UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

FORM 10-K

(Mark One)

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

For the fiscal year ended December 31, 2024

OR

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

Commission File Number 001-40475

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 ☒ NO ☐

Indicate by check mark if the Registrant is not required to file reports pursuant to Section 13 or 15(d) of the Act. YES ☐ NO ☒

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

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

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

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

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

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

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

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

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

The aggregate market value of the voting and non-voting common stock held by non-affiliates of the Registrant, as of June 28, 2024, the last business day of the Registrant's most recently completed second fiscal quarter, was approximately $1.3 billion based on the closing price of $41.89 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 February 25, 2025 was 59,105,147.

DOCUMENTS INCORPORATED BY REFERENCE

Portions of the Registrant's definitive proxy statement for its 2025 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, 2024, are incorporated by reference into Part III of this Annual Report on Form 10-K.

JANUX THERAPEUTICS, INC.
Annual Report on Form 10-K
For the Fiscal Year Ended December 31, 2024

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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;
- 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 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 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 rely on third parties to conduct, supervise, and/or 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 and the third parties with whom we work 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 (or the third parties with whom we work) 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 December 2024 we announced updated interim clinical data for JANX007 which displayed meaningful and prolonged prostate-specific antigen (PSA) level drops, encouraging anti-tumor activity, a favorable safety profile including CRS and treatment-related adverse events (TRAEs) primarily limited to Cycle 1 and lower grades 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 carcinoma, squamous cell carcinoma of the head and neck, non-small cell lung cancer, renal cell carcinoma, small cell lung cancer, pancreatic ductal adenocarcinoma and triple-negative breast cancer. The first patient for this trial was dosed in April 2023 and in February 2024 we announced positive early data for 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 U.S. Food and Drug Administration (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

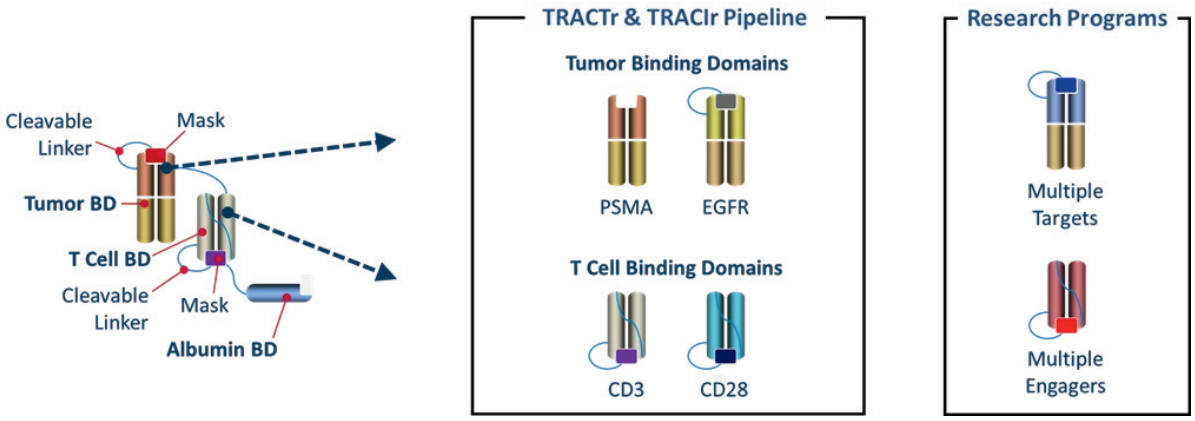
We believe our proprietary TRACTr and TRACIr platforms offer the potential to expand the breadth of patients that can be treated with TCEs and non-TCE based immunomodulators while reducing the risk of life-threatening toxicities. Each of our

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.

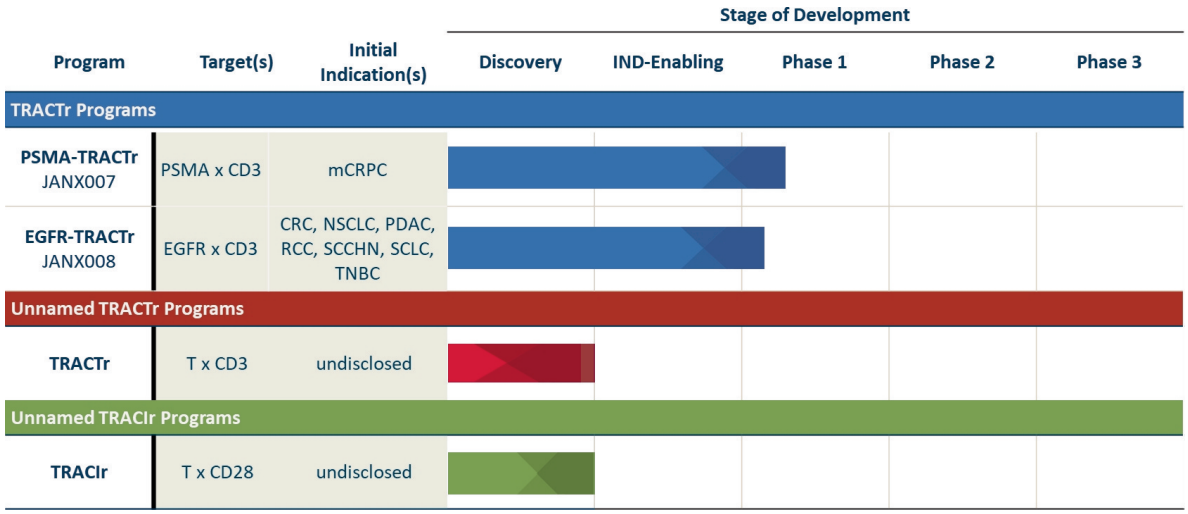
A schematic of our proprietary TRACTrs and TRACIrs in development and their modular components is depicted below.



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 castration-resistant prostate cancer (mCRPC), colorectal carcinoma (CRC), renal cell carcinoma (RCC), squamous cell carcinoma of the head and neck (SCCHN), small cell lung cancer (SCLC), non-small cell lung cancer (NSCLC), pancreatic ductal adenocarcinoma (PDAC) and triple-negative breast cancer (TNBC).

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 is expected to lead to an estimated 35,770 deaths in the United States in 2025. 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 December 2024 we announced updated interim clinical data for JANX007 which displayed meaningful and prolonged PSA drops, encouraging anti-tumor activity, a favorable safety profile including CRS and TRAEs primarily limited to Cycle 1 and lower grades, 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.

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. TNBC, PDAC, RCC, SCCHN, SCLC and NSCLC also represent tumor types for which EGFR is frequently overexpressed, and anti-EGFR antibodies have received marketing approvals in multiple of these indications. 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 CRC, RCC, SCCHN, SCLC, NSCLC, PDAC and TNBC. The first patient for this trial was dosed in April 2023 and in February 2024 we announced positive early data for 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 December 2024 we announced updated interim clinical data for JANX007 which displayed meaningful and prolonged PSA drops, encouraging anti-tumor activity, a favorable safety profile including CRS and TRAEs primarily limited to Cycle 1 and lower grades, 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, TNBC, PDAC, SCLC, 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:

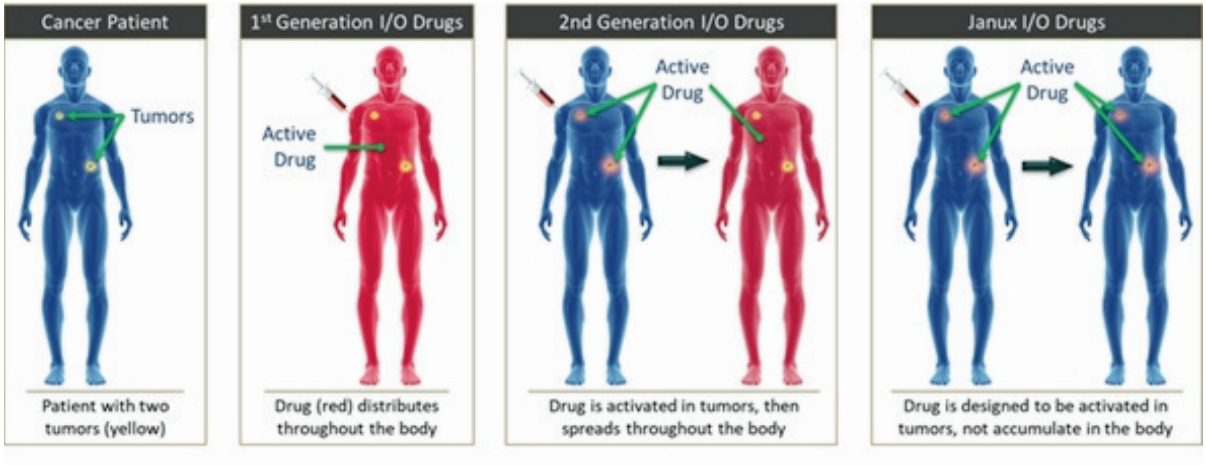
- **Cytokine release syndrome (CRS).** CRS arises from the systemic activation of T cells and can result in life-threatening elevations in inflammatory cytokines such as IL-6. Severe and acute CRS leading to dose-limiting toxicities and deaths has been observed upon the dosing of TCEs developed using 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 1. 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.

