ 51,426
Restricted cash	816	816
Total cash and cash equivalents and restricted cash	$ 20,021	$ 52,242

Short-Term Investments

Short-term investments consist of U.S. Treasury securities, U.S. agency bonds, U.S. agency discount notes, asset-backed securities, corporate debt securities and commercial paper, all of which are highly rated by Moody's, S&P, and Fitch. The Company has classified these investments as available-for-sale, as the sale of such investments may be required prior to maturity to implement management strategies, and therefore has classified all investment securities as current assets. Those investments with maturity dates of three months or less at the date of purchase are presented as cash equivalents in the accompanying balance sheets. Short-term investments are carried at fair value with the unrealized gains and losses included in accumulated other comprehensive income (loss) as a component of stockholders' equity until realized. Any premium or discount arising at purchase is amortized or accreted to interest income as an adjustment to yield using the straight-line method over the life of the instrument. The Company records an allowance for

credit losses when unrealized losses are due to credit-related factors. Realized gains and losses are calculated using the specific identification method and recorded as interest income.

The following tables summarize short-term investments (in thousands):

	As of December 31, 2023			
	Amortized Cost	Unrealized Gains	Unrealized Losses	Estimated Fair Value
U.S. Treasury securities	$ 71,072	$ 242	$ (14)	$ 71,300
U.S. agency bonds	166,699	591	(187)	167,103
Asset-backed securities	5,078	—	(23)	5,055
Corporate debt securities	1,999	—	—	1,999
Commercial paper	79,310	56	—	79,366
Total	$ 324,158	$ 889	$ (224)	$ 324,823

	As of December 31, 2022			
	Amortized Cost	Unrealized Gains	Unrealized Losses	Estimated Fair Value
U.S. Treasury securities	$ 63,675	$ —	$ (659)	$ 63,016
U.S. agency bonds	67,421	—	(401)	67,020
U.S. agency discount notes	4,321	13	—	4,334
Corporate debt securities	1,975	—	(5)	1,970
Commercial paper	139,733	26	(509)	139,250
Total	$ 277,125	$ 39	$ (1,574)	$ 275,590

The amortized cost and estimated fair value in the tables above exclude $

2.2
million and $

0.7
million of accrued interest receivable as of December 31, 2023 and 2022, respectively. Accrued interest receivable is included in prepaid expenses and other current assets in the accompanying balance sheets.

Contractual maturities of available-for-sale debt securities are as follows (in thousands):

	As of December 31, 2023	
	Due in 1 Year or Less	Due Between 1 and 3 Years
U.S. Treasury securities	$ 34,426	$ 36,874
U.S. agency bonds	89,801	77,302
Asset-backed securities	5,055	—
Corporate debt securities	1,999	—
Commercial paper	79,366	—
Total	$ 210,647	$ 114,176

	As of December 31, 2022	
	Due in 1 Year or Less	Due Between 1 and 3 Years
U.S. Treasury securities	$ 57,369	$ 5,647
U.S. agency bonds	37,202	29,818
U.S. agency discount notes	4,334	—
Corporate debt securities	—	1,970
Commercial paper	139,250	—
Total	$ 238,155	$ 37,435

As of December 31, 2023,

15
out of

45
of our available-for-sale debt securities were in an aggregate gross unrealized loss position. The Company relies on both qualitative and quantitative factors to determine whether the unrealized loss for each available-for-sale debt security at any balance sheet date is due to a credit loss. Qualitative factors may include a credit downgrade, severity of the decline in fair value below amortized cost and other adverse conditions related specifically to the security, as well as the intent to sell the security, or whether the Company will “more likely than not” be required to sell the security before recovery of its amortized cost basis. The Company considers the decline in market value for the securities to be primarily attributable to current economic conditions and interest rate adjustments, rather than credit-related factors and does not intend to sell any securities prior to maturity.

No

allowance for credit losses has been recorded as of December 31, 2023 or December 31, 2022.

The following tables summarize our available-for-sale debt securities in an unrealized loss position for which an allowance for credit losses has not been recorded, aggregated by major security type and length of time in a continuous unrealized loss position (in thousands):

	As of December 31, 2023					
	Less Than 12 Months		12 Months or Longer		Total	
	Fair Value	Unrealized Losses	Fair Value	Unrealized Losses	Fair Value	Unrealized Losses
U.S. Treasury securities	$ 5,892	$ (14)	$ —	$ —	$ 5,892	$ (14)
U.S. agency bonds	63,583	(169)	9,970	(18)	73,553	(187)
Asset-backed securities	5,055	(23)	—	—	5,055	(23)
Total	$ 74,530	$ (206)	$ 9,970	$ (18)	$ 84,500	$ (224)

	As of December 31, 2022					
	Less Than 12 Months		12 Months or Longer		Total	
	Fair Value	Unrealized Losses	Fair Value	Unrealized Losses	Fair Value	Unrealized Losses
U.S. Treasury securities	$ 15,566	$ (82)	$ 47,450	$ (577)	$ 63,016	$ (659)
U.S. agency bonds	67,020	(401)	—	—	67,020	(401)
Corporate debt securities	1,970	(5)	—	—	1,970	(5)
Commercial paper	118,840	(509)	—	—	118,840	(509)

Total	$ 203,396	$ 997)	$ 47,450	$ 577)	$ 250,846	$ 1,574)

Concentrations of Credit Risk

Financial instruments that potentially subject the Company to significant concentrations of credit risk consist primarily of cash, cash equivalents and short-term investments. The Company invests its cash reserves in money market funds or available-for-sale debt securities in accordance with its investment policy. The Company's investment policy includes guidelines on acceptable investment securities, limits interest-bearing security investments to certain types of debt and money market instruments issued by the U.S. government and institutions with investment grade credit ratings and places restrictions on maturities and concentration by asset class and issuer in order to maintain appropriate diversification. In accordance with the Company's policies, the Company monitors exposure with its counterparties. The Company also maintains deposits in federally insured financial institutions in excess of federally insured limits. The Company has not experienced any losses in such account and management believes that the Company is not exposed to significant credit risk.

The Company is also subject to credit risk from its accounts receivable. The Company generally does not perform evaluations of customers' financial condition and generally does not require collateral. For the years ended December 31, 2023 and 2022, all of the Company's revenue related to a single customer.

Property and Equipment, Net

Property and equipment, net consists of laboratory equipment, furniture and fixtures and computer equipment and software. Property and equipment is stated at cost and depreciated over the estimated useful lives of the assets (generally five years) using the straight-line method. Repairs and maintenance costs are charged to expense as incurred.

An impairment loss is recorded if and when events and circumstances indicate that assets might be impaired and the undiscounted cash flows estimated to be generated by those assets are less than the carrying amount of those assets. The Company has not recognized any impairment losses through December 31, 2023.

Deferred Revenue

When the Company is entitled to bill its customers and receive payment from its customers in advance of its obligation to provide services or transfer goods to its customers, the Company includes the amounts in deferred revenue on its balance sheets. For further discussion, refer to the Company's revenue recognition policy below.

Leases

The Company determines if a contract contains a lease at the inception of the contract and evaluates each lease agreement to determine whether the lease is an operating or finance lease. For leases where the Company is the lessee, right-of-use ("ROU") assets represent the Company's right to use an underlying asset for the lease term and lease liabilities represent an obligation to make lease payments arising from the lease. Liabilities from operating leases are included in current portion of operating lease liabilities, and operating lease liabilities, net of current portion on the accompanying balance sheets. The Company does not have any financing leases. Short-term leases with an initial term of 12 months or less are not recorded on the balance sheet. The Company does not have material short-term lease costs.

Lease liabilities are measured at the present value of the lease payments not yet paid discounted using the discount rate for the lease established at the lease commencement date. To determine the present value, the implicit rate is used when readily determinable. For those leases where the implicit rate is not provided, the Company determines an incremental borrowing rate ("IBR") based on the information available at the lease commencement date in determining the present value of lease payments. The IBR is the rate of interest that a lessee would have to pay to borrow on a collateralized basis over a similar term an amount equal to the lease payments in a similar economic environment. ROU assets are measured as the present value of the lease payments and also include any prepaid lease payments made and any other indirect costs incurred, and exclude any lease incentives received. Lease terms may include the impact of options to extend or terminate the lease when it is reasonably certain that the Company will exercise that option. Lease expense for operating leases is recognized on a straight-line basis over the lease term. The Company's operating leases are subject to additional variable charges, including common area maintenance, property taxes, property insurance and other variable costs. Given the variable nature of such costs, they are recognized as expense as incurred. The Company has elected the practical expedient to account for the lease and non-lease components, such as common area maintenance charges, as a single lease component for the Company's facilities leases. The Company has elected to recognize lease incentives, such as tenant improvement allowances, at the lease commencement date as a reduction to the ROU asset and lease liabilities balance until paid to it by the lessor to the extent that the lease provides a specified fixed or maximum level of reimbursement and the Company is reasonably certain to incur reimbursable costs at least equaling such amounts.

Revenue Recognition

The Company recognizes revenue in a manner that depicts the transfer of control of a product or a service to a customer and reflects the amount of the consideration the Company is entitled to receive in exchange for such product or service. In doing so, the Company follows a five-step approach: (i) identify the contract with a customer, (ii) identify the performance obligations in the contract, (iii) determine the transaction price, (iv) allocate the transaction price to the performance obligations, and (v) recognize revenue when (or as) the customer obtains control of the product or service. The Company considers the terms of a contract and all relevant facts and circumstances when applying the revenue recognition standard.

A customer is a party that has entered into a contract with the Company, where the purpose of the contract is to obtain a product or a service that is an output of the Company's ordinary activities in exchange for consideration. To be considered a contract, (i) the contract must be approved (in writing, orally, or in accordance with other customary business practices), (ii) each party's rights regarding the product or the service to be transferred can be identified, (iii) the payment terms for the product or the service to be transferred can be identified, (iv) the contract must have commercial substance (that is, the risk, timing or amount of future cash flows is expected to change as a result of the contract), and (v) it is probable that the Company will collect substantially all of the consideration to which it is entitled to receive in exchange for the transfer of the product or the service.

A performance obligation is defined as a promise to transfer a product or a service to a customer. The Company identifies each promise to transfer a product or a service (or a bundle of products or services, or a series of products and services that are substantially the same and have the same pattern of transfer) that is distinct. A product or a service is distinct if both (i) the customer can benefit from the product or the service either on its own or together with other resources that are readily available to the customer and (ii) the

Company's promise to transfer the product or the service to the customer is separately identifiable from other promises in the contract. Each distinct promise to transfer a product or a service is a unit of accounting for revenue recognition. If a promise to transfer a product or a service is not separately identifiable from other promises in the contract, such promises should be combined into a single performance obligation.

The transaction price is the amount of consideration the Company is entitled to receive in exchange for the transfer of control of a product or a service to a customer. To determine the transaction price, the Company considers the existence of any significant financing component, the effects of any variable elements, noncash considerations and consideration payable to the customer. If a significant financing component exists, the transaction price is adjusted for the time value of money. If an element of variability exists, the Company must estimate the consideration it expects to receive and uses that amount as the basis for recognizing revenue as the product or the service is transferred to the customer. There are two methods for determining the amount of variable consideration: (i) the expected value method, which is the sum of probability-weighted amounts in a range of possible consideration amounts, and (ii) the mostly likely amount method, which identifies the single most likely amount in a range of possible consideration amounts.

With respect to variable consideration relating to development and regulatory milestone payments, if it is probable that a significant revenue reversal would not occur, the associated payment value is included in the transaction price. For development and regulatory milestones that are uncertain in nature and highly dependent on factors outside of our control, the aggregate consideration is determined to be fully constrained and is not included in the transaction price until the underlying events occur or the associated approvals are received. At the end of each reporting period, the Company re-evaluates the probability of achievement of each milestone and any related constraint, and if necessary, adjust our estimate of the overall transaction price. Any such adjustments are recorded on a cumulative catch-up basis, which would affect the reported amount of revenues in the period of adjustment.

For arrangements that include sales-based royalties, including milestone payments based on a level of sales, and the license is deemed to be the predominant item to which the royalties relate, the Company recognizes 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).

If a contract has multiple performance obligations, the Company allocates the transaction price to each distinct performance obligation in an amount that reflects the consideration the Company is entitled to receive in exchange for satisfying each distinct performance obligation. For each distinct performance obligation, revenue is recognized when (or as) the Company transfers control of the product or the service applicable to such performance obligation.

In those instances where the Company first receives consideration in advance of satisfying its performance obligation, the Company classifies such consideration as deferred revenue until (or as) the Company satisfies such performance obligation. In those instances where the Company first satisfies its performance obligation prior to its receipt of consideration, the consideration is recorded as accounts receivable.

The Company expenses incremental costs of obtaining and fulfilling a contract as and when incurred if the expected amortization period of the asset that would be recognized is one year or less, or if the amount of the asset is immaterial. Otherwise, such costs are capitalized as contract assets if they are incremental to the contract and amortized to expense proportionate to revenue recognition of the underlying contract.

Research and Development Expenses

All research and development costs are expensed in the period incurred. Payments for these activities are based on the terms of the individual agreements, which may differ from the pattern of costs incurred, and payments made in advance of performance are reflected in the accompanying balance sheets as prepaid expenses. The Company records accruals for estimated costs incurred for ongoing research and development activities. When evaluating the adequacy of the accrued expenses, the Company analyzes progress of the services, including the phase or completion of events, invoices received and contracted costs. Significant judgments and estimates may be made in determining the prepaid or accrued balances at the end of any reporting period. Actual results could differ from the Company's estimates.

Patent Costs

Costs related to filing and pursuing patent applications are recorded as general and administrative expense and expensed as incurred since recoverability of such expenditures is uncertain.

Stock-Based Compensation

Janux Therapeutics, Inc.
Notes to Financial Statements - (Continued)

Stock-based compensation expense represents the grant date fair value of equity awards, consisting of stock options and employee stock purchase rights, recognized on a straight-line basis over the requisite service period for stock options and over the respective offering period for employee stock purchase plan rights. The Company estimates the fair value of equity awards using the Black-Scholes option pricing model and recognizes forfeitures as they occur.

Income Taxes

The Company accounts for income taxes under the asset and liability method, which requires the recognition of deferred tax assets and liabilities for the expected future tax consequences of events that have been included in the financial statements. Under this method, deferred tax assets and liabilities are determined on the basis of the differences between the financial statement and tax basis of assets and liabilities using enacted tax rates in effect for the year in which the differences are expected to reverse. The effect of a change in tax rates on deferred tax assets and liabilities is recognized in income in the period that includes the enactment date.

The Company recognizes net deferred tax assets to the extent that the Company believes these assets are more likely than not to be realized. In making such a determination, management considers all available positive and negative evidence, including future reversals of existing taxable temporary differences, projected future taxable income, tax-planning strategies, and results of recent operations. If management determines that the Company would be able to realize its deferred tax assets in the future in excess of their net recorded amount, management would make an adjustment to the deferred tax asset valuation allowance, which would reduce the provision for income taxes.

The Company records uncertain tax positions on the basis of a two-step process whereby (1) management determines whether it is more likely than not that the tax positions will be sustained on the basis of the technical merits of the position and (2) for those tax positions that meet the more-likely-than-not recognition threshold, management recognizes the largest amount of tax benefit that is more than 50 percent likely to be realized upon ultimate settlement with the related tax authority. The Company recognizes interest and penalties related to unrecognized tax benefits within income tax expense. Any accrued interest and penalties are included within the related tax liability.

Comprehensive Loss

Comprehensive loss is defined as a change in equity during a period from transactions and other events and circumstances from non-owner sources. The only component of other comprehensive loss is unrealized gain (loss) on available-for-sale securities. Comprehensive losses have been reflected in the statements of operations and comprehensive loss and as a separate component in the statements of stockholders' equity.

Segment Reporting

Operating segments are identified as components of an enterprise about which separate discrete financial information is available for evaluation by the chief operating decision maker, or decision-making group, in making decisions on how to allocate resources and assess performance. The Company views its operations and manages its business as

one
operating segment.

No
product revenue has been generated since inception and all assets are held in the United States.

Net Loss Per Share

Basic net loss per share is computed by dividing the net loss by the weighted-average number of shares of common stock outstanding for the period, including pre-funded common stock warrants that were issued in an underwritten offering in July 2023 (Note 5), without consideration for potentially dilutive securities. The pre-funded common stock warrants are included in the calculation of basic and diluted net loss per share as the exercise price of $

0.001
per share is non-substantive and the shares are issuable for little or no consideration. The Company has excluded weighted-average unvested shares of

27,458
shares and

182,194
shares from the weighted-average number of shares of common stock outstanding for the years ended December 31, 2023 and 2022, respectively. Diluted net loss per share is computed by dividing the net loss by the weighted-average number of shares of common stock and dilutive common stock equivalents outstanding for the period determined using the treasury-stock and if-converted methods. For all periods presented, there is no difference in the number of shares used to calculate basic and diluted shares outstanding as inclusion of the potentially dilutive securities would be anti-dilutive.

Potentially dilutive securities not included in the calculation of diluted net loss per share, because to do so would be anti-dilutive, are as follows (in common stock equivalent shares):

	December 31,	
	2023	2022
Common stock options	7,989,192	7,345,444
Unvested common stock	10,319	68,406
Employee stock purchase plan shares	13,796	10,423
Total potentially dilutive shares	8,013,307	7,424,273

Emerging Growth Company Status

The Company is an emerging growth company, as defined in the Jumpstart Our Business Startups Act of 2012 ("JOBS Act"). Under the JOBS Act, emerging growth companies can delay adopting new or revised accounting standards issued subsequent to the enactment of the JOBS Act until such time as those standards apply to private companies. The Company has irrevocably elected not to avail itself of this exemption from new or revised accounting standards and, therefore, will be subject to the same new or revised accounting standards as other public companies that are not emerging growth companies.

Accounting Pronouncements Pending Adoption

In December 2023, the FASB issued ASU 2023-07, Segment Reporting (Topic 280) - Improvements to Reportable Segment Disclosures. The new standard requires a company to disclose incremental segment information on an annual and interim basis, including significant segment expenses and measures of profit or loss that are regularly provided to the chief operating decision maker (CODM). The standard is effective for the Company beginning in fiscal year 2024 and interim periods within fiscal year 2025, with early adoption permitted. The Company does not expect to early adopt the new standard. The Company is currently evaluating the impact of ASU 2023-07 on the financial statements and related disclosures and will adopt the new standard using a retrospective approach.

In December 2023, the FASB also issued ASU 2023-09, Income Taxes (Topic 740) - Improvements to Income Tax Disclosures. The new standard requires a company to expand its existing income tax disclosures, specifically related to the rate reconciliation and income taxes paid. The standard is effective for the Company beginning in fiscal year 2025, with early adoption permitted. The Company does not expect to early adopt the new standard. The new standard is expected to be applied prospectively, but retrospective application is permitted. The Company is currently evaluating the impact of ASU 2023-09 on the financial statements and related disclosures.

2. Balance Sheet Details

Property and equipment, net consist of the following (in thousands):

	December 31,	
	2023	2022
Laboratory equipment	$ 8,454	$ 6,838
Furniture and fixtures	792	752
Computer equipment and software	628	323
Assets not placed in service	43	145
Total property and equipment	9,917	8,058
Less: accumulated depreciation	(2,914)	(972)

Property and equipment, net		
	$ 7,003	$ 7,086

Accrued expenses consist of the following (in thousands):

	December 31,	
	2023	2022
Accrued compensation		
	$ 3,303	$ 2,671
Accrued research and development		
	3,535	4,716
Other accrued expenses		
	529	623
Unvested stock liabilities		
	20	169
Accrued expenses		
	$ 7,387	$ 8,179

Janux Therapeutics, Inc.
Notes to Financial Statements - (Continued)

3. Commitments and Contingencies

License Agreement with WuXi Biologics (Hong Kong) Limited

In April 2021, the Company entered into a cell line license agreement ("Cell Line License Agreement") with WuXi Biologics (Hong Kong) Limited ("WuXi Biologics"), pursuant to which the Company received a non-exclusive, worldwide, sublicensable license under certain of WuXi Biologics' patent rights, know-how and biological materials ("WuXi Biologics Licensed Technology"), to use the WuXi Biologics Licensed Technology to make, use, sell, offer for sale and import certain therapeutic products produced through the use of the cell line licensed by WuXi Biologics under the Cell Line License Agreement ("WuXi Biologics Licensed Product").

In consideration for the license, the Company paid WuXi Biologics a non-refundable, one-time license fee of $ 0.2 million upon WuXi Biologics' achievement of a certain technical milestone. This one-time license fee was recognized as research and development expense when incurred since the WuXi Biologics Licensed Technology had no alternative future use. If the Company does not engage WuXi Biologics or its affiliates to manufacture the WuXi Biologics Licensed Products for its commercial supplies, the Company is required to make royalty payments to WuXi Biologics in an amount equal to a low single-digit percentage of specified portions of net sales of WuXi Biologics Licensed Products manufactured by a third-party manufacturer. The Company has the right (but not the obligation) to buy out its remaining royalty obligations with respect to each WuXi Biologics Licensed Product by paying WuXi Biologics a one-time payment in an amount ranging from low single digit million dollars to a maximum of $ 15.0 million depending on the development and commercialization stage of the WuXi Biologics Licensed Product (the "Buyout Option"), and upon such payment, the Company's license with respect to such WuXi Biologics Licensed Product will become fully paid-up, irrevocable, and perpetual. The royalty obligations will remain in effect during the term of the Cell Line License Agreement so long as the Company has not exercised the Buyout Option.

The Cell Line License Agreement will continue indefinitely unless terminated (i) by the Company upon three months' prior written notice and the Company's payment of all amounts due to WuXi Biologics through the effective date of termination, (ii) by either party for the other party's material breach that remains uncured for 30 days after written notice, and (iii) by WuXi Biologics if the Company fails to make a payment and such failure continues for 30 days after receiving notice of such failure.

Operating Leases

In October 2021, the Company entered into a lease agreement (the "Torrey Plaza Lease") to lease office and laboratory space in San Diego, California. The Company determined this facilities lease was an operating lease at the inception of the lease contract. According to accounting standards, the Torrey Plaza Lease commenced on April 1, 2022 and has a term of 130 months from the commencement date. The Torrey Plaza Lease provides an option to extend the term of the lease for a period of 5 years beyond the initial term, which the Company is not reasonably certain to exercise and therefore was not considered in determining the ROU assets and lease liabilities balance.