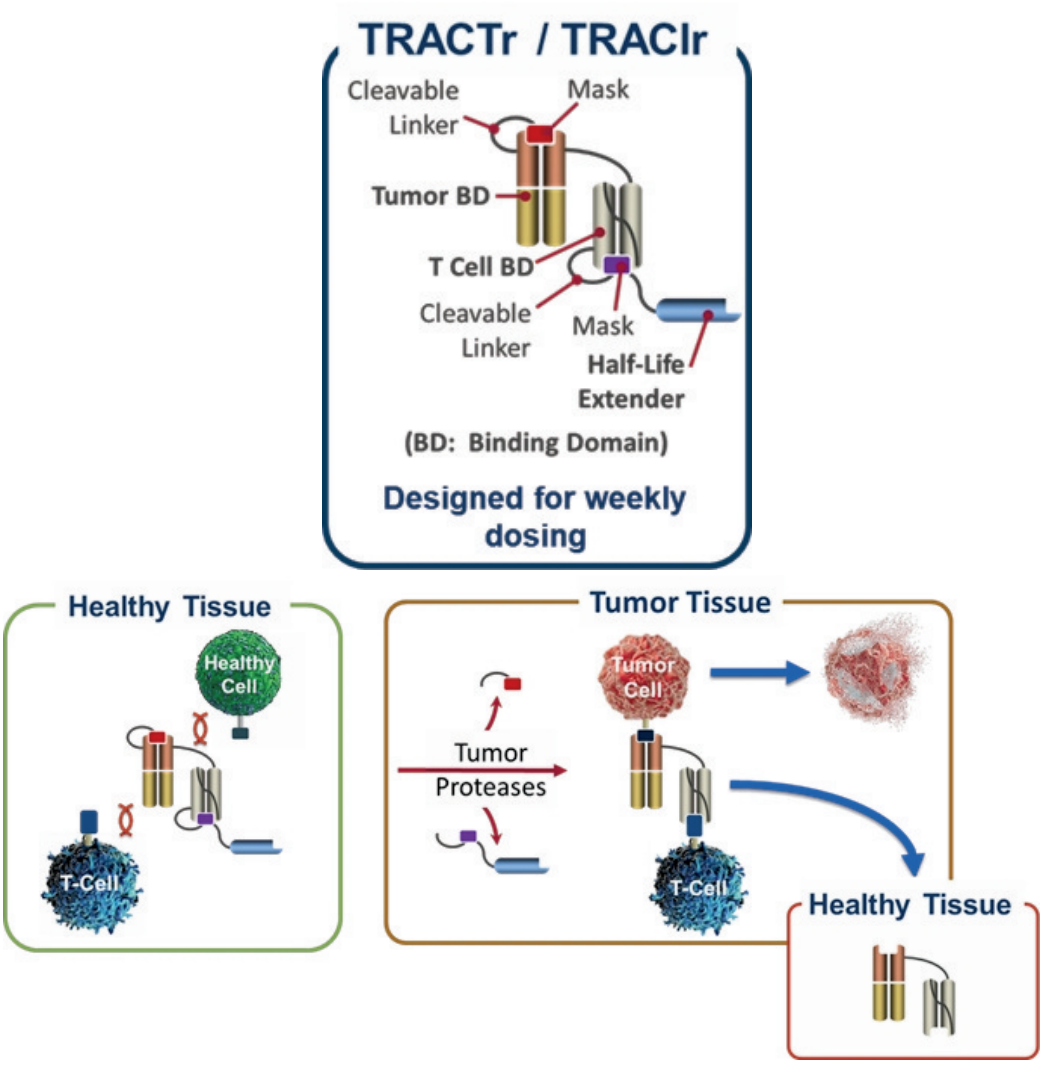
TRACTr and TRACIr design and structure

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.

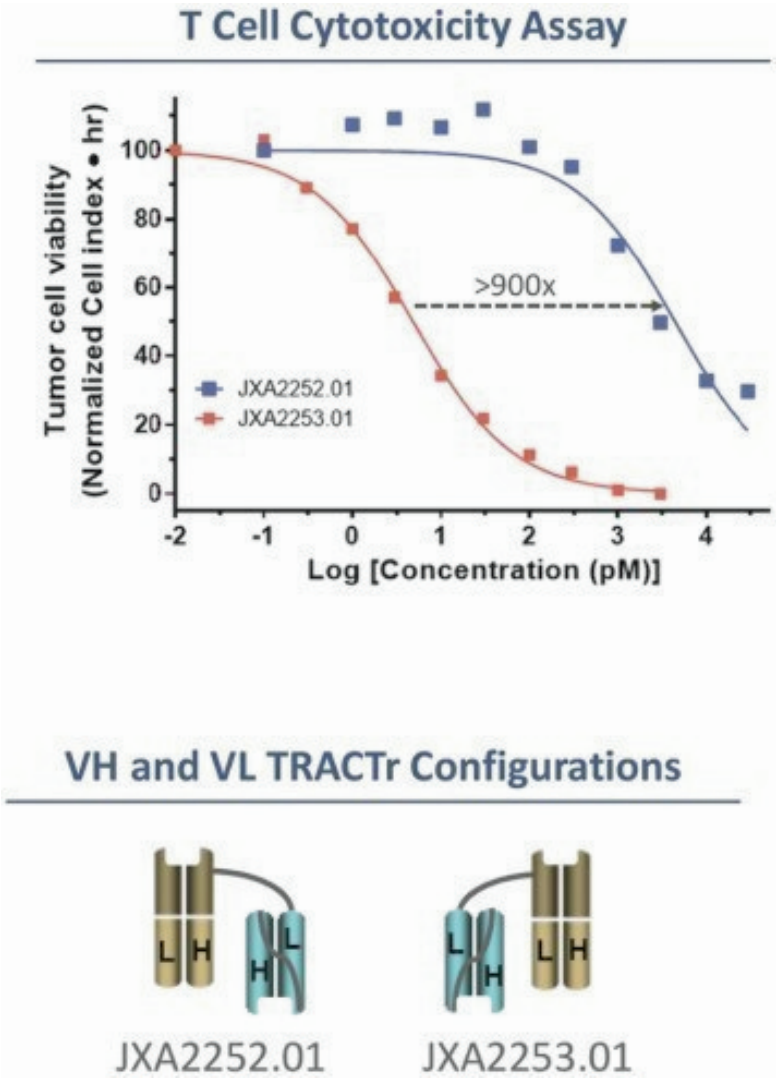


Our TRACTr and TRACIr development process

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.

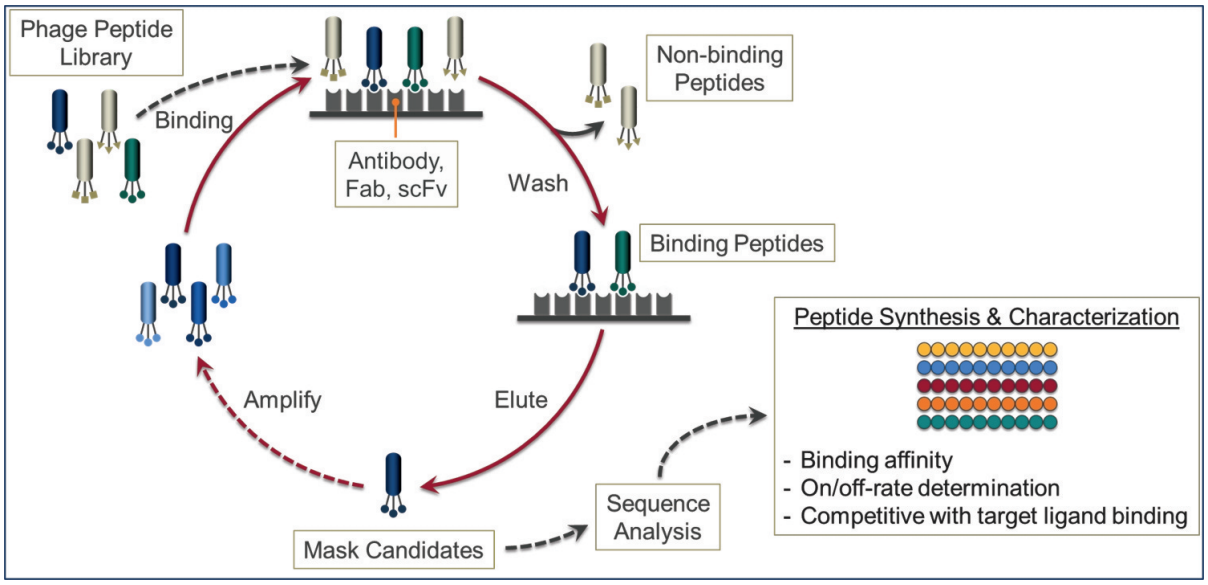
- **Antigen-binding domains.** Our initial product candidates are based on antigen binding domains, which have been incorporated into other products associated with clinical activity. As we expand our pipeline, we are developing proprietary antigen binding domains against novel targets.
- **Geometry 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 2. 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)



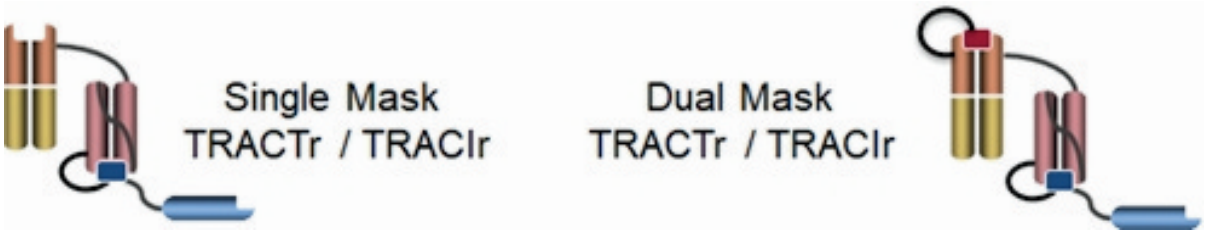
- **Mask Discovery**. Each mask sequence is designed to be optimized for a specific antigen-binding domain through an iterative process of phage display and quantitative binding assays designed to select for those masks that can prevent binding to the target antigen. We use a directed evolution-based 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 3. 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



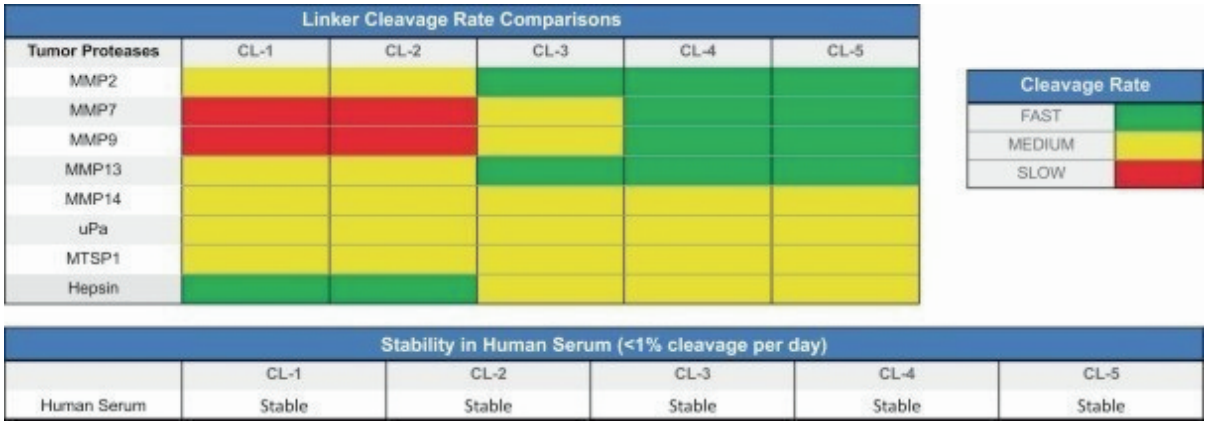
- **Single versus dual masks**. Our technology allows us to develop product candidates with either one or both antigen-binding domains masked depending on the tumor target's profile. For tumor targets with minimal healthy tissue expression or toxicity concerns, we develop single mask TRACTrs or TRACIrs 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 4. 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