As required under the terms of the Torrey Plaza Lease, in October 2021 the Company entered into a standby letter of credit, which is secured by a money market account in the amount of $ 0.8 million. The letter of credit is subject to draw down by the landlord upon certain events of breach or default by the Company. The letter of credit amount is subject to a 50 % reduction subject to certain conditions on or following the date that is 54 months following the contractual lease commencement date.

Future minimum noncancelable operating lease payments as of December 31, 2023 are as follows (in thousands):

2024	3,403
2025	3,505
2026	3,611
2027	3,719
2028	3,830
Thereafter	16,872
Total minimum lease payments	34,940

Less: Imputed interest	(10,398)
Total operating lease liabilities	24,542
Less: Current portion of operating lease liabilities	(1,517)
Operating lease liabilities, net of current portion	$ 23,025

The Torrey Plaza lease has a remaining lease term of 9.1 years and a discount rate of

8
% as of December 31, 2023. Operating lease expense included in the measurement of lease liabilities for year ended December 31, 2023 was $

3.4
million. Cash paid for amounts included in the measurement of lease liabilities for the year ended December 31, 2023 was $

2.8
million. Operating lease expense included in the measurement of lease liabilities for year ended December 31, 2022 was $

2.8
million. Cash paid for amounts included in the measurement of lease liabilities for the year ended December 31, 2022 was $

0.2
million.

Contingencies

From time to time, the Company may be subject to claims or lawsuits arising in the ordinary course of business. The Company accrues a liability for such matters when it is probable that future expenditures will be made and such expenditures can be reasonably estimated. As of December 31, 2023, the Company is not currently party to any material legal proceedings.

4. Related Party Transactions

In January 2021, the Company entered into a Support Services Agreement (the “2021 Support Services Agreement”) with Avalon BioVentures, Inc. ("Avalon") that outlines the terms of services provided by Avalon to the Company, as well as the fees charged for such services. Avalon is a shared service company that provides certain back-office and administrative and research and development support services, including facilities support, to the portfolio companies of Avalon Ventures, an entity that beneficially owns greater than

5
% of our outstanding capital stock. The 2021 Support Services Agreement was most recently renewed in January 2024 and will continue to renew for additional one-year renewal periods until terminated by the parties. Either party may terminate the 2021 Support Services Agreement with 30 days written notice.

Operating expense recognized by the Company under the 2021 Support Services Agreement for the year ended December 31, 2023 was immaterial. The Company recognized $

0.5
million of research and development expenses and $

0.1
million of general and administrative expenses under the 2021 Support Services Agreement for the year ended December 31, 2022.

5. Stockholders’ Equity

Shelf Registration Statement

In August 2022, the Company filed a shelf registration statement (File No. 333-266720), which was declared effective in September 2022. The shelf registration statement provides the Company with the ability to offer up to $

400.0
million of certain securities, including shares of its common stock, from time to time. The specific terms of any offering under the shelf registration statement are established at the time of such offering.

In August 2022, the Company entered into an Open Market Sale Agreement℠ (“Sale Agreement”) with Jefferies LLC (“Jefferies”) to sell shares of common stock, from time to time, through an “at the market offering” program having an aggregate offering price of up to $

100.0
million through which Jefferies would act as sales agent. In May 2023 , the Company terminated the Sale Agreement.

In May 2023, the Company entered into an ATM Equity Offering℠ Sales Agreement (“New Sale Agreement”) with BofA Securities, Inc. (“BofA”) to sell shares of common stock, from time to time, through an “at the market offering” program having an aggregate offering price of up to $

150.0
million through which BofA would act as sales agent. There was no activity from the New Sale Agreement during the year ended December 31, 2023. As of December 31, 2023, $

150.0
million of common stock remained available for sale under the New Sale Agreement. In February 2024, the Company delivered written notice to BofA that it was suspending and terminating the prospectus related to the shares of its common stock issuable pursuant to the terms of the New Sale Agreement. As a result, the Company will not make any sales of its securities pursuant to the New Sale Agreement, unless and until a new prospectus, prospectus supplement, or a new registration statement relating to the shares of its common stock is filed. Other than the termination of the prospectus, the New Sale Agreement remains in full force and effect.

In July 2023, the Company closed an underwritten offering of

4,153,717
shares of its common stock and pre-funded warrants to purchase

583,483
shares of common stock at an exercise price of $

0.001
per share. The shares of common stock were sold at a price of $

12.46
per share and the pre-funded common stock warrants were sold at a price of $

12.459
per pre-funded common stock warrant, resulting in gross proceeds of $

59.0
million. Fees related to the offering included underwriting discounts, commissions, and offering expenses in the aggregate amount of $

2.5
million, resulting in net proceeds of $

56.5
million. The pre-funded common stock warrants will not expire until exercised in full and are exercisable in cash or by means of a cashless exercise.

The Company has assessed the pre-funded common stock warrants for appropriate equity or liability classification. The pre-funded common stock warrants are equity classified because they (i) are freestanding financial instruments that are legally detachable and separately exercisable from the equity instruments, (ii) are immediately exercisable, (iii) do not embody an obligation for the Company to repurchase its shares, (iv) permit the holders to receive a fixed number of shares of common stock upon exercise, (v) are indexed to the Company's common stock and (vi) meet the equity classification criteria.

In addition, such pre-funded common stock warrants do not provide any guarantee of value or return and do not provide the warrant holders with the option to settle any unexercised warrants for cash outside of the Company's control. The pre-funded common stock warrants also include a separate provision whereby the exercisability of the warrants may be limited if, upon exercise, the warrant holder or any of its affiliates would beneficially own more than

19.9

% of the Company's outstanding common stock. The Company valued the pre-funded common stock warrants at issuance, concluding that their sale price approximated their fair value. Accordingly, the pre-funded common stock warrants are accounted for as a component of additional paid-in capital at the time of issuance.

2017 Equity Incentive Plan

In August 2017, the Company adopted the Janux Therapeutics, Inc. 2017 Equity Incentive Plan (the "2017 Plan"), which provided for the grant of incentive stock options, nonstatutory stock options, restricted stock awards and other stock awards to its employees, members of its board of directors and consultants. The maximum term of options granted under the 2017 Plan is ten years and, in general, the options issued under the 2017 Plan vest over a four-year period from the vesting commencement date. The 2017 Plan allows for the early exercise of stock options, which may be subject to repurchase by the Company at the original exercise price. Upon the effectiveness of the 2021 Plan defined and described below, no further grants will be made under the 2017 Plan. Any outstanding awards granted under the 2017 Plan will remain subject to the terms of the 2017 Plan and applicable award agreements.

2021 Equity Incentive Plan

In June 2021, the Company adopted the 2021 Equity Incentive Plan (the "2021 Plan," and together with the 2017 Plan the "Plans"). Under the 2021 Plan, the Company may grant stock options, stock appreciation rights, restricted stock, restricted stock units, performance stock awards, performance cash awards and other forms of stock awards to employees, directors and consultants. The maximum term of options granted under the 2021 Plan is ten years and, in general, the options issued under the 2021 Plan vest over a four-year period from the vesting commencement date. The 2021 Plan does not permit early exercises. A total of

2,775,890

new shares of common stock were initially reserved for issuance under the 2021 Plan. The number of shares reserved that were remaining under the 2017 Plan as of the effective date of the 2021 Plan, or

1,424,110

shares, were added to the shares initially reserved under the 2021 Plan upon its effectiveness and any future cancellations under the 2017 Plan will become available for future issuance under the 2021 Plan. In addition, the number of shares of common stock available for issuance under the 2021 Plan automatically increases on January 1 of each calendar year through January 1, 2031, in an amount equal to 5% of the total number of shares of the Company's common stock on the last day of the calendar month before the date of each automatic increase, or a lesser number of shares determined by the Company's board of directors. As of December 31, 2023, there were

9,169,849

shares authorized for issuance under the 2021 Plan, inclusive of shares added from 2017 Plan cancellations.

A summary of the Company's stock option activity under its Plans is as follows (in thousands, except share, per share data and years):

	Number of Outstanding Options	Weighted-Average Exercise Price	Weighted-Average Remaining Contractual Term (in years)	Aggregate Intrinsic Value
Balance at December 31, 2022	7,345,444	$ 11.67	8.3	$ 29,806
Granted	2,019,450	$ 13.80		
Exercised	(253,545)	$ 8.86		
Forfeited or cancelled	(1,122,157)	$ 13.25		

Balance at December 31, 2023				
	7,989,192	$ 12.08	7.8	$ 16,733
Vested and expected to vest at December 31, 2023				
	7,989,192	$ 12.08	7.8	$ 16,733
Exercisable at December 31, 2023				
	5,226,145	$ 9.89	7.3	$ 16,596

The weighted-average grant date fair value of option grants for the years ended December 31, 2023 and 2022 was $ 10.02 and $ 12.35, respectively. The total intrinsic value of stock options exercised for the years ended December 31, 2023 and 2022 was $ 1.9 million and $ 0.1 million, respectively. As of December 31, 2023, total unrecognized stock-based compensation cost associated with option grants was $ 34.1 million, which is expected to be recognized over a remaining weighted-average period of approximately 2.2 years.

The assumptions used in the Black-Scholes option pricing model to determine the fair value of stock option grants under the Plans were as follows:

	Year Ended December 31,	
	2023	2022
Risk-free interest rate		
	3.5% – 4.7%	1.5% – 4.2%
Expected volatility		
	82% – 87%	81% – 85%
Expected term (in years)		
	5.3 – 6.1	5.3 – 6.1
Expected dividend yield		
	—	—

Risk-free interest rate. The risk-free interest rate is based on the U.S. Treasury yield in effect at the time of grant for zero coupon U.S. Treasury notes with maturities similar to the expected term of the awards.

Expected volatility. Given the Company's limited historical stock price volatility data, the expected volatility assumption is based on volatilities of a peer group of similar companies whose share prices are publicly available, including the Company's historical volatility, weighted by years of available trading data within the expected term. The peer group was developed based on companies in the biotechnology industry. The Company will continue to apply this process until a sufficient amount of historical information regarding the volatility of its own stock price becomes available.

Expected term. The expected term represents the period of time that options are expected to be outstanding. Because the Company does not have sufficient historical exercise behavior to provide a reasonable basis upon which to estimate the expected term, it determines the expected life assumption using the simplified method, for employees, which is an average of the contractual term of the option and its vesting period. The expected term for nonemployee options is generally the contractual term.

Expected dividend yield. The Company bases the expected dividend yield assumption on the fact that it has never paid cash dividends and has no present intention to pay cash dividends and, therefore, used an expected dividend yield of zero.

2021 Employee Stock Purchase Plan

In June 2021, the Company adopted the 2021 Employee Stock Purchase Plan (the "ESPP"), which became effective on June 10, 2021. The ESPP permits eligible employees who elect to participate in an offering under the ESPP to have up to 15% of their eligible earnings withheld, subject to certain limitations, to purchase shares of common stock pursuant to the ESPP. The price of common stock purchased under the ESPP is equal to 85% of the lower of the fair market value of the common stock at the commencement date of each offering period or the relevant date of purchase. A total of 466,000 shares of common stock were approved to be initially reserved for issuance under the ESPP. In addition, the number of shares of common stock available for issuance under the ESPP automatically increases on January 1 of each calendar year through January 1, 2031, in an amount equal to the

lesser of (i)

1
% of the total number of shares of the Company's common stock on the last day of the calendar month before the date of each automatic increase and (ii)

932,000
shares; provided that before the date of any such increase, the Company's board of directors may determine that such increase will be less than the amount set forth in clauses (i) and (ii). In June 2021, employees began to enroll in the ESPP and the Company's first offering period commenced. Stock-based compensation expense related to the ESPP was $

0.9
million and $

0.6
million for the years ended December 31, 2023 and 2022, respectively. As of December 31, 2023, total unrecognized stock-based compensation expense related to the ESPP was $

0.7
million, which is expected to be recognized over a remaining weighted-average period of approximately 1.6 years.

Stock-Based Compensation Expense

Stock-based compensation expense has been reported in the statements of operations and comprehensive loss as follows (in thousands):

	Year Ended December 31, 2023	2022
Research and development	$ 7,873	$ 7,235
General and administrative	12,132	9,968
Total	$ 20,005	$ 17,203

Unvested Stock Liabilities

A summary of the Company's unvested shares and unvested stock liabilities is as follows (in thousands, except share data):

	Number of Unvested Shares	Weighted-Average Grant Date Fair Value	Unvested Stock Liabilities
Balance at December 31, 2022	68,406	$ 1.94	$ 169
Vested shares	(58,087)	$ 2.00	(149)
Balance at December 31, 2023	10,319	$ 1.57	$ 20

Common Stock Reserved for Future Issuance

Common stock reserved for future issuance consists of the following:

	December 31, 2023	2022
Common stock options outstanding	7,989,192	7,345,444
Shares available for issuance under the Plans	5,198,941	4,012,001
Shares available for issuance under the ESPP	1,142,750	816,478
Pre-funded common stock warrants	503,226	—
Total	14,834,109	12,173,923

6. Research Collaboration and Exclusive License Agreement

In December 2020, the Company entered into a research collaboration and exclusive license agreement (the "Merck Agreement"), pursuant to which the Company granted Merck Sharp & Dohme Corp. ("Merck") an exclusive, worldwide, royalty-bearing, sublicensable license to certain of its patent rights and know-how for up to

two

collaboration targets (“First Collaboration Target” and “Second Collaboration Target”, together the “Collaboration Targets”) related to next generation T cell engager immunotherapies for the treatment of cancer. In each case, once the Collaboration Targets are designated by Merck, they have the right to research, develop, make, have made, use, import, offer to sell, and sell compounds and any licensed products related thereto. Merck selected the First Collaboration Target upon execution of the Merck Agreement and selected the Second Collaboration Target in May 2022. Following the research term, Merck will have the sole right to research, develop, manufacture, and commercialize the licensed compounds and products directed against the Collaboration Targets. Consideration in the Merck Agreement consists of (i) an $

8.0

million non-refundable and non-creditable upfront fee, (ii) $

8.0

million paid upon the selection of the Second Collaboration Target, (iii) research program funding (iv) development and regulatory milestones, (v) commercial milestones, and (vi) royalty payments. Under the Merck Agreement, the Company is eligible to receive up to an aggregate of $

142.5

million per Collaboration Target in milestone payments ($

285.0

million collectively for both Collaboration Targets), contingent on the achievement of certain regulatory and development milestones. Merck is also required to make milestone payments to the Company upon the successful completion of certain commercial milestones, in an aggregate amount not to exceed $

350.0

million for each licensed product under either of the Collaboration Targets. The Merck Agreement provides that Merck is obligated to pay to the Company tiered royalty payments on a product-by-product and country-by-country basis, ranging from low single-digit to low teens percentage royalty rates on specified portions of annual net sales for licensed products under either of the Collaboration Targets that are commercialized. Such royalties are subject to reduction, on a product-by-product and country-by-country basis, for licensed products not covered by patent claims, or that

require Merck to obtain a license to obtain a license to third-party intellectual property in order to commercialize the licensed products, or that are subject to compulsory licensing.

The Merck Agreement will terminate at the end of the calendar year in which the expiration of all royalty obligations occurs for all licensed products under the agreement. Merck has the unilateral right to terminate the Merck Agreement in its entirety or on a Collaboration Target by Collaboration Target basis at any time and for any reason upon prior written notice to the Company. Both parties have the right to terminate the agreement for an uncured material breach, certain illegal or unethical activities, and insolvency of the other party. Upon expiration of the agreement but not early termination thereof, and provided all payments due under the agreement have been made, Merck's exclusive licenses under the agreement will become fully paid-up and perpetual.

The Company concluded that Merck represented a customer and has accounted for the initial units of account in accordance with FASB's Accounting Standards Codification 606, Revenue from Contracts with Customers ("ASC 606"). As it relates to Merck's option to select a Second Collaboration Target, which was exercised in May 2022, the Company concluded that this option represented a customer option to purchase additional goods or services that is not a material right and, therefore, is accounted for as a separate contract and separate performance obligation to purchase the additional goods or services.

The Company identified its performance obligations under the Merck Agreement and each Collaboration Target as the grant to Merck of an exclusive license to certain of its intellectual property subject to certain conditions, its conduct of research services and the Company's participation in a joint research committee. The Company determined that these performance obligations should be accounted for as one combined performance obligation for each Collaboration Target since they are not distinct. The Company also determined that the combined performance obligation for each Collaboration Target is transferred over the expected term of the conduct of the research services.

In accordance with ASC 606, the Company determined that the initial transaction price under the Merck Agreement for the First Collaboration Target is $

11.4
million, consisting of the upfront, non-refundable and non-creditable payment of $

8.0
million and the aggregate estimated reimbursable research program funding of $

3.4
million. The Company determined that the initial transaction price under the Merck Agreement for the Second Collaboration Target is $

12.0
million, consisting of the upfront, non-refundable and non-creditable payment of $

8.0
million and the aggregate estimated reimbursable research program funding of $

4.0
million. The performance obligations related to the First Collaboration Target were completed as of December 31, 2023. The aggregate amount of the transaction price allocated to the performance obligations that were unsatisfied (or partially unsatisfied) as of December 31, 2023 was $

3.1
million for the Second Collaboration Target.

The Company concluded that there was not a significant financing component under the Merck Agreement. With respect to the remaining variable consideration within the Merck Agreement, including milestone and royalty payments, the Company determined that as of December 31, 2023 these payments were probable of significant revenue reversal as their achievement is highly dependent on factors outside the Company's control. Therefore, this aggregate consideration has been fully constrained and is not included in the transaction price at December 31, 2023. At the end of each subsequent reporting period, the Company will re-evaluate the probability of achievement of each milestone and any related constraint, and if necessary, adjust its estimate of the overall transaction price. Any such adjustments are recorded on a cumulative catch-up basis, which would affect the reported amount of revenues in the period of adjustment.

Consideration received for each Collaboration Target is recorded as deferred revenue and recognized as revenue over time in conjunction with the Company's conduct of research services as the research services are the primary component of the combined performance obligations for each Collaboration Target. Revenue associated with the upfront payment and research program funding for each Collaboration Target is recognized based on actual total full-time equivalent employees ("FTEs") utilized as a percentage of total FTEs expected to be utilized over the expected term of conduct of the research services performed for each respective Collaboration Target. The Company estimates the remaining term of these research services, over which revenue will be recognized, to be 0.7 years for the Second Collaboration Target as of December 31, 2023.

The Company recognized $

8.1
million and $

8.6
million of revenue under the Merck Agreement for the years ended December 31, 2023 and 2022, respectively. As of December 31, 2023, aggregate deferred revenue related to the Merck Agreement was $

1.7
million, all of which was classified as current. The Company did

no

t have an accounts receivable balance outstanding as of December 31, 2023 and 2022. The remaining performance obligations under the Merck

Agreement relate to the Company's conduct of research services for the Second Collaboration Target and the Company's participation in a joint research committee.

7. Income Taxes

The Company has no t recorded a current or deferred tax expense or benefit for the years ended December 31, 2023 or 2022. The net losses for the years ended December 31, 2023 and 2022 were generated solely in the United States.

A reconciliation of the Company's income tax expense (benefit) to the amount computed by applying the federal statutory income tax rate is summarized as follows (in thousands):

	Year Ended December 31,	
	2023	2022
Expected tax benefit computed at federal statutory rate	$ (12,242)	$ (13,242)
State income taxes, net of federal tax benefit	(2,827)	(3,754)
Permanent differences	3,567	1,899
Research and development credits	(4,300)	(2,930)
Reserve for uncertain tax positions	1,058	715
Other	124	80
Change in valuation allowance	14,620	17,232
Income tax expense (benefit)	$ —	$ —

Significant components of the Company's net deferred tax assets (liabilities) are summarized as follows (in thousands):

	December 31,	
	2023	2022
Deferred tax assets:		
Net operating loss carryforwards	$ 18,745	$ 16,261
Capitalized research and development	15,698	8,310
Lease liability	6,868	7,081
Research and development credit carryforwards	6,597	3,377
Stock-based compensation	4,005	3,453
Other	713	430

Total deferred tax assets	52,626	38,912
Valuation allowance	(44,981)	(30,976)
Net deferred tax assets	7,645	7,936
Deferred tax liabilities:		
ROU asset	(5,831)	(6,235)
Property and equipment	(1,498)	(1,519)
Other	(316)	(182)
Total gross deferred tax liabilities	(7,645)	(7,936)
Net deferred tax assets	$ —	$ —

Deferred income tax assets and liabilities are recorded for differences between the financial statement and tax basis of the assets and liabilities that will result in taxable or deductible amounts in the future based on enacted laws and rates applicable to the periods in which the differences are expected to affect taxable income. Valuation allowances are established when necessary to reduce deferred tax assets to the amount expected to be realized.

The Company has evaluated the available evidence supporting the realization of its gross deferred tax assets, including the amount and timing of future taxable income, and has determined it is more likely than not that the assets will not be realized. Due to uncertainties surrounding the realizability of the deferred tax assets, the Company maintains a full valuation allowance against its deferred tax assets at December 31, 2023 and 2022.

At December 31, 2023, the Company had federal and state net operating loss ("NOL") carryforwards of $

49.9
million and $

117.6
million, respectively. Federal NOL carryforwards totaling $

0.5
million begin to expire in 2037 , unless previously utilized, and federal NOL carryforwards of $

49.4
million generated after 2017, may be carried forward indefinitely but can only be utilized to offset

80
% of future taxable income. State NOL carryforwards totaling $

117.6
million begin to expire in 2037 , unless previously utilized. In addition, the Company also has federal and state research and development ("R&D") credit carryforwards totaling $

6.4
million and $

3.1
million respectively. The federal R&D credit carryforwards will begin to expire in 2037 unless previously utilized. The state R&D credit carryforwards do not expire.