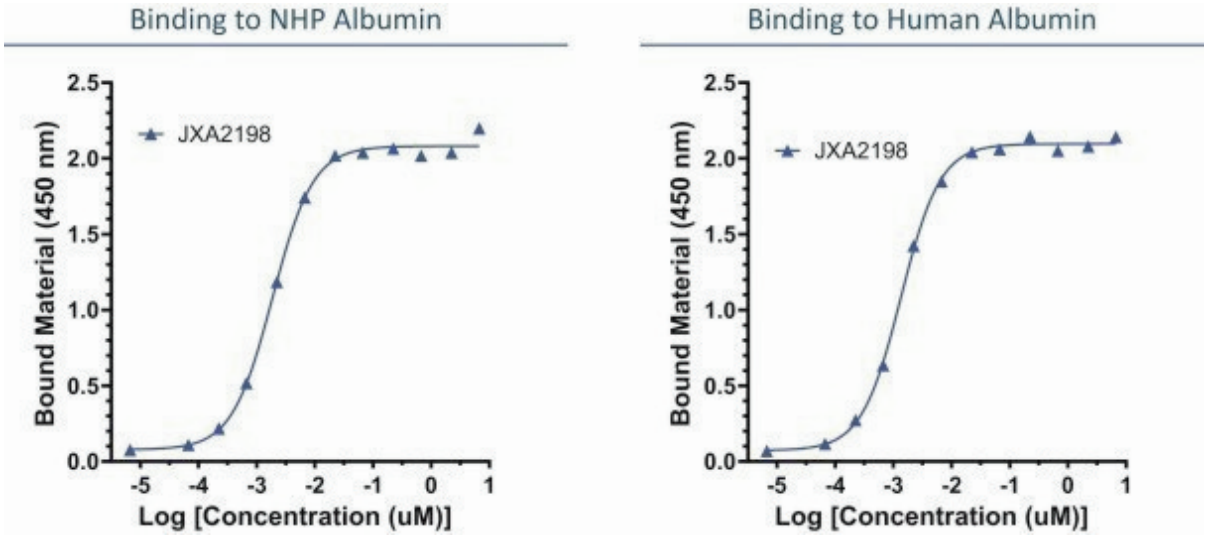
- **Cleavage linker**. We optimized the selection of cleavage linkers by a process involving identifying the predominant proteases in solid tumors and mining databases for potential substrates of these proteases. We then screened peptide sequences for their sensitivity to cleavage by these proteases. 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 the figure below, our albumin-binding domain has a nearly identical binding affinity to albumin from these two species.

Figure 5. 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:
  - Manufacturability using standard mammalian cell expression systems;
  - Drug-like properties such as solubility, thermal stability, and stability in human serum; and
  - 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.

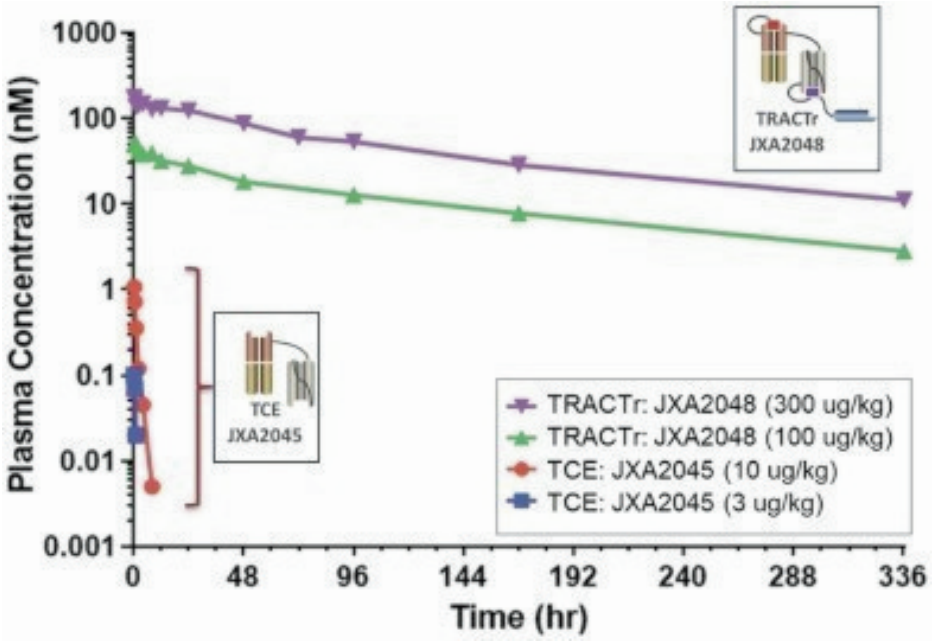
Initial proof of technology study

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 demonstrating 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.

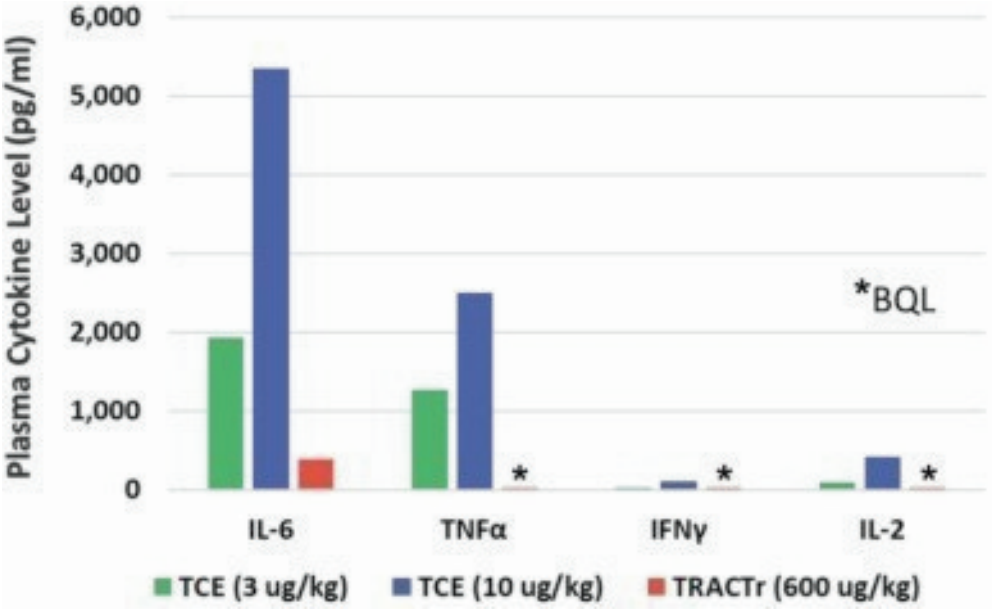
Our EGFR-TRACTr included an albumin-binding domain intended to increase its half-life in serum to extend the interval between dosing while simultaneously utilizing the protease-mediated cleavage of the linker to remove the domain once our TRACTr was activated. In NHPs, our EGFR-TRACTr was found to have 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 6. 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 7. 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 (TNFα), interferon gamma (IFNγ), and interleukin-2 (IL-2). TNFα, IFNγ, and IL-2 were all below the quantification limit (BQL)

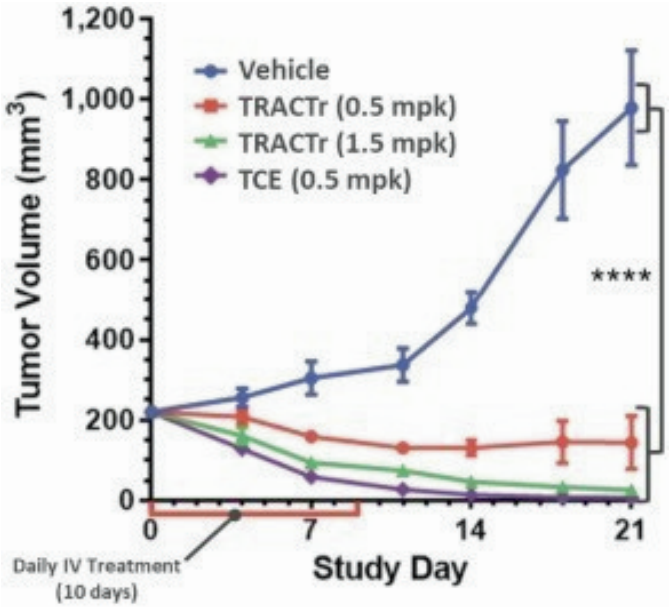


The lack of induction of inflammatory cytokines in NHPs associated with CRS in humans is consistent with the potential for the peptide masks to prevent antigen binding and thereby T cell activation. In these studies, the EGFR-TRACTr maximum tolerated dose (MTD) was higher than 600µg/kg due to a lack 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.

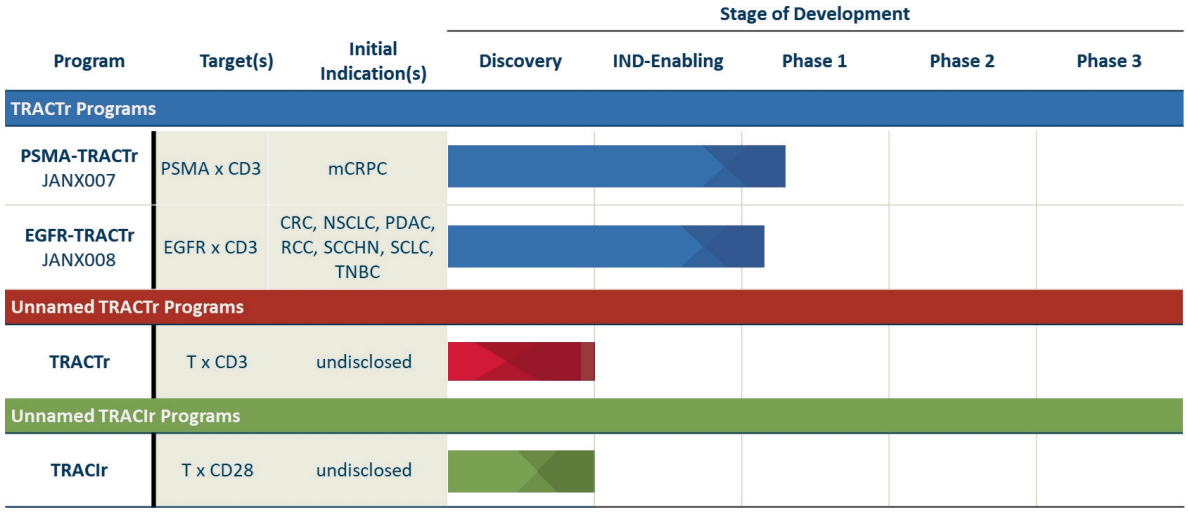
With the observation of reduced CRS risk for our EGFR-TRACTr relative to the EGFR-TCE (at a substantially lower dose than the TRACTr) in our NHP study, and the observation of comparable anti-tumor activity of our EGFR-TRACTr and the EGFR-TCE (at one third of the dose of the our TRACTr) in our mouse model 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 8. 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, SCLC, NSCLC, PDAC and TNBC. Our wholly-owned pipeline is summarized below:



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 December 2024 we announced updated interim clinical data for JANX007 which displayed meaningful and prolonged PSA drops, encouraging anti-tumor activity, a favorable safety profile including CRS and TRAEs primarily limited to Cycle 1 and lower grades, 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 2025, an estimated 313,780 new prostate cancer diagnoses in the United

States are expected, representing approximately 15 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 37 percent. There will be an estimated 35,770 deaths in the United States due to prostate cancer in 2025.

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 progress and develop castration-resistant prostate cancer.