Utilization of the Company's NOL and R&D credit carryforwards may be subject to substantial annual limitations in the event a cumulative ownership change has occurred, or that could occur in the future, as required by Section 382 of the Internal Revenue Code

of 1986, as amended (the "Code"). In general, an "ownership change," as defined by Section 382 of the Code, results from a transaction, or series of transactions over a three-year period, resulting in an ownership change of more than 50% of the outstanding stock of a company by certain stockholders or public groups. Such an ownership change may limit the amount of NOL and R&D credit carryforwards that can be utilized annually to offset future taxable income and tax, respectively. The Company has not completed such an ownership change analysis pursuant to Section 382 of the Code. If ownership changes have occurred or occur in the future, the amount of remaining tax attribute carryforwards available to offset taxable income and income tax expense in future years may be restricted or eliminated. If eliminated, the related asset would be removed from deferred tax assets with a corresponding reduction in the valuation allowance. Due to the existence of the valuation allowance, limitations created by future ownership changes, if any, will not impact the Company's effective tax rate.

The Company recognizes a tax benefit from an uncertain tax position when it is more likely than not that the position will be sustained upon examination by tax authorities. Further, due to the existence of the valuation allowance, future changes in the Company's unrecognized tax benefits will not impact the effective tax rate.

The following table summarizes the changes to the Company’s gross unrecognized tax benefits for the years ended December 31, 2023 and 2022 (in thousands):

	Year Ended December 31,	
	2023	2022
Balance at beginning of year	$ 1,273	$ 510
Increases related to prior year tax positions	126	—
Increases related to current year tax positions	990	763
Balance at end of year	$ 2,389	$ 1,273

The Company had

no

accrual for interest or penalties on the Company's balance sheets at December 31, 2023 or 2022, and has not recognized interest and/or penalties in the statement of operations and comprehensive loss for the years ended December 31, 2023 and 2022. As of December 31, 2023 and 2022, the Company had unrecognized tax benefits of $

2.4
million and $

1.3
million, respectively, which if recognized currently, should not impact the effective tax rate due to the Company maintaining a full valuation allowance. The Company does not expect that there will be a significant change in the unrecognized tax benefit over the next twelve months.

The Company is subject to taxation in the United States and various state jurisdictions. All of the Company's tax years are subject to examination by federal and state tax authorities due to the carryforward of unutilized net operating losses and research and development credits. Further, the Company is not currently under examination by any federal, state or local tax authority.

8. 401(k) Plan

Effective April 2021, the Company adopted a defined contribution retirement savings plan under Section 401(k) of the Internal Revenue Code available to eligible employees. Employee contributions are voluntary and determined on an individual basis, limited to the maximum amount allowable under federal tax regulations. Under the plan, the Company makes a mandatory annual contribution of up to

3
% of eligible employees’ compensation. Employer contributions for the years ended December 31, 2023 and 2022 were $

0.4
million and $

0.2
million, respectively.

9. Subsequent Events

In March 2024, the Company closed an underwritten offering of

5,397,301
shares of its common stock and pre-funded warrants to purchase

1,935,483
shares of common stock. The shares of common stock were sold at a price of $

46.50
per share and the pre-funded common stock warrants were sold at a price of $

46.499
per pre-funded common stock warrant, resulting in gross proceeds of $

341.0
million. Fees related to the offering included underwriting discounts, commissions, and estimated offering expenses in the aggregate amount of $

20.8
million, resulting in estimated net proceeds of $

320.2
million.

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

Not applicable.

Item 9A. Controls and Procedures.

Evaluation of Disclosure Controls and Procedures

As required by Rules 13a-15(b) and 15d-15(b) of the Exchange Act, our management with the participation of our Chief Executive Officer and our Acting Chief Financial Officer, evaluated the effectiveness of our disclosure controls and procedures as of December 31, 2023. The term “disclosure controls and procedures” as defined in Rules 13a-15(e) and 15d-15(e) under the Exchange Act, means controls and other procedures of a company that are designed to ensure that information required to be disclosed by a company in the reports that it files or submits under the Exchange Act is recorded, processed, summarized and reported, within the time periods specified in the SEC’s rules and forms. Disclosure controls and procedures include, without limitation, controls and procedures designed to ensure that information required to be disclosed by a company in the reports that it files or submits under the Exchange Act is accumulated and communicated to the company’s management, including its principal executive and principal financial officer, as appropriate to allow timely decisions regarding required disclosure. Management recognizes that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving their objectives, and 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, 2023, our Chief Executive Officer and our Acting Chief Financial Officer concluded that, as of such date, our disclosure controls and procedures were effective at the reasonable assurance level.

Management’s Report on Internal Control over Financial Reporting

Management is responsible for establishing and maintaining adequate internal control over financial reporting, as such term is defined in Rule 13a-15(f) under the Exchange Act. Our management conducted an assessment of the effectiveness of our internal control over financial reporting based on the criteria set forth in “Internal Control-Integrated Framework (2013)” issued by the Committee of Sponsoring Organization of the Treadway Commission. Based on this assessment, management concluded that, as of December 31, 2023, our internal control over financial reporting was effective.

This Annual Report on Form 10-K does not include an attestation report of our independent registered public accounting firm on internal control over financial reporting due to an exemption established by the JOBS Act for “emerging growth companies.”

Changes in Internal Control over Financial Reporting

There were no changes in our internal control over financial reporting that occurred during the quarter ended December 31, 2023 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

Item 9B. Other Information.

Trading Arrangements

During the three months ended December 31, 2023, no director or officer adopted or terminated any Rule 10b5-1 trading arrangement or any non-Rule 10b5-1 trading arrangement (as such terms are defined pursuant to Item 408(a) of Regulation S-K).

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

Not applicable.

PART III

Item 10. Directors, Executive Officers and Corporate Governance.

Information required by this item and not set forth below will be set forth in the sections headed "Election of Directors" and "Executive Officers" contained in our definitive Proxy Statement to be filed with the Commission within 120 days after the conclusion of our year ended December 31, 2023 (the “Proxy Statement”) pursuant to General Instructions G(3) of Form 10-K and is incorporated herein by reference.

We have adopted a Code of Business Conduct and Ethics that applies to all officers, directors and employees, including our principal executive officer, principal financial officer, principal accounting officer or controller, or person performing similar functions. A current copy of the Code of Business Conduct and Ethics is available on the Corporate Governance section of our website at www.januxrx.com. If we make any substantive amendments to the Code of Business Conduct and Ethics or grants any waiver from a provision of the Code of Business Conduct and Ethics to any executive officer or director that are required to be disclosed pursuant to SEC rules, we will promptly disclose the nature of the amendment or waiver on our website or in a current report on Form 8-K.

Item 11. Executive Compensation.

The information required by this item will be set forth in the sections headed "Executive and Director Compensation" and "Director Compensation" contained in our Proxy Statement and is incorporated herein by reference.

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

The information required by this item will be set forth in the sections headed "Security Ownership of Certain Beneficial Owners and Management" and "Executive and Director Compensation" contained in our Proxy Statement and is incorporated herein by reference.

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

The information required by this item will be set forth in the sections headed "Certain Related-Person Transactions" and "Information Regarding the Board of Directors and Corporate Governance" contained in our Proxy Statement and is incorporated herein by reference.

Item 14. Principal Accounting Fees and Services.

The information required by this item will be set forth in the section headed "Ratification of Selection of Independent Registered Public Accounting Firm" contained in our Proxy Statement and is incorporated herein by reference.

PART IV

Item 15. Exhibits and Financial Statement Schedules.

(a) Documents filed as part of this report.

(1) Financial Statements. The following financial statements of Janux Therapeutics, Inc., together with the report of Ernst & Young LLP, an independent registered public accounting firm, required to be filed pursuant to Part II, Item 8 of this Annual Report on Form 10-K are included on the following pages:

(2) Financial Statement Schedules. All financial statement schedules have been omitted because they are not applicable, not required, or the information required is shown in the financial statements or the notes thereto.

(3) List of exhibits required by Item 601 of Regulation S-K. See part (b) below.

(b) Exhibits.

Exhibit Number	Description
3.1	Amended and Restated Certificate of Incorporation (incorporated by reference to Exhibit 3.1 to the Registrant's Current Report on Form 8-K, filed with the SEC on June 15, 2021).
3.2	Amended and Restated Bylaws (incorporated by reference to Exhibit 3.2 to the Registrant's Current Report on Form 8-K, filed with the SEC on June 15, 2021).
4.1	Reference is made to Exhibit 3.1 and 3.2.
4.2	Form of Common Stock Certificate of the Registrant (incorporated by reference to Exhibit 4.1 to the Registrant's Registration Statement on Form S-1 (File No. 333-256297), as amended, filed with the SEC on June 7, 2021).
4.3	Amended and Restated Investors' Rights Agreement, by and between the Registrant and certain of its stockholders, dated April 15, 2021, as amended (incorporated by reference to Exhibit 4.2 to the Registrant's Registration Statement on Form S-1 (File No. 333-256297), as amended, filed with the SEC on June 7, 2021).
4.4	Description of Registrant's Common Stock. (incorporated by reference to Exhibit 4.4 to the Registrant's Annual Report on Form 10-K, filed with the SEC on March 18, 2022).
4.5	Form of Pre-Funded Warrant (incorporated by reference to Exhibit 4.1 to the Registrant's Current Report on Form 8-K, filed with the SEC on July 18, 2023).
10.1+	Form of Indemnity Agreement, by and between the Registrant and its directors and officers (incorporated by reference to Exhibit 10.1 to the Registrant's Registration Statement on Form S-1 (File No. 333-256297), filed with the SEC on May 19, 2021).
10.2+	Janux Therapeutics, Inc. 2017 Equity Incentive Plan, as amended, and Forms of Option Agreement, Notice of Exercise and Early Exercise Stock Purchase Agreement thereunder (incorporated by reference to Exhibit 10.2 to the Registrant's Registration Statement on Form S-1 (File No. 333-256297), filed with the SEC on May 19, 2021).
10.3+	Janux Therapeutics, Inc. 2021 Equity Incentive Plan, and Forms of Option Grant Notice, Option Agreement and Notice of Exercise thereunder (incorporated by reference to Exhibit 10.3 to the Registrant's Registration Statement on Form S-1 (File No. 333-256297), as amended, filed with the SEC on June 7, 2021).
10.4+	Janux Therapeutics, Inc. 2021 Employee Stock Purchase Plan (incorporated by reference to Exhibit 10.4 to the Registrant's Registration Statement on Form S-1 (File No. 333-256297), as amended, filed with the SEC on June 7, 2021).

10.5+	Amended and Restated Non-Employee Director Compensation Policy.
10.6+	Employment Agreement, by and between the Registrant and David Campbell, Ph.D., dated January 1, 2021 (incorporated by reference to Exhibit 10.6 to the Registrant's Registration Statement on Form S-1 (File No. 333-256297), filed with the SEC on May 19, 2021).
10.7+	Employment Agreement, by and between the Registrant and Andy Meyer, dated February 17, 2021 (incorporated by reference to Exhibit 10.7 to the Registrant's Registration Statement on Form S-1 (File No. 333-256297), filed with the SEC on May 19, 2021).
10.8*	Research Collaboration and Exclusive License Agreement, by and between the Registrant and Merck Sharp & Dohme Corp., dated December 17, 2020 (incorporated by reference to Exhibit 10.8 to the Registrant's Registration Statement on Form S-1 (File No. 333-256297), filed with the SEC on May 19, 2021).
10.9*	Support Services Agreement, by and between the Registrant and Avalon BioVentures, Inc. (formerly COI Pharmaceuticals, Inc.), dated January 1, 2021 (incorporated by reference to Exhibit 10.9 to the Registrant's Registration Statement on Form S-1 (File No. 333-256297), filed with the SEC on May 19, 2021).
10.10*	Cell Line License Agreement, by and between the Registrant and WuXi Biologics (Hong Kong) Limited, dated April 19, 2021 (incorporated by reference to Exhibit 10.10 to the Registrant's Registration Statement on Form S-1 (File No. 333-256297), filed with the SEC on May 19, 2021).
10.11+	Consulting Agreement, by and between the Registrant and Sheila Gujrathi, M.D., dated March 10, 2021 (incorporated by reference to Exhibit 10.11 to the Registrant's Registration Statement on Form S-1 (File No. 333-256297), filed with the SEC on May 19, 2021).
10.12+	Janux Therapeutics, Inc. 2021 Change in Control and Severance Benefit Plan (incorporated by reference to Exhibit 10.12 to the Registrant's Registration Statement on Form S-1 (File No. 333-256297), filed with the SEC on May 19, 2021).
10.13+	Employment Agreement, by and between the Registrant and Wayne Godfrey, M.D., dated May 4, 2021 (incorporated by reference to Exhibit 10.13 to the Registrant's Registration Statement on Form S-1 (File No. 333-256297), as amended, filed with the SEC on June 7, 2021).
10.14+	Employment Agreement, by and between the Registrant and Tommy DiRaimondo, Ph.D., dated January 1, 2021.
10.15+	Employment Agreement, by and between the Registrant and Byron Robinson, Ph.D., dated January 20, 2022 (incorporated by reference to Exhibit 10.15 to the Registrant's Annual Report on Form 10-K, filed with the SEC on March 18, 2022).
10.16	Open Market Sale Agreement℠, dated August 9, 2022, by and between the Registrant and Jefferies LLC (incorporated by reference to Exhibit 1.2 to the Registrant's Registration Statement on Form S-3 (File No. 333-266720), filed August 9, 2022).
10.17	Lease, by and between the Registrant and Pacific Plaza Owner LLC, dated October 1, 2021 (incorporated by reference to Exhibit 10.17 to the Registrant's Annual Report on Form 10-K, filed with the SEC on March 18, 2022).
10.18	ATM Equity Offering℠ Sales Agreement, dated May 9, 2023, by and between the Registrant and BofA Securities, Inc. (incorporated by reference to Exhibit 1.1 to the Registrant's Current Report on Form 8-K, filed with the SEC on May 9, 2023).
10.19+	Transition and Consulting Agreement, by and between the Registrant and Shahram Salek-Ardakani, Ph.D., dated November 10, 2022 (incorporated by reference to Exhibit 10.19 to the Registrant's Annual Report on Form 10-K, filed with the SEC on March 10, 2023).
10.20+	Employment Agreement, by and between the Registrant and Charles Winter, dated February 12, 2021 (incorporated by reference to Exhibit 10.20 to the Registrant's Annual Report on Form 10-K, filed with the SEC on March 10, 2023).
10.21	Underwriting Agreement, between the Company and BofA Securities, Inc., dated as of July 17, 2023 (incorporated by reference to Exhibit 1.1 of the Registrant's Current Report on Form 8-K, filed with the SEC on July 18, 2023).
10.22	Janux Therapeutics, Inc. Incentive Compensation Recoupment Policy.
23.1	Consent of Independent Registered Public Accounting Firm.
24.1	Power of Attorney (see signature page).
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	Certification 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.
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 With Embedded Linkbases Document

104	Cover Page Interactive Data File (embedded within the Inline XBRL document)

\+ Indicates management contract or compensatory plan.

* Certain portions of this exhibit are omitted because they are not material and would likely cause competitive harm to the Registrant if disclosed.

Item 16. Form 10-K Summary

Not applicable.

SIGNATURES

Pursuant to the requirements of Section 13 or 15(d) of the Securities Exchange Act of 1934, as amended, the Registrant has duly caused this Report to be signed on its behalf by the undersigned, thereunto duly authorized**.**

JANUX THERAPEUTICS, INC.

Date: March 8, 2024

By: /s/ David Campbell, Ph.D.
David Campbell, Ph.D.
President and Chief Executive Officer

POWER OF ATTORNEY

KNOW ALL PERSONS BY THESE PRESENTS, that each person whose signature appears below constitutes and appoints David Campbell and Tighe Reardon, and each of them, his or her true and lawful attorneys-in-fact, each with full power of substitution, for him or her in any and all capacities, to sign any amendments to this Annual Report on Form 10-K and to file the same, with exhibits thereto and other documents in connection therewith, with the Securities and Exchange Commission, hereby ratifying and confirming all that each of said attorneys-in-fact or their substitute or substitutes may do or cause to be done by virtue hereof.

Pursuant to the requirements of the Securities Exchange Act of 1934, as amended, this Report has been signed below by the following persons on behalf of the Registrant in the capacities and on the dates indicated.

Name	Title	Date
/s/ David Campbell, Ph.D. David Campbell, Ph.D.	President and Chief Executive Officer and Director *(Principal Executive Officer)*	March 8, 2024
/s/ Tighe Reardon Tighe Reardon	Acting Chief Financial Officer *(Principal Financial and Accounting Officer)*	March 8, 2024
/s/ Jay Lichter, Ph.D. Jay Lichter, Ph.D.	Chairperson of the Board of Directors	March 8, 2024
/s/ Ron Barrett, Ph.D. Ron Barrett, Ph.D.	Director	March 8, 2024
/s/ Vickie Capps Vickie Capps	Director	March 8, 2024
/s/ Sheila Gujrathi, M.D. Sheila Gujrathi, M.D.	Director	March 8, 2024
/s/ Winston Kung Winston Kung	Director	March 8, 2024
/s/ Alana McNulty Alana McNulty	Director	March 8, 2024
/s/ Jake Simson, Ph.D. Jake Simson, Ph.D.	Director	March 8, 2024

Exhibit 10.5

JANUX THERAPEUTICS, INC.

AMENDED AND RESTATED NON-EMPLOYEE DIRECTOR COMPENSATION POLICY

Each member of the Board of Directors (the "***Board***") who is not also serving as an employee of or consultant to Janux Therapeutics, Inc. (the "***Company***") or any of its subsidiaries (each such member, an "***Eligible Director***") will receive the compensation described in this Non-Employee Director Compensation Policy for his or her Board service upon and following the date of the underwriting agreement between the Company and the underwriters managing the initial public offering of the Company's common stock (the "***Common Stock***"), pursuant to which the Common Stock is priced in such initial public offering (the "***Effective Date***"). An Eligible Director may decline all or any portion of his or her compensation by giving notice to the Company prior to the date cash may be paid or equity awards are to be granted, as the case may be. This policy is initially effective as of the Effective Date (and subsequently amended and restated effective January 1, 2024) and may be amended at any time in the sole discretion of the Board or the Compensation Committee of the Board.

Annual Cash Compensation

The annual cash compensation amount set forth below is payable to Eligible Directors in equal quarterly installments, payable in arrears on the last day of each fiscal quarter in which the service occurred. If an Eligible Director joins the Board or a committee of the Board at a time other than effective as of the first day of a fiscal quarter, each annual retainer set forth below will be pro-rated based on days served in the applicable fiscal quarter, with the pro-rated amount paid on the last day of the first fiscal quarter in which the Eligible Director provides the service and regular full quarterly payments thereafter. All annual cash fees are vested upon payment.

1. Annual Board Service Retainer:
    a. All Eligible Directors: $40,000
    b. Chair of the Board Service Retainer (in addition to Eligible Director Service Retainer): $35,000

2. Annual Committee Chair Service Retainer:
    a. Chair of the Audit Committee: $15,000
    b. Chair of the Compensation Committee: $12,000
    c. Chair of the Nominating and Corporate Governance Committee: $8,500

3. Annual Committee Member Service Retainer (not applicable to Committee Chairs):
    a. Member of the Audit Committee: $7,500
    b. Member of the Compensation Committee: $6,000
    c. Member of the Nominating and Corporate Governance Committee: $4,250

1.

Equity Compensation

The equity compensation set forth below will be granted under the Company's 2021 Equity Incentive Plan (the "***Plan***"), subject to the approval of the Plan by the Company's stockholders. All stock options granted under this policy will be nonstatutory stock options, with an exercise price per share equal to 100% of the Fair Market Value (as defined in the Plan) of the underlying Common Stock on the date of grant, and a term of ten years from the date of grant (subject to earlier termination in connection with a termination of service as provided in the Plan).

1. Initial Grant: For each Eligible Director who is first elected or appointed to the Board following the Effective Date, on the date of such Eligible Director's initial election or appointment to the Board (or, if such date is not a market trading day, the first market trading day thereafter), the Eligible Director will be automatically, and without further action by the Board or the Compensation Committee of the Board, granted a stock option to purchase 35,000 shares of Common Stock (the "***Initial Grant***"). The shares subject to each Initial Grant will vest in equal monthly installments over a three year period such that the option is fully vested on the third anniversary of the date of grant, subject to the Eligible Director's Continuous Service (as defined in the Plan) through each such vesting date and will vest in full upon a Change in Control (as defined in the Plan).

2. Annual Grant: On the date of each annual stockholder meeting of the Company held after the Effective Date (an "***Annual Meeting***"), each Eligible Director who continues to serve as a non-employee member of the Board following such Annual Meeting will be automatically, and without further action by the Board or the Compensation Committee of the Board, granted a stock option to purchase 17,500 shares of Common Stock (the "***Annual Grant***"). If an Eligible Director is elected or appointed for the first time to be an Eligible Director after the date of the Company's first Annual Meeting and other than at an Annual Meeting, then the Eligible Director will be automatically, and without further action by the Board or the Compensation Committee of the Board, granted a prorated Annual Grant on the date of the Eligible Director's election or appointment (the "***Prorated Annual Grant***") that will be subject to the number of shares of Common Stock equal to 17,500 multiplied by a fraction (the numerator of which is equal to (i) 12 *minus* (ii) the number of completed months since the most recent Annual Meeting as of the Eligible Director's date of election or appointment, and the denominator of which is 12), with the resulting number of shares rounded down to the nearest whole share. The shares subject to the Annual Grant or Prorated Annual Grant will vest in equal monthly installments over the 12 months following the date of grant, provided that the Annual Grant will in any case be fully vested on the date of Company's next Annual Meeting, subject to the Eligible Director's Continuous Service through such vesting date; provided, further, that the shares subject to the Annual Grant or Prorated Annual Grant will vest in full upon a Change in Control.

Non-Employee Director Compensation Limit

Notwithstanding the foregoing, the aggregate value of all compensation granted or paid, as applicable, to any individual for service as a Non-Employee Director (as defined in the Plan) shall in no event exceed the limits set forth in the Plan.

Exhibit 10.14

January 1, 2021 Thomas
DiRaimondo
Re: Employment Terms

Dear Tommy:

Janux Therapeutics, Inc. (the ***"Company")*** is pleased to offer you employment beginning on January 1, 2021 (the ***"Start Date").***

Position

Your initial position will be Director, Research, responsible for performing such duties as are assigned to you from time to time, reporting to the Company's President & CEO. You will primarily work at our office located in San Diego, California, although you may be reasonably required to perform your duties at places other than your primary office location from time to time, and undertake reasonable business travel. The Company may change your position, duties, and work location from time to time in its discretion.