Treatment options for mCRPC

Castration-resistant prostate cancer is cancer that is still growing despite the fact that hormone therapy (an orchiectomy or a luteinizing hormone-releasing hormone agonist or antagonist) is maintaining testosterone levels in the body as low as what would be expected if the body was castrated. The cancer might still respond to other forms of hormone therapy, though such therapy may not be effective.

A novel hormonal therapy may be added to the existing hormone therapy, especially if the cancer is causing few or no symptoms. These include abiraterone, enzalutamide, apalutamide and darolutamide.

The prostate cancer vaccine sipuleucel-T is another option for men whose cancer is causing few or no symptoms. This might not lower PSA levels, but it can often help men live longer.

For cancers that are no longer responding to a novel hormonal therapy, several options might be available. If it has not been used already, chemotherapy with the drug docetaxel is often the first choice because it has been shown to help men live longer, as well as to reduce pain. If docetaxel does not work or stops working, other chemotherapy drugs, such as cabazitaxel, may be effective.

Depending on which treatments a patient has had, other options at some point might include: a different type of hormone therapy, such as abiraterone or enzalutamide (if not already used); or for cancers that are PSMA positive, the radiopharmaceutical lutetium Lu 177 vipivotide tetraxetan (Pluvicto) is an option. If the cancer cells have a mutation in a DNA repair gene such as BRCA1 or BRCA2 a PARP inhibitor, such as rucaparib, olaparib, talazoparib or niraparib typically along with hormone therapy is warranted. If the cancer cells have certain gene changes (MSI-H, dMMR, or high TMB) then immunotherapy with pembrolizumab or dostarlimab are options.

PSMA is a validated prostate cancer antigen

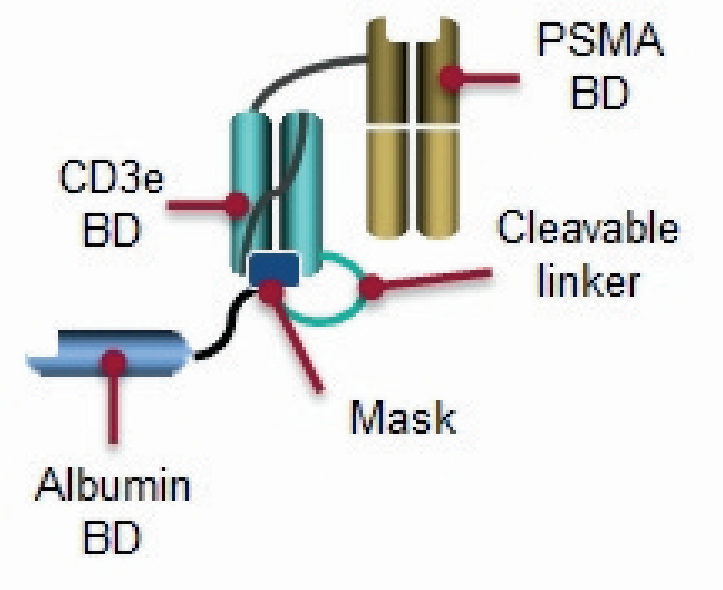
PSMA is a prostate-specific transmembrane protein expressed at a 100-fold to a 1,000-fold higher level in prostate adenocarcinoma than in the benign prostate. Of importance, PSMA expression is (i) increased when patients are on ADT and (ii) highest in high-grade and mCRPC. Over half of prostate cancer 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. 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.

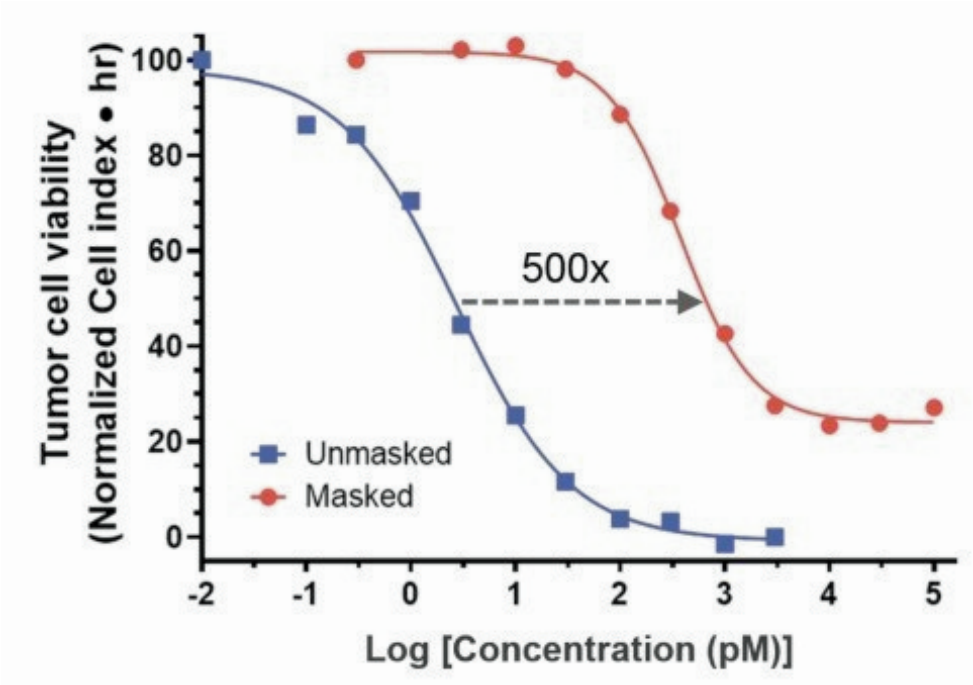
Our solution: JANX007

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.



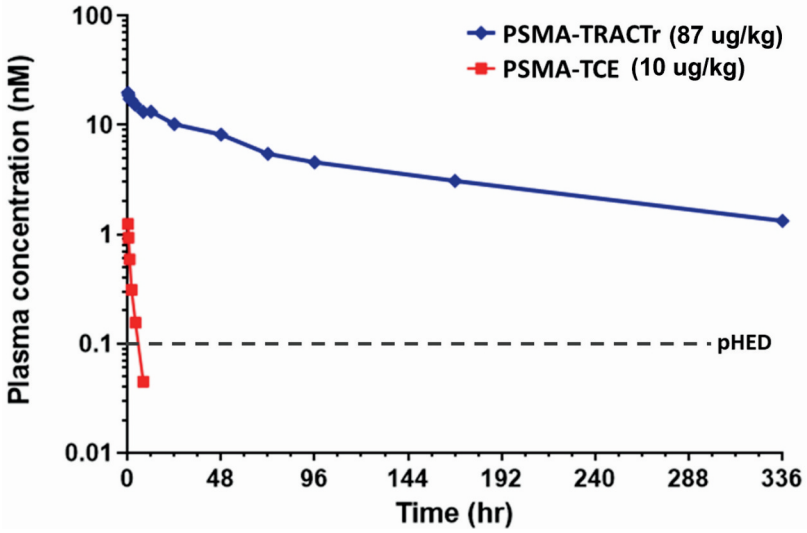
We found that our PSMA-TRACTr product candidate exhibited a 500-fold shift in activating T cell killing of PSMA expressing tumor cells in an in vitro assay when it was masked than when the mask was removed, as shown in the figure below. We believe this difference in activity has the potential to greatly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

Figure 9. 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.

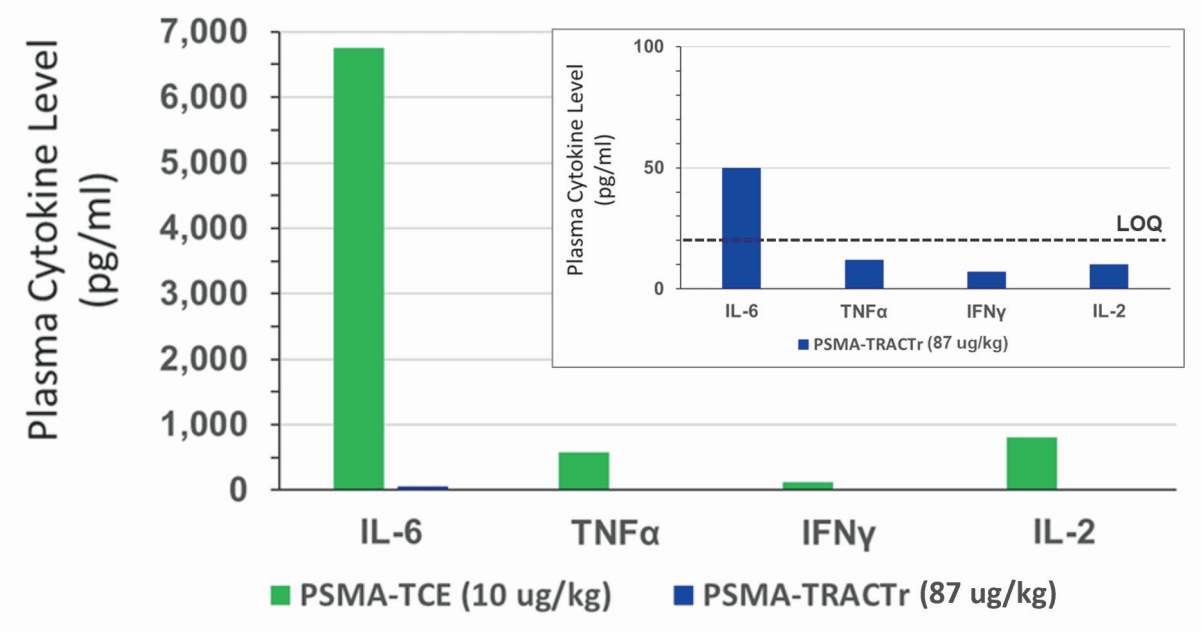
Figure 10. Our PSMA-TRACTr had a half-life of 119 hours in NHPs



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 11. 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.



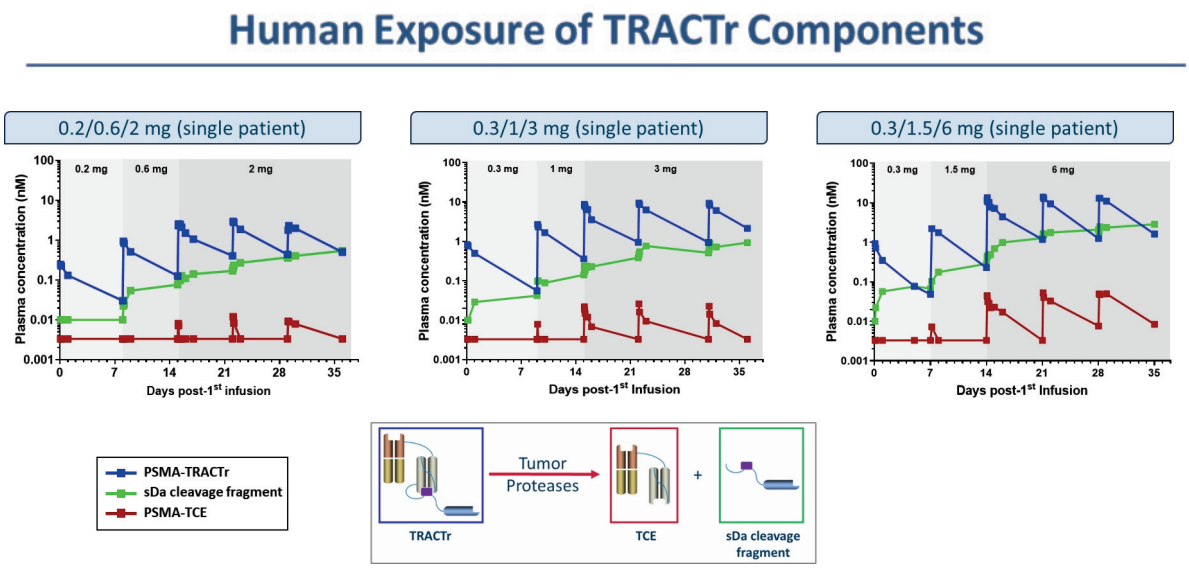
Clinical development

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 December 2024 we announced updated interim clinical data for JANX007 which displayed meaningful and prolonged PSA drops, encouraging anti-tumor activity, a favorable safety profile including CRS and TRAEs primarily limited to Cycle 1 and lower grades, and PK consistent with the TRACTr mechanism-of-action.

PK data

JANX007 updated interim PK data showed consistency with tumor cleavage dependent activity and TRACTr cleavage was observed with minimal accumulation of activated TCE. We believe this is consistent with TRACTr design principles and our desired mechanism of action. Specifically, the cleavage fragment comprising the albumin binding domain indicates TRACTr activation is occurring and we observed TRACTr and TCE plasma levels below the preclinical activity threshold with systemic levels of activated TCE more than 100-fold lower than TRACTr across doses.

Figure 12. Interim updated clinical PK data has been consistent with TRACTr design principles: TRACTr cleavage with minimal plasma accumulation of activated TCE

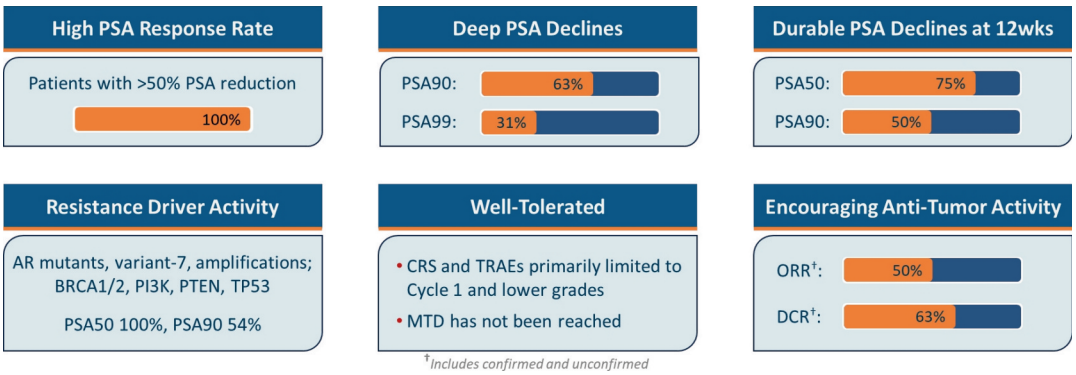


Safety and efficacy data

As of the November 15, 2024 data cutoff, 16 pre-PLUVICTO patients had been treated once-weekly at a target dose ranging from 2 mg to 9 mg in the Phase 1a clinical trial. High PSA response rates and deep PSA declines were observed across all doses; 100% of patients achieved best PSA50 declines, 63% of patients achieved best PSA90 declines, and 31% of patients achieved best PSA99 declines. Durability of PSA declines at a target dose ≥ 2 mg were observed; 75% of patients maintained PSA50 declines at ≥ 12 weeks and 50% of patients maintained PSA90 declines at ≥ 12 weeks. Deep and durable PSA responses were observed irrespective of resistance driver aberration status, or prior treatments with a taxane or ARPi. In RECIST-evaluable patients, anti-tumor activity was observed with confirmed and unconfirmed partial responses in 50% (4/8) of patients.

JANX007 was well-tolerated with CRS and CRS-related adverse events primarily limited to Cycle 1 and Grade 1 and 2. Similarly, TRAEs not associated with CRS were primarily limited to Cycle 1 and Grade 1 and 2. The maximum tolerable dose for JANX007 has not yet been reached.

Figure 13. Interim clinical data supports development in early lines of therapy



Our EGFR-TRACTr (JANX008) for the treatment of colorectal carcinoma, squamous cell carcinoma of the head and neck, non-small cell lung cancer, renal cell carcinoma, small cell lung cancer, pancreatic ductal adenocarcinoma and triple-negative breast cancer

JANX008 is being studied in a Phase 1 clinical trial for the treatment of multiple solid cancers including CRC, SCCHN, NSCLC, RCC, SCLC, PDAC and TNBC. The first patient for this trial was dosed in April 2023 and in February 2024 we announced positive early data for 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 will be approximately 154,270 new cases of colorectal cancer in the United States in 2025 and approximately 52,900 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

Most people with stage IV metastatic colorectal cancer will get chemotherapy and/or targeted therapies. Some of the most commonly used regimens include: FOLFOX: leucovorin, 5-FU, and oxaliplatin; FOLFIRI: leucovorin, 5-FU, and irinotecan; CAPEOX: capecitabine and oxaliplatin; FOLFOXIRI: leucovorin, 5-FU, oxaliplatin, and irinotecan; one of the above chemotherapy combinations, plus one or more targeted drugs; 5-FU and leucovorin, with or without a targeted drug; Capecitabine, with or without a targeted drug; Irinotecan, with or without a targeted drug; Cetuximab or panitumumab; Regorafenib, trifluridine and tipiracil, alone or in combination with bevacizumab. For people whose cancers cells have high levels of microsatellite instability or changes in one of the MMR genes, an immunotherapy drug, such as pembrolizumab, nivolumab or dostarlimab, can be an option.

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. The NCI estimated that approximately 71,100 men and women in the United States were diagnosed with head and neck cancers in 2024. Additionally, there were an estimated 16,110 deaths from head and neck cancer in 2024. EGFR is overexpressed in approximately 90 percent of head and neck cancers.

Treatment options for SCCHN

The treatment for recurrent/metastatic head and neck squamous cell carcinoma with immune checkpoint inhibitors (anti-PD1) with or without chemotherapy has led to an improvement in survival, however only 15-19% of patients remain alive at four years, highlighting the poor overall survival and high unmet need for improved therapies. Some of the key evolving novel therapeutics beyond anti-PD1 have included therapeutic vaccine therapies, bispecific antibodies/fusion proteins and multitargeted kinase inhibitors, and antibody-drug conjugates.

Non-small cell lung cancer overview

It is estimated that there will be approximately 226,650 new lung cancer cases and 124,730 lung cancer deaths in the United States in 2025. 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

Metastatic NSCLC patients' tumors will be tested for certain gene mutations (such as in the KRAS, EGFR, ALK, ROS1, BRAF, RET, MET, or NTRK genes). If one of these genes is mutated in the patients' cancer cells, the likely first treatment will be a targeted therapy. Tumors with higher levels of PD-L1 are more likely to respond to certain immunotherapy drugs (known as immune

checkpoint inhibitors), which might be an option either alone or along with 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 (RCC), 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 2025 are that approximately 81,610 new cases of kidney cancer will be diagnosed and approximately 14,390 people will die from this disease.

Treatment options for RCC

In RCC, greater than 90 percent of patients express EGFR. First line treatment of 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 remains as an option in the more favorable risk patients. In the first line treatment setting with checkpoint inhibitor combinations, the objective response rates range from approximately 40-70% with median progression-free survival (mPFS) from 12-24 months and median overall survival (mOS) typically being greater than 37 months.

Almost all first line patients become resistant to standard therapy with less than 50% being eligible to receive second line therapy. The majority of second line 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 second line 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 second line treatment options.

Small cell lung cancer overview

Small cell lung cancer is a type of rapidly-growing cancer that forms in the lung tissues and accounts for approximately 15 percent of lung cancer cases. It is estimated that there will be approximately 226,650 new lung cancer cases and 124,730 lung cancer deaths in the United States in 2025. The overall five-year survival for all patients diagnosed with SCLC is approximately seven percent.

Treatment options for SCLC

There are many ways to treat small cell lung cancer, but the most common types of treatment are radiation, chemotherapy, and/or immunotherapy. Many times, more than one kind of treatment is used.

Pancreatic ductal adenocarcinoma overview

Pancreatic ductal adenocarcinoma is the most common form of pancreatic cancer, comprising more than 80% of pancreatic cancer cases. The disease originates in the cells of the pancreas's ducts, which transport fluids containing digestive enzymes into the small intestine. It is estimated that there will be approximately 67,440 new pancreatic cancer cases and 51,980 pancreatic cancer deaths in the United States in 2025. The overall five-year survival for all patients diagnosed with pancreatic cancer is approximately 13 percent.

Treatment options for PDAC

Chemotherapy is typically the primary treatment for metastatic pancreatic cancer. It can sometimes reduce or slow the growth of these cancers and might help people live longer, but it is not expected to cure the cancer.

Gemcitabine is one of the most frequently used drugs. It can be used alone (especially for patients in poor health), or it can be combined with other drugs (likepaclitaxel, capecitabine, cisplatin or the targeted drug erlotinib).

Another option, especially for patients who are otherwise in good health, is a combination of chemotherapy drugs called FOLFIRINOX. This consists of 4 drugs: 5-FU, leucovorin, irinotecan and oxaliplatin. This treatment might help people live longer than getting gemcitabine alone, but it can also have additional side effects.

In certain cases, immunotherapy or targeted therapy may be options for people whose cancer cells have certain genetic alterations.

Triple-negative breast cancer overview

Triple-negative breast cancer is an aggressive type of invasive breast cancer. TNBC differs from other types of invasive breast cancer in that it tends to grow and spread more rapidly, has fewer treatment options and tends to have a worse prognosis. Triple-negative breast cancer makes up about 10-15% of all breast cancers. It is estimated that there will be approximately 316,950 new breast cancer cases and 42,170 breast cancer deaths in the United States in 2025. The overall five-year survival for all patients diagnosed with metastatic TNBC is approximately 12 percent.

Treatment options for TNBC

Triple-negative breast cancer has fewer treatment options than other types of invasive breast cancer. This is because the cancer cells do not have the estrogen or progesterone receptors or sufficient HER2 protein to make hormone therapy or targeted HER2 drugs work effectively. Because hormone therapy and anti-HER2 drugs are not choices for TNBC, chemotherapy is often used.