As a full-time, exempt employee, you will be expected to work the Company's normal business hours as well as additional hours as required by the nature of your work assignments, and you will not be eligible for overtime compensation.

Compensation and Benefits

You will be compensated at an annual base salary of $172,414 per year, less payroll deductions and withholdings, paid on the Company's normal payroll schedule.

You will also be eligible to earn an annual discretionary bonus with a target of 20% of your base salary (or annualized base earnings, as applicable). The amount of this bonus will be determined in the sole discretion of the Company and based, in part, on your performance and the performance of the Company during the calendar year, as well as any other criteria the Company deems relevant. The bonus is not earned until paid and no pro-rated amount will be paid if your employment terminates for any reason prior to the payment date.

During your employment, you will be eligible to participate in the benefits plans offered to similarly situated employees by the Company from time to time, subject to plan terms and generally applicable Company policies. A full description of current benefits is available for your review. Currently, exempt employees do not accrue vacation. Supervisors will approve paid vacation requests based on the employee's progress on work goals or milestones, status of projects, fairness to the working team, and productivity and efficiency of the employee. Since vacation is not allotted or accrued, there is no "unused" vacation time to be carried over from one year to the next nor paid out upon termination. A full description of current benefits is available for your review. The Company may change compensation, benefits from time to time in its discretion.

Confidential Information and Company Policies

As a Company employee, you will be expected to abide by Company rules and policies. As a condition of employment, you must sign and comply with the attached Employee Confidential Information and Inventions Assignment Agreement which prohibits unauthorized use or disclosure of the Company's proprietary

information, among other obligations.

By signing this letter you are representing that you have full authority to accept this position and perform the duties of the position without conflict with any other obligations and that you are not involved in any situation that might create, or appear to create, a conflict of interest with respect to your loyalty or duties to the Company. You specifically warrant that you are not subject to an employment agreement or restrictive covenant preventing full performance of your duties to the Company. You agree not to bring to the Company or use in the performance of your responsibilities at the Company any materials or documents of a former employer that are not generally available to the public, unless you have obtained express written authorization from the former employer for their possession and use. You also agree to honor all obligations to former employers during your employment with the Company.

At-Will Employment

Your employment with the Company will be "at-will." You may terminate your employment with the Company at any time and for any reason whatsoever simply by notifying the Company. Likewise, the Company may terminate your employment at any time, with or without cause or advance notice. Your employment at-will status can only be modified in a written agreement signed by you and by an officer of the Company.

Conditions, Dispute Resolution, and Complete Agreement

This offer is contingent upon a satisfactory reference check and satisfactory proof of your right to work in the United States. If the Company informs you that you are required to complete a background check, this offer is contingent upon satisfactory clearance of such background check. You agree to assist as needed and to complete any documentation at the Company's request to meet these conditions.

To ensure the rapid and economical resolution of disputes that may arise in connection with your employment with the Company, you and the Company agree that any and all disputes, claims, or causes of action, in law or equity, including but not limited to statutory claims, arising from or relating to the enforcement, breach, performance, or interpretation of this Agreement, your employment with the Company, or the termination of your employment, shall be resolved pursuant to the Federal Arbitration Act, 9 U.S.C. § 1-16, to the fullest extent permitted by law, by final, binding and confidential arbitration conducted by JAMS or its successor, under JAMS' then applicable rules and procedures for employment disputes before a single arbitrator (available upon request and also currently available at http://www.jamsadr.com/rules-employment-arbitration/). **You acknowledge that by agreeing to this arbitration procedure, both you and the Company waive the right to resolve any such dispute through a trial by jury or judge or administrative proceeding.** In addition, all claims, disputes, or causes of action under this section, whether by you or the Company, must be brought in an individual capacity, and shall not be brought as a plaintiff (or claimant) or class member in any purported class or representative proceeding, nor joined or consolidated with the claims of any other person or entity. The arbitrator may not consolidate the claims of more than one person or entity, and may not preside over any form of representative or class proceeding. To the extent that the preceding sentences regarding class claims or proceedings are found to violate applicable law or are otherwise found unenforceable, any claim(s) alleged or brought on behalf of a class shall proceed in a court of law rather than by arbitration. This paragraph shall not apply to any action or claim that cannot be subject to mandatory arbitration as a matter of law, including, without limitation, claims brought pursuant to the California Private Attorneys General Act of 2004, as amended, the California Fair Employment and Housing Act, as amended, and the California Labor Code, as amended, to the extent such claims are not permitted by applicable law(s) to be submitted to mandatory arbitration and the applicable law(s) are not preempted by the Federal Arbitration Act or otherwise invalid (collectively, the ***"Excluded Claims").*** In the event you intend to bring multiple claims,

including one of the Excluded Claims listed above, the Excluded Claims may be filed with a court, while any other claims will remain subject to mandatory arbitration. You will have the right to be represented by legal

counsel at any arbitration proceeding. Questions of whether a claim is subject to arbitration under this agreement shall be decided by the arbitrator. Likewise, procedural questions which grow out of the dispute and bear on the final disposition are also matters for the arbitrator. The arbitrator shall: (a) have the authority to compel adequate discovery for the resolution of the dispute and to award such relief as would otherwise be permitted by law; and (b) issue a written statement signed by the arbitrator regarding the disposition of each claim and the relief, if any, awarded as to each claim, the reasons for the award, and the arbitrator's essential findings and conclusions on which the award is based. The arbitrator shall be authorized to award all relief that you or the Company would be entitled to seek in a court of law. The Company shall pay all JAMS arbitration fees in excess of the administrative fees that you would be required to pay if the dispute were decided in a court of law. Nothing in this letter agreement is intended to prevent either you or the Company from obtaining injunctive relief in court to prevent irreparable harm pending the conclusion of any such arbitration. Any awards or orders in such arbitrations may be entered and enforced as judgments in the federal and state courts of any competent jurisdiction.

This letter, together with your Employee Confidential Information and Inventions Assignment Agreement, forms the complete and exclusive statement of your employment agreement with the Company. It supersedes any other agreements or promises made to you by anyone, whether oral or written. Changes in your employment terms, other than those changes expressly reserved to the Company's discretion in this letter, require a written modification signed by an officer of the Company. If any provision of this offer letter agreement is determined to be invalid or unenforceable, in whole or in part, this determination shall not affect any other provision of this offer letter agreement and the provision in question shall be modified so as to be rendered enforceable in a manner consistent with the intent of the parties insofar as possible under applicable law. This letter may be delivered and executed via facsimile, electronic mail (including pdf or any electronic signature complying with the U.S. federal ESIGN Act of 2000, Uniform Electronic Transactions Act or other applicable law) or other transmission method and shall be deemed to have been duly and validly delivered and executed and be valid and effective for all purposes.

Please sign and date this letter, and the enclosed Employee Confidential Information and Inventions Assignment Agreement and return them to me by January 4, 2021, if you wish to accept continued at-will employment at the Company under the terms described above.

We look forward to your favorable reply and to a productive and enjoyable work relationship.

Sincerely,

/s/ David Campbell
David Campbell
President and Chief Executive Officer

Understood and Accepted:

/s/ Thomas DiRaimondo 01/01/2021
Thomas DiRaimondo

TDiRaimondo@januxrx.com
Email

Attachment: Employee Confidential Information and Inventions Assignment Agreement

Exhibit 10.22

JANUX THERAPEUTICS, INC.
INCENTIVE COMPENSATION RECOUPMENT POLICY

1. INTRODUCTION

The Compensation Committee (the "***Compensation Committee***") of the Board of Directors (the "***Board***") of Janux Therapeutics, Inc., a Delaware corporation (the "***Company***"), has determined that it is in the best interests of the Company and its stockholders to adopt this Incentive Compensation Recoupment Policy (this "***Policy***") providing for the Company's recoupment of Recoverable Incentive Compensation that is received by Covered Officers of the Company under certain circumstances. Certain capitalized terms used in this Policy have the meanings given to such terms in Section 3 below.

This Policy is designed to comply with, and shall be interpreted to be consistent with, Section 10D of the Exchange Act, Rule 10D-1 promulgated thereunder ("***Rule 10D-1***") and Nasdaq Listing Rule 5608 (the "***Listing Standards***").

2. EFFECTIVE DATE

This Policy shall apply to all Incentive Compensation that is received by a Covered Officer on or after October 2, 2023 (the "***Effective Date***"). Incentive Compensation is deemed "***received***" in the Company's fiscal period in which the Financial Reporting Measure specified in the Incentive Compensation award is attained, even if the payment or grant of such Incentive Compensation occurs after the end of that period.

3. DEFINITIONS

"***Accounting Restatement***" means an accounting restatement that the Company is required to prepare due to the material noncompliance of the Company with any financial reporting requirement under the securities laws, including any required accounting restatement to correct an error in previously issued financial statements that is material to the previously issued financial statements, or that would result in a material misstatement if the error were corrected in the current period or left uncorrected in the current period.

"***Accounting Restatement Date***" means the earlier to occur of (a) the date that the Board, a committee of the Board authorized to take such action, or the officer or officers of the Company authorized to take such action if Board action is not required, concludes, or reasonably should have concluded, that the Company is required to prepare an Accounting Restatement, or (b) the date that a court, regulator or other legally authorized body directs the Company to prepare an Accounting Restatement.

"***Administrator***" means the Compensation Committee or, in the absence of such committee, the Board.

"***Code***" means the U.S. Internal Revenue Code of 1986, as amended, and the regulations promulgated thereunder.

"***Covered Officer***" means each current and former Executive Officer.

"***Exchange***" means the Nasdaq Stock Market.

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

"***Executive Officer***" means the Company's president, principal financial officer, principal accounting officer (or if there is no such accounting officer, the controller), any vice-president of the Company in charge of a principal business unit, division, or function (such as sales, administration, or finance), any other officer who performs a policy-making function, or any other person who performs similar policy-making functions for the Company. Executive officers of the Company's parent(s) or subsidiaries are deemed executive officers of the Company if they perform such policy-making functions for the Company. Policy-making function is not intended to include policy-making functions that are not significant. Identification of an executive officer for purposes of this Policy would include at a minimum executive officers identified pursuant to Item 401(b) of Regulation S-K promulgated under the Exchange Act.

"***Financial Reporting Measures***" means measures that are determined and presented in accordance with the accounting principles used in preparing the Company's financial statements, and any measures derived wholly or in part from such measures, including Company stock price and total stockholder return ("***TSR***"). A measure need not be presented in the Company's financial statements or included in a filing with the SEC in order to be a Financial Reporting Measure.

"***Incentive Compensation***" means any compensation that is granted, earned or vested based wholly or in part upon the attainment of a Financial Reporting Measure.

"***Lookback Period***" means the three completed fiscal years immediately preceding the Accounting Restatement Date, as well as any transition period (resulting from a change in the Company's fiscal year) within or immediately following those three completed fiscal years (except that a transition period of at least nine months shall count as a completed fiscal year). Notwithstanding the foregoing, the Lookback Period shall not include fiscal years completed prior to the Effective Date.

"***Recoverable Incentive Compensation***" means Incentive Compensation received by a Covered Officer during the Lookback Period that exceeds the amount of Incentive Compensation that would have been received had such amount been determined based on the Accounting Restatement, computed without regard to any taxes paid (*i.e.*, on a gross basis without regarding to tax withholdings and other deductions). For any compensation plans or programs that take into account Incentive Compensation, the amount of Recoverable Incentive Compensation for purposes of this Policy shall include, without limitation, the amount contributed to any notional account based on Recoverable Incentive Compensation and any earnings to date on that notional amount. For any Incentive Compensation that is based on stock price or TSR, where the Recoverable Incentive Compensation is not subject to mathematical recalculation directly from the information in an Accounting Restatement, the Administrator will determine the amount of Recoverable Incentive Compensation based on a reasonable estimate of the effect of the Accounting Restatement on the stock price or TSR upon which the Incentive Compensation was received. The Company shall maintain documentation of the determination of that reasonable estimate and provide such documentation to the Exchange in accordance with the Listing Standards.

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

4. Recoupment

(a) Applicability of Policy. This Policy applies to Incentive Compensation received by a Covered Officer (i) after beginning services as an Executive Officer, (ii) who served as an Executive Officer at any time during the performance period for such Incentive Compensation, (iii) while the Company had a class of securities listed on a national securities exchange or a national securities association, and (iv) during the Lookback Period.

(b) Recoupment Generally. Pursuant to the provisions of this Policy, if there is an Accounting Restatement, the Company must reasonably promptly recoup the full amount of the Recoverable Incentive Compensation, unless the conditions of one or more subsections of Section 4(c) of this Policy are met and the Compensation Committee, or, if such committee does not consist solely of independent directors, a majority of the independent directors serving on the Board, has made a determination that recoupment would be impracticable. Recoupment is required regardless of whether the Covered Officer engaged in any misconduct and regardless of fault, and the Company's obligation to recoup Recoverable Incentive Compensation is not dependent on whether or when any restated financial statements are filed.

(c) Impracticability of Recovery. Recoupment may be determined to be impracticable if, and only if:

(i) the direct expense paid to a third party to assist in enforcing this Policy would exceed the amount of the applicable Recoverable Incentive Compensation; provided that, before concluding that it would be impracticable to recover any amount of Recoverable Incentive Compensation based on expense of enforcement, the Company shall make a reasonable attempt to recover such Recoverable Incentive Compensation, document such reasonable attempt(s) to recover, and provide that documentation to the Exchange in accordance with the Listing Standards; or

(ii) recoupment of the applicable Recoverable Incentive Compensation would likely cause an otherwise tax-qualified retirement plan, under which benefits are broadly available to employees of the Company, to fail to meet the requirements of Code Section 401(a)(13) or Code Section 411(a) and regulations thereunder.

(d) Sources of Recoupment. To the extent permitted by applicable law, the Administrator shall, in its sole discretion, determine the timing and method for recouping Recoverable Incentive Compensation hereunder, provided that such recoupment is undertaken reasonably promptly. The Administrator may, in its discretion, seek recoupment from a Covered Officer from any of the following sources or a combination thereof, whether the applicable compensation was approved, awarded, granted, payable or paid to the Covered Officer prior to, on or after the Effective Date: (i) direct repayment of Recoverable Incentive Compensation previously paid to the Covered Officer; (ii) cancelling prior cash or equity-based awards (whether vested or unvested and whether paid or unpaid); (iii) cancelling or offsetting against any planned future cash or equity-based awards; (iv) forfeiture of deferred compensation, subject to compliance with Code Section 409A; and (v) any other method authorized by applicable law or contract. Subject to

compliance with any applicable law, the Administrator may effectuate recoupment under this Policy from any amount otherwise payable to the Covered Officer, including amounts payable to such individual under any otherwise applicable Company plan or program, *e.g.*, base salary, bonuses or commissions and compensation previously deferred by the Covered Officer. The Administrator need not utilize the same method of recovery for all Covered Officers or with respect to all types of Recoverable Incentive Compensation.

(e) No Indemnification of Covered Officers. Notwithstanding any indemnification agreement, applicable insurance policy or any other agreement or provision of the Company's certificate of incorporation or bylaws to the contrary, no Covered Officer shall be entitled to indemnification or advancement of expenses in connection with any enforcement of this Policy by the Company, including paying or reimbursing such Covered Officer for insurance premiums to cover potential obligations to the Company under this Policy.

(f) Indemnification of Administrator. Any members of the Administrator, and any other members of the Board who assist in the administration of this Policy, shall not be personally liable for any action, determination or interpretation made with respect to this Policy and shall be indemnified by the Company to the fullest extent under applicable law and Company policy with respect to any such action, determination or interpretation. The foregoing sentence shall not limit any other rights to indemnification of the members of the Board under applicable law or Company policy.

(g) No "Good Reason" for Covered Officers. Any action by the Company to recoup or any recoupment of Recoverable Incentive Compensation under this Policy from a Covered Officer shall not be deemed (i) "good reason" for resignation or to serve as a basis for a claim of constructive termination under any benefits or compensation arrangement applicable to such Covered Officer, or (ii) to constitute a breach of a contract or other arrangement to which such Covered Officer is party.

5. Administration

Except as specifically set forth herein, this Policy shall be administered by the Administrator. The Administrator shall have full and final authority to make any and all determinations required under this Policy. Any determination by the Administrator with respect to this Policy shall be final, conclusive and binding on all interested parties and need not be uniform with respect to each individual covered by this Policy. In carrying out the administration of this Policy, the Administrator is authorized and directed to consult with the full Board or such other committees of the Board as may be necessary or appropriate as to matters within the scope of such other committee's responsibility and authority. Subject to applicable law, the Administrator may authorize and empower any officer or employee of the Company to take any and all actions that the Administrator, in its sole discretion, deems necessary or appropriate to carry out the purpose and intent of this Policy (other than with respect to any recovery under this Policy involving such officer or employee).

6. Severability

If any provision of this Policy or the application of any such provision to a Covered Officer shall be adjudicated to be invalid, illegal or unenforceable in any respect, such invalidity, illegality or unenforceability shall not affect any other provisions of this Policy, and the invalid, illegal or unenforceable provisions shall be deemed amended to the minimum extent necessary to render any such provision or application enforceable.

7. No Impairment of Other Remedies

Nothing contained in this Policy, and no recoupment or recovery as contemplated herein, shall limit any claims, damages or other legal remedies the Company or any of its affiliates may have against a Covered Officer arising out of or resulting from any actions or omissions by the Covered Officer. This Policy does not preclude the Company from taking any other action to enforce a Covered Officer's obligations to the Company, including, without limitation, termination of employment and/or institution of civil proceedings. This Policy is in addition to the requirements of Section 304 of the Sarbanes-Oxley Act of 2002 ("***Sarbanes-Oxley Section 304***") that are applicable to the Company's Chief Executive Officer and Chief Financial Officer and to any other compensation recoupment policy and/or similar provisions in any employment, equity plan, equity award, or other individual agreement, to which the Company is a party or which the Company has adopted or may adopt and maintain from time to time; provided, however, that compensation recouped pursuant to this policy shall not be duplicative of compensation recouped pursuant to Sarbanes-Oxley Section 304 or any such compensation recoupment policy and/or similar provisions in any such employment, equity plan, equity award, or other individual agreement except as may be required by law.

8. Amendment; Termination

The Administrator may amend, terminate or replace this Policy or any portion of this Policy at any time and from time to time in its sole discretion. The Administrator shall amend this Policy as it deems necessary to comply with applicable law or any Listing Standard.

9. Successors

This Policy shall be binding and enforceable against all Covered Officers and, to the extent required by Rule 10D-1 and/or the applicable Listing Standards, their beneficiaries, heirs, executors, administrators or other legal representatives.

10. Required Filings

The Company shall make any disclosures and filings with respect to this Policy that are required by law, including as required by the SEC.

* * * * *

JANUX THERAPEUTICS, INC.
INCENTIVE COMPENSATION RECOUPMENT POLICY

FORM OF EXECUTIVE ACKNOWLEDGMENT

I, the undersigned, agree and acknowledge that I am bound by, and subject to, the **JANUX THERAPEUTICS, INC.** Incentive Compensation Recoupment Policy, as may be amended, restated, supplemented or otherwise modified from time to time (the "***Policy***"). In the event of any inconsistency between the Policy and the terms of any employment agreement, offer letter or other individual agreement with **JANUX THERAPEUTICS, INC.** (the "***Company***") to which I am a party, or the terms of any compensation plan, program or agreement, whether or not written, under which any compensation has been granted, awarded, earned or paid to me, the terms of the Policy shall govern.

In the event that the Administrator (as defined in the Policy) determines that any compensation granted, awarded, earned or paid to me must be forfeited or reimbursed to the Company pursuant to the Policy, I will promptly take any action necessary to effectuate such forfeiture and/or reimbursement. I further agree and acknowledge that I am not entitled to indemnification, and hereby waive any right to advancement of expenses, in connection with any enforcement of the Policy by the Company.

Agreed and Acknowledged:

By:_

Name: _
Title: _
Date: _

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. 333-266720) of Janux Therapeutics, Inc.,
2. Registration Statement (Form S-8 No. 333-257039) pertaining to the 2017 Equity Incentive Plan (Prior Plan), the 2021 Equity Incentive Plan, and the 2021 Employee Stock Purchase Plan of Janux Therapeutics, Inc., and
3. Registration Statements (Form S-8 Nos. 333-263712 and 333-270470) pertaining to the 2021 Equity Incentive Plan, and the 2021 Employee Stock Purchase Plan of Janux Therapeutics, Inc.;

of our report dated March 8, 2024, with respect to the financial statements of Janux Therapeutics, Inc., included in this Annual Report (Form 10-K) for the year ended December 31, 2023.

/s/ Ernst & Young LLP

San Diego, California
March 8, 2024

Exhibit 31.1

CERTIFICATION OF CHIEF EXECUTIVE OFFICER PURSUANT TO SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002

I, David Campbell, certify that:

1. I have reviewed this Annual Report on Form 10-K of Janux 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(s) 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(s) 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 8, 2024

By: /s/ David Campbell, Ph.D.

David Campbell, Ph.D.
President and Chief Executive Officer
(Principal Executive Officer)

Exhibit 31.2

CERTIFICATION OF CHIEF FINANCIAL OFFICER PURSUANT TO SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002

I, Tighe Reardon, certify that:

1. I have reviewed this Annual Report on Form 10-K of Janux 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(s) 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(s) 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 8, 2024

By: /s/ Tighe Reardon
Tighe Reardon
Acting Chief Financial Officer
(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 Janux Therapeutics Inc. (the "Company") for the year ended December 31, 2023 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. § 1350, that to his knowledge:

(1) The Report fully complies with the requirements of section 13(a) or 15(d) of the Securities Exchange Act of 1934, as amended; and

(2) The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Date: March 8, 2024 By: /s/ David Campbell, Ph.D.
David Campbell, Ph.D.
President and Chief Executive Officer
(Principal Executive Officer)

Date: March 8, 2024 By: /s/ Tighe Reardon
Tighe Reardon
Acting Chief Financial Officer
(Principal Financial and Accounting Officer)