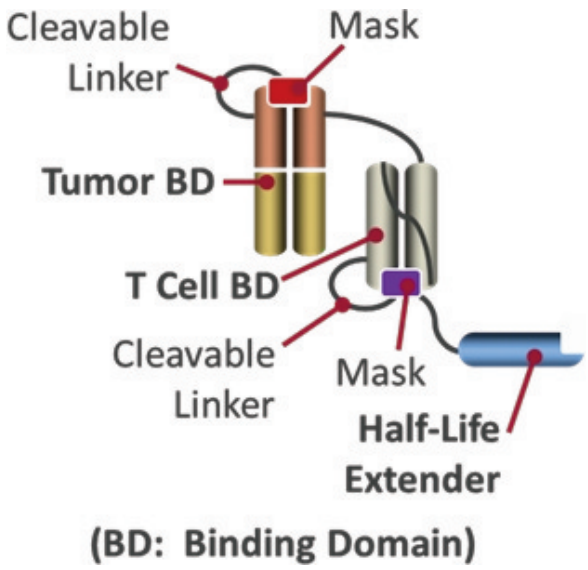
If the cancer has not metastasized, surgery is an option. Chemotherapy might be applied first to reduce a large tumor, followed by surgery. Chemotherapy is often recommended after surgery to decrease the chances of the cancer returning. Radiation might also be an option depending on certain characteristics of the tumor and the type of surgery that was performed.

For patients with metastatic TNBC, platinum chemotherapy, targeted drugs like a PARP inhibitors or antibody-drug conjugates, or immunotherapies with chemotherapy might be considered.

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.

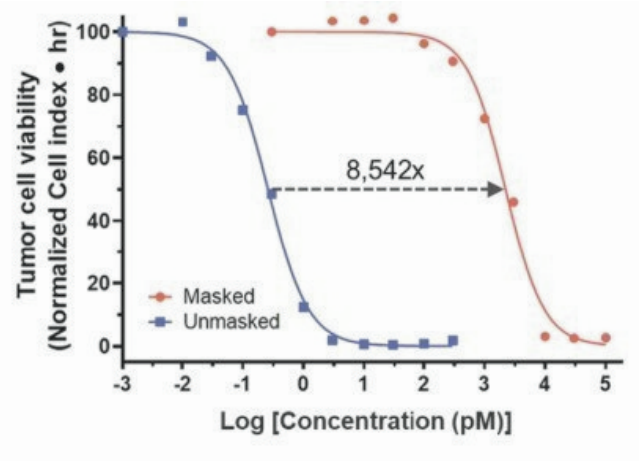
Figure 14. Structure of JANX008



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.

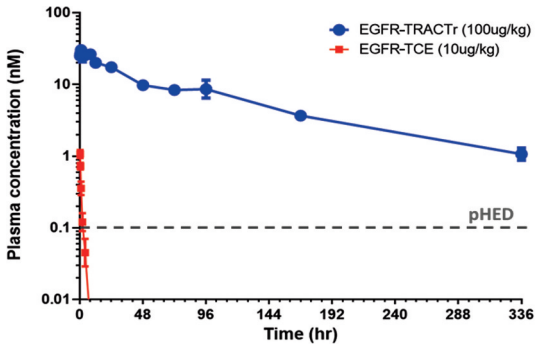
Since these cells harbor KRAS mutations and are resistant to anti-EGFR antibodies, the observed EGFR-TCE activity suggests that EGFR inhibitor-resistant (including KRAS mutants sensitive to our EGFR-TRACTr) CRC will be sensitive to our EGFR-TRACTr. Our observation is consistent with published studies 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 15. 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 the figure below, we illustrate our EGFR-TRACTr and the EGFR-TCE half-lives in a study in NHPs.

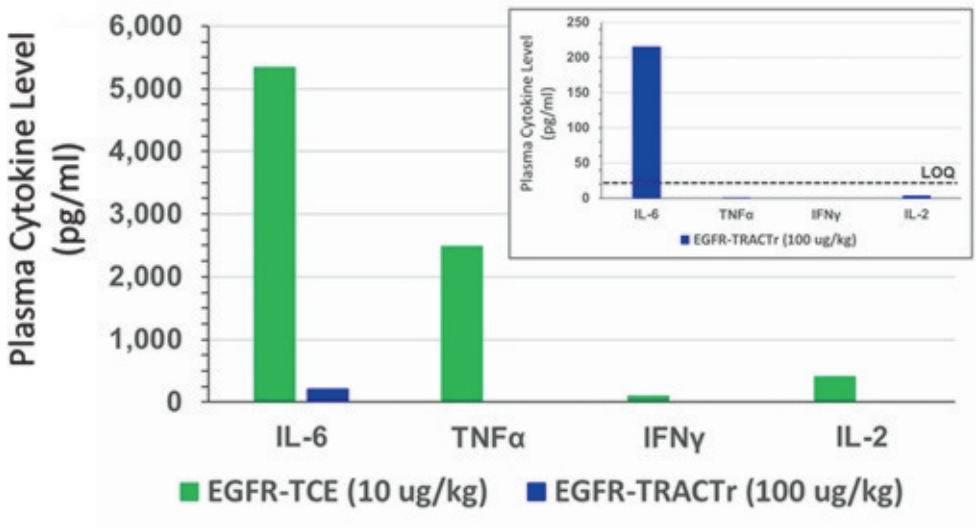
Figure 16. Our EGFR-TRACTr had a half-life of approximately 94 hours in NHPs



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 17. 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



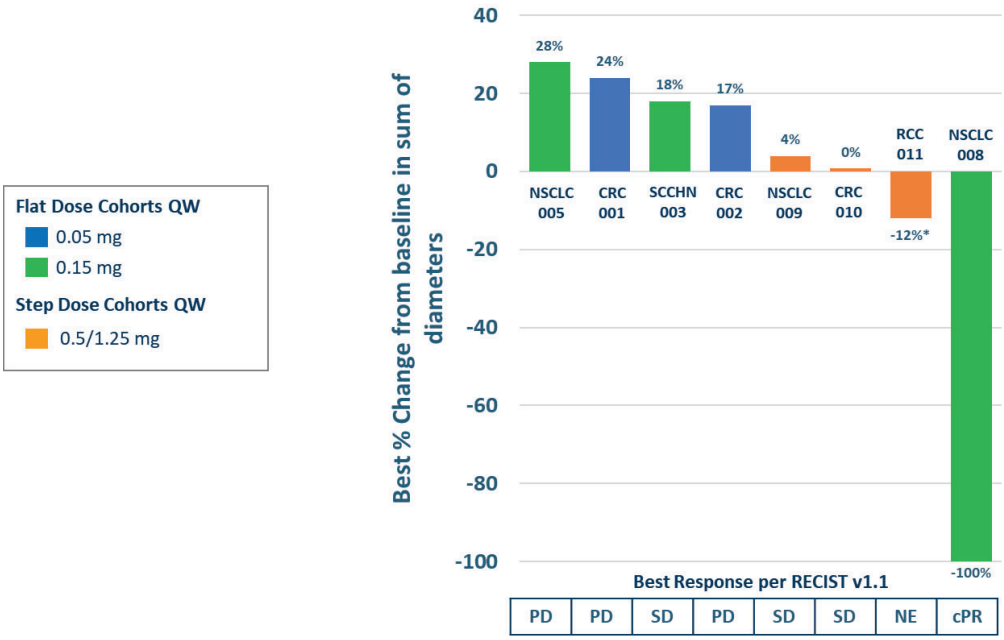
Clinical development

JANX008 is being studied in a Phase 1 clinical trial for the treatment of multiple solid cancers including colorectal carcinoma, squamous cell carcinoma of the head and neck, non-small cell lung cancer, renal cell carcinoma, small cell lung cancer, pancreatic ductal adenocarcinoma and triple-negative breast cancer. The first patient for this trial was dosed in April 2023 and in February 2024 we announced positive early data for 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 18. 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 19. 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 tolerable 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-per-dose 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 the materials and components required for the manufacture of our product candidates.

All 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 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 and future manufacturing campaign capacity 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., TCEs, 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 Abbvie, Amgen, Crescendo Biologics, Johnson & Johnson, Lava Therapeutics, Chugai/Roche, Regeneron, Takeda and Vir Biotechnology; T cell immunomodulators from Astellas, Regeneron, Johnson & Johnson and Xencor; antibody-drug conjugates from Johnson & Johnson; CAR T cell therapies from Gilead; and radiopharmaceuticals from AstraZeneca, Novartis, Lantheus/Lilly, 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, 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, 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 AbbVie, AstraZeneca, Genmab/BioNTech, Inhibrx, Incyte/Merus, Chugai/Roche and Xencor.

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, Merck & Co., Takeda, Vir Biotechnology, 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, 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, or (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 14, 2025, we own 29 pending U.S. provisional and non-provisional patent applications, three U.S. patents, nine pending patent applications filed under the Patent Cooperation Treaty (PCT) and 94 foreign patent applications. Specifically, we have two U.S. non-provisional patent applications 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, 18 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, nine foreign patent applications, and two PCT patent applications that cover 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 21 foreign patent applications specific to JANX007 and two U.S. non-provisional patent applications, two U.S. provisional patent applications, one U.S. patent, two PCT patent applications, and 13 foreign patent applications specific to JANX008. We have two U.S. provisional patent applications, six U.S. non-provisional patent applications, three PCT patent applications, and 26 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 four U.S. provisional patent applications 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 2046, 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 (EU), 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, the 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 European Medicines Agency (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 is intended to harmonize and streamline clinical trial authorizations, simplify adverse event reporting procedures, improve the supervision of clinical trials and increase transparency. Specifically, the Regulation, which is directly applicable in all EU Member States, introduces a streamlined application procedure via a single entry point, the Clinical Trials Information System ("CTIS"); a single set of documents to be prepared and submitted for the application as well as simplified reporting procedures for clinical trial sponsors. A harmonized procedure for the assessment of applications for clinical trials has been introduced and is divided into two parts. Part I assessment is led by the competent authorities of a reference Member State selected by the trial sponsor and relates to clinical trial aspects that are considered to be scientifically harmonized across EU Member States. This assessment is then submitted to the competent authorities of concerned Member States in which the trial is to be conducted for their review. Part II is assessed separately by the competent authorities and Ethics Committees in each concerned EU Member State. Individual EU Member States retain the power to authorize the conduct of clinical trials on their territory. The CTR foresaw a three-year transition period that ended on January 31, 2025. Since this date, all new or ongoing trials are subject to the provisions of the CTR.

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. Medicines used 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

In the EU, 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 conditions; (2) either (a) such conditions affect 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 to justify the necessary investment in developing the medicinal product; and (3) there exists no satisfactory authorized method of diagnosis, prevention or treatment of the condition that has been authorized in the EU or, even if such method exists, the product will be of significant benefit to those affected by that condition.

Regulation (EC) No 847/2000 sets out further provisions for implementation of the criteria for designation of a medicinal product as an orphan medicinal product. An application for the designation of a medicinal product as an orphan medicinal product must be submitted at any stage of development of the medicinal product but before filing of an MAA. An MA for an orphan medicinal product may only include indications designated as orphan. For non-orphan indications treated with the same active pharmaceutical ingredient, a separate marketing authorization has to be sought.

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 and the European Commission cannot grant an MA 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 designation, 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-authorization 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 ("PSURs").

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

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 health care professionals, misleading and comparative advertising and unfair commercial practices. General requirements for advertising and promotion of medicinal products, such as directed-to-consumer advertising of prescription medicinal products are established in EU law. However, details are governed by regulations in individual EU Member States 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 ("SmPC"), which may require approval by the competent national authorities in connection with an MA. The SmPC is the document that provides information to physicians and other health care professionals 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.

Data Privacy and Security

In the ordinary course of our business, we 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 (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.

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, as described below, the provision of benefits or advantages to physicians and other health care professionals to induce or encourage the prescription, recommendation, endorsement, purchase, supply, order or use of medicinal products is also prohibited in the EU. Interactions between pharmaceutical companies and health care professionals are governed by strict laws, such as national anti-bribery laws of European countries, national sunshine rules, regulations, industry self-regulation codes of conduct and physicians' codes of professional conduct. Failure to comply with these requirements could result in reputational risk, public reprimands, administrative penalties, fines or imprisonment

Payments made to physicians and other health care professionals in certain European Union Member States must be publicly disclosed. Moreover, agreements with physicians and other health care professionals often may require prior notification and approval by the physician's or health care professional's employer, their competent professional organization and/or the regulatory authorities of 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, as well as ownership and investment interests held by the physicians described above and their 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 (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. In December 2021, Regulation No 2021/2282 on HTA, was adopted in the EU. This Regulation, which entered into application on January 12, 2025 and has a phased implementation, 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 permits 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 continue to be responsible for assessing non-clinical (e.g., economic, social, ethical) aspects of health technologies, and making decisions on pricing and reimbursement.

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 and access to health insurance.

There have been executive, judicial and congressional challenges and amendments to certain aspects of the Affordable Care Act. For example, on August 16, 2022, the Inflation Reduction Act of 2022 (IRA) was signed 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 second Trump 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, the American Rescue Plan Act of 2021 was signed into law, which eliminated the statutory Medicaid drug rebate cap, previously set at 100% of a drug's average manufacturer price, for single source and innovator multiple source drugs, effective January 1, 2024.

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, the IRA also, among other things, (1) directs the U.S. Department of Health and Human Services (HHS) to negotiate the price of certain high expenditure, single-source biologics that have been on the market for at least 11 years covered under Medicare (the Medicare Drug Price Negotiation Program) and (2) imposes rebates under Medicare Part B and Medicare Part D to penalize price increases that outpace inflation. These provisions began to take effect progressively in fiscal year 2023. On August 15, 2024, HHS announced the agreed-upon price of the first ten drugs that were subject to price negotiations, although the Medicare Drug Price Negotiation Program is currently subject to legal challenges. On January 17, 2024, HHS selected fifteen additional products covered under Part D for price negotiation in 2025. Each year thereafter more Part B and Part D products will become subject to the Medicare Drug Price Negotiation Program. Further, on December 7, 2023, announced an initiative to control the price of prescription drugs through the use of march-in

rights under the Bayh-Dole Act was announced. 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, particularly in light of the recent U.S. Presidential and Congressional elections.

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 began to apply on January 2025 through a phased implementation, 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 permits 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 and on 10 April 2024, the Parliament adopted its related position. The proposed revisions remain to be agreed and adopted by the European Council. Moreover, on December 1, 2024, a new European Commission took office. The proposal could, therefore, still be subject to revisions. If adopted in the form proposed, the European Commission proposals to revise the existing EU laws governing authorization of medicinal products may result in a number of changes to the regulatory framework governing medicinal products, including 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. Even if favorable coverage and reimbursement status is attained for one or more products for which we receive regulatory approval, less favorable coverage policies and reimbursement rates may be implemented in the future. 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, 2024, we had 81 full-time employees. Of these employees, 63 were engaged in research and development and 18 were engaged in general and administrative activities. As of December 31, 2024, we had 74 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, 2024 and 2023, our net losses were $69.0 million and $58.3 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, 2024, we had $1.0 billion in cash, cash equivalents and short-term investments. Based upon our current operating plan, we estimate that our existing cash, 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, 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 the military conflict in Ukraine and Russia, the war in the Middle East, epidemics 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 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), a Risk Management Plan, 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 have and may continue to 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 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 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 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 Risk Management Plans or 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's, and other regulatory authorities' policies may change and additional government regulations may be enacted that could prevent, limit or delay regulatory approval of our product candidates. We 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 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 rely on third parties to conduct, supervise, and/or 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 Bulk Drug Substance (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 have limited control over 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.

Our ongoing manufacturing activities with WuXi Biologics may expose us to additional risk. Certain Chinese biotechnology companies may become subject to trade restrictions, sanctions, other regulatory requirements, or proposed legislation by the U.S. government, which would restrict or even prohibit our ability to work with such entities, thereby potentially disrupting the supply of material to us. Any U.S. executive action, legislative action, or potential sanctions with China could materially impact our work with WuXi Biologics. U.S. executive agencies have the ability to designate entities and individuals on various governmental prohibited and restricted parties lists. Depending on the designation, potential consequences can range from a comprehensive prohibition on all transactions or dealings with designated parties, or a limited prohibition on certain types of activities, such as exports and financing activities, with designated parties. Any unfavorable government policies on international trade, such as export controls, capital controls or tariffs, new legislation or regulations, renegotiation of existing trade agreements, or any retaliatory trade actions due to recent trade tension, may impede, delay, limit, or increase the cost of potentially manufacturing our product candidates including pursuant to any manufacturing service arrangements with WuXi Biologics. Such events could have an adverse effect on our business, financial condition and results of operations.

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, the EMA 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 medical conditions 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. Even if favorable coverage and reimbursement status is attained for one or more products for which we receive regulatory approval, less favorable coverage policies and reimbursement rates may be implemented in the future. 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. Equivalent competent foreign authorities sometimes adopt an equivalent approach with similar consequences.

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, 2024, we had 81 full-time 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, BeiGene, Bristol Myers Squibb, Gilead, Johnson & Johnson, Eli Lilly, Merck & Co., Novartis, Pfizer, Regeneron, Roche/Genentech, Takeda and Xencor. Other companies using PSMA-targeting therapeutics for the treatment of cancer include AbbVie, Amgen, Bayer, Crescendo Biologics, Eli Lilly, Johnson and Johnson, Lava Therapeutics, Novartis, Regeneron and Vir Biotechnology. We also face competition from biologic prodrug developers such as Adagene, Chugai Pharmaceutical Co./Roche Holding AG, CytomX Therapeutics, Merck & Co., Takeda and Vir Biotechnology.

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. 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, 2024, we had $66.2 million of U.S. federal NOL carryforwards and $167.6 million of state NOL carryforwards. Of the total federal NOLs, $65.7 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 NOL carryforwards 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 loss carryforwards 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 NOL carryforwards 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 NOL carryforwards is suspended or otherwise limited, which could accelerate or permanently increase state taxes owed.

For example, California imposed limits on the usability of California state net operating losses to offset taxable income in tax years beginning after 2023 and before 2027.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 health epidemic or pandemic may also materially affect us economically. While the potential economic impact brought by, and the duration of, a health crise 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 and amendments to certain aspects of the Affordable Care Act. For example, on August 16, 2022, the Inflation Reduction Act of 2022 (IRA) was signed 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 second Trump 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, the American Rescue Plan Act of 2021 was signed into law, which eliminated the statutory Medicaid drug rebate cap, previously 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, the IRA,

among other things, (1) directs the U.S. Department of Health and Human Services (HHS) to negotiate the price of certain high-expenditure single-source biologics that have been on the market for at least 11 years covered under Medicare (the Medicare Drug Price Negotiation Program) and (2) imposes rebates under Medicare Part B and Medicare Part D to penalize price increases that outpace inflation. These provisions began to take effect progressively in fiscal year 2023. On August 15, 2024, HHS announced the agreed-upon prices of the first ten drugs that were subject to price negotiations, although the Medicare Drug Price Negotiation Program is currently subject to legal challenges. On January 17, 2024, HHS selected fifteen additional products covered under Part D for price negotiation in 2025. Each year thereafter more Part B and Part D products will become subject to the Medicare Drug Price Negotiation Program. Further, on December 7, 2023, an initiative to control the price of prescription drugs through the use of march-in rights under the Bayh-Dole Act was announced. 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.

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. For example, the regulatory landscape related to clinical trials in the EU has undergone recent changes. The EU Clinical Trials Regulation, or CTR, which was adopted in April 2014 and repeals the EU Clinical Trials Directive, became effective on January 31, 2022. The CTR permits trial sponsors to make a single submission to both the competent authority and an ethics committee in each EU Member State, leading to a single decision for each EU Member State. The assessment procedure for the authorization of clinical trials has been harmonized as well, including a joint assessment of some elements of the application by all EU Member States in which the trial is to be conducted, and a separate assessment by each EU Member State with respect to specific requirements related to its own territory, including ethics rules. Each EU Member State's decision is communicated to the sponsor through a centralized EU portal, the Clinical Trial Information System, or CTIS. The CTR provides a three-year transition period. The extent to which ongoing clinical trials will be governed by the CTR varies. For clinical trials in relation to which an application for approval was made on the basis of the Clinical Trials Directive 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 foresaw a three-year transition period that ended on January 31, 2025. Since this date, all new or ongoing trials are subject to the provisions of the CTR.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. 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. This Health Technology Assessment ("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. In December 2021, Regulation No 2021/2282 on HTA, was adopted in the EU. This Regulation, which entered into application on January 12, 2025 and has a phased implementation, 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 permits 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 continue to be responsible for assessing non-clinical (e.g., economic, social, ethical) aspects of health technologies, and making decisions on pricing and reimbursement.

In addition, on April 26, 2023, the European Commission adopted a proposal for a new Directive and Regulation to revise the existing pharmaceutical legislation and on April 10, 2024, the European Union Parliament adopted its related position. The proposed revisions remain to be agreed and adopted by the European Council. Moreover, on December 1, 2024, a new European Commission took office. The proposal could, therefore, still be subject to revisions. 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 number of changes to the regulatory

framework governing medicinal products, including 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, particularly in light of the recent U.S. Presidential and Congressional elections, 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. The United Kingdom is now a third country to the EU.

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 and such changes were laid in parliament on December 12, 2024. These resulting legislative amendments will, if implemented in their current form, bring the UK into closer alignment 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. Applications are governed by the Human Medicines Regulations (SI 2012/1916) and are made electronically through the MHRA Submissions Portal. The MHRA has introduced changes to national licensing procedures, including procedures to prioritize access to new medicines that will benefit patients, a 150-day assessment (subject to clock-stops) and a rolling review procedure. The rolling-review procedure permits the separate or joint submission of quality, non-clinical, and clinical data to the MHRA which can be reviewed on a rolling basis. After an application under the rolling-review procedure has been validated, the decision should be received within 100 days (subject to clock-stops).

In addition, since January 1, 2024, the MHRA may rely on the International Recognition Procedure ("IRP"), when reviewing certain types of MAAs. Pursuant to the IRP, the MHRA will take into account the expertise and decision-making of trusted regulatory partners (e.g., the regulatory in Australia, Canada, Switzerland, Singapore, Japan, the U.S.A. and the EU). The MHRA will conduct a targeted assessment of IRP applications but retain the authority to reject applications if the evidence provided is considered insufficiently robust. The IRP allows medicinal products approved by such trusted regulatory partners that meet certain criteria to undergo a fast-tracked MHRA review to obtain and/or update a MA in the United Kingdom. Applications should be decided within a maximum of 60 days if there are no major objections identified that cannot be resolved within such 60 day period and the approval from the trusted regulatory partner selected has been granted within the previous 2 years or if there are such major objections identified or such approval hasn't been granted within the previous 2 years within 110 days. Applicants can submit initial MAAs to the IRP but the procedure can also be used throughout the lifecycle of a product for post-authorization procedures including line extensions, variations and renewals.

All existing EU marketing authorizations for centrally authorized products were automatically converted or grandfathered into the UK's 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 remained within the scope of authorizations of the EU in relation to centrally authorized medicinal products until January 1, 2025. However, on January 1, 2025, a new arrangement as part of the so-called "Windsor Framework" came into effect and reintegrated Northern Ireland under the regulatory authority of the MHRA with respect to medicinal products.

The Windsor Framework removes EU licensing processes and EU labelling and serialization requirements in relation to Northern Ireland and introduces a UK-wide licensing process for medicines. 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 the UK, 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 the UK.

We and the third parties with whom we work 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 (or the third parties with whom we work) 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 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 and allows private litigants affected by certain data breaches to recover significant statutory damages. The CCPA (and other U.S. comprehensive privacy laws) exempt some data processed in the context of clinical trials, but these developments t increase compliance costs and potential liability with respect to other personal information we maintain about residents in these states. 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 are 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 data privacy and security. For example, the European Union's General Data Protection Regulation (EU GDPR), the United Kingdom's GDPR (UK GDPR) (collectively, the 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 GDPR, government regulators impose temporary or definitive bans on data processing, as well as fines of up to 20 million euros under the EU GDPR, £17.5 million under 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.

Our employees and personnel use generative artificial intelligence (AI) technologies to perform their work, and the disclosure and use of personal data in generative AI technologies is subject to various privacy laws and other privacy obligations. Governments have passed and are likely to pass additional laws regulating generative AI. Our use of this technology could result in additional compliance costs, regulatory investigations and actions, and lawsuits. If we are unable to use generative AI, it could make our business less efficient and result in competitive disadvantages.

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, white papers, and other statements regarding data privacy and security. If these policies, materials or statements are found to be deficient, lacking in transparency, deceptive, unfair, misleading, 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 with whom we work. 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 the third parties upon with whom we work may fail to comply with such obligations, which could negatively impact our business operations and compliance posture.

If we or any of the third parties with whom we work 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 or restrictions 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 have adopted 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. Regulators in the United States are also increasingly scrutinizing certain personal data transfers and may impose data localization requirements, for example, the Biden Administration's executive order Preventing Access to Americans' Bulk Sensitive Personal Data and United States Government-Related Data by Countries of Concern.

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. European applications now have the option, upon grant of a patent, of becoming a Unitary Patent which will be subject to the jurisdiction of the Unitary Patent Court (UPC). This is 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 Patent Cooperation Treaty applications, U.S. patent applications, 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 aspects 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 a 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. 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. As another example, the Supreme Court of the United States held in Amgen v. Sanofi (2023) that a functionally claimed genus of antibodies that bind and block the PCSK9 receptor was invalid for failing to comply with the enablement requirement of the Patent Act. In addition, the Federal Circuit 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. While we do not believe that any of the patents owned or licensed by us will be found invalid based on these decisions, 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

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

Our stock price has been and may continue to 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;
- 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 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, 2024, we had 59,064,606 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 as of January 1, 2025, we are not exempted and will incur significant legal, accounting and other expenses related to these stated requirements. 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 officer. 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 health epidemics or pandemics, 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 third parties with whom we work (such as 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 with whom we work 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 with whom we work. 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 with whom we work 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 with whom we work are subject to a variety of evolving threats, including, but not limited to social-engineering attacks (including through deep fakes, which are 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, 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 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 with whom we work experience a security incident or other interruption, we could experience adverse consequences. While we may be entitled to damages if the third parties with whom we work 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 that of the third parties with whom we work 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 with whom we work), but we have not been and may not be able to detect, mitigate, and remediate all such vulnerabilities including on a timely basis. It may also be difficult and/or costly to detect, investigate, mitigate, contain, and remediate a security incident. Further, we may experience delays in developing and deploying remedial measures designed to address any such identified vulnerabilities. Vulnerabilities could be exploited and result in a security incident. Actions taken by us or the third parties with whom we work to detect, investigate, mitigate, contain, and remediate a security incident could result in outages, data losses, and disruptions of our business. Threat actors may also gain access to other networks and systems after a compromise of our networks and systems.

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 with whom we work. For example, we have been the target of unsuccessful phishing attempts in the past, and expect such attempts will continue in the future. A security incident or other interruption could disrupt our ability (and that of third parties with whom we work) to provide our services. A security incident or other interruption could disrupt our ability (and that of third parties with whom we work) 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 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, or we may voluntarily choose, to notify relevant stakeholders of security incidents, including affected individuals, customers, regulators, and investors, or to take other actions, such as providing credit monitoring and identity theft protection services. Such disclosures and related actions can be costly, and the disclosures or the failure to comply with such applicable requirements could lead to adverse consequences. If we (or a third-party with whom we work) 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 third parties' with whom we work 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, arson 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 cease to 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. 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.

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 Senior Director of IT, with the assistance of our legal department, 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, systems and data, 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, an incident response policy; incident detection and response processes; a vulnerability management policy; a disaster recovery plan; risk assessments; encrypting certain data; network security controls; data segregation; 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 Senior Director of IT discuss cybersecurity risk with management, including our 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 Senior Director of IT, who has 20 years of experience in IT and cybersecurity and is a member of the Information Systems Audit and Control Association (ISACA).

Our Senior Director of IT 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 General Counsel is responsible for approving budgets and, along with our Senior Director of IT, 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 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 Senior Director of IT concerning significant cybersecurity threats, related risks and the processes we have implemented to address them. The audit committee also has access to various reports, summaries and presentations related to cybersecurity threats, risks 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.

Market Information

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 25, 2025, there were 59,105,147 shares of common stock issued and held by approximately 16 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

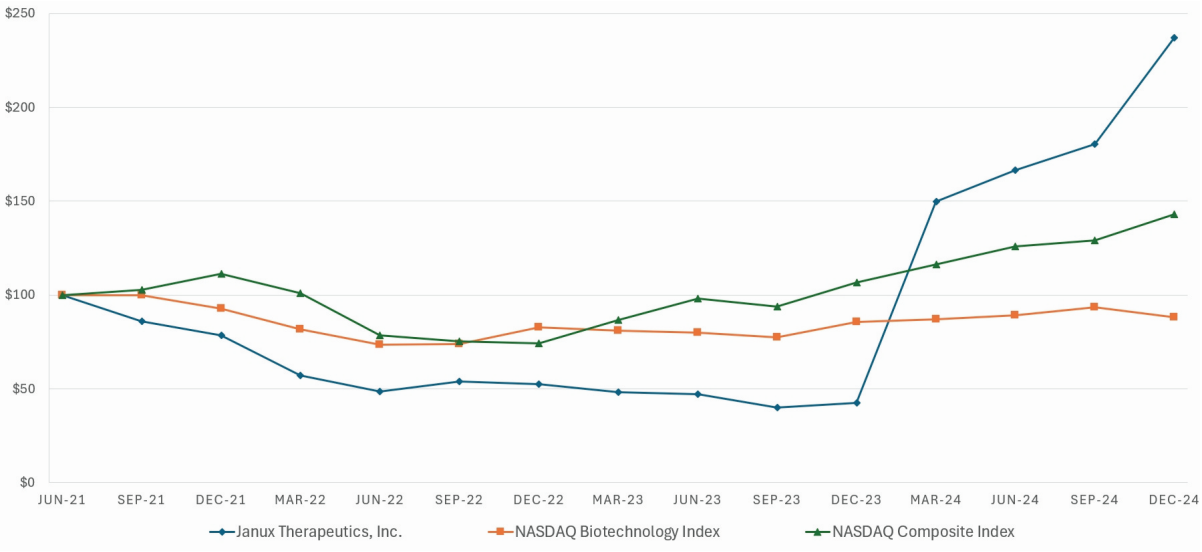
Information about securities authorized for issuance under our equity compensation plans is incorporated herein by reference to Item 12 of Part III of this Annual Report on Form 10-K.

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

The following stock performance graph illustrates a comparison from June 11, 2021 (the date our common stock commenced trading on the Nasdaq Global Market) through December 31, 2024, of the total cumulative stockholder return on our common stock, the Nasdaq Composite Index and the Nasdaq Biotechnology Index. The figures represented below assume an investment of $100 in our common stock at the closing price of $25.15 on June 11, 2021 and in the Nasdaq Composite Index and the Nasdaq Biotechnology Index on June 11, 2021, and that all dividends were reinvested, although dividends have not been declared on our common stock. The comparisons in the graph are required by the SEC and are not intended to forecast or be indicative of possible future performance of our common stock.



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, 2024, we have used $18.5 million 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 the balance of 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."

Additionally, our discussion and analysis below are focused on our financial results and liquidity and capital resources for the years ended December 31, 2024 and 2023, including year-over-year comparisons of our financial performance and condition for these years. Discussion and analysis of the year ended December 31, 2022 specifically, as well as the year-over-year comparison of our financial performance and condition for the years ended December 31, 2023 and 2022, are located in the section titled "Management's Discussion and Analysis of Financial Condition and Results of Operations" included in the Annual Report on Form 10-K for the year ended December 31, 2023, as filed with the SEC on March 8, 2024.

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 December 2024 we announced updated interim clinical data for JANX007 which displayed meaningful and prolonged PSA drops, encouraging anti-tumor activity, a favorable safety profile including CRS and treatment-related adverse events (TRAEs) primarily limited to Cycle 1 and lower grades, 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 carcinoma, squamous cell carcinoma of the head and neck, non-small cell lung cancer, renal cell carcinoma, small cell lung cancer, pancreatic ductal adenocarcinoma and triple-negative breast cancer. The first patient for this trial was dosed in April 2023 and in February 2024 we announced positive early data for 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 $69.0 million and $58.3 million for the years ended December 31, 2024 and 2023, respectively. As of December 31, 2024, we had an accumulated deficit of $237.8 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, 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 provided research funding under the collaboration through August 2024, after which our research services for both collaboration targets were completed.

Risks and Uncertainties

Global economic and business activities continue to face widespread macroeconomic uncertainties, including those associated with 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 us, 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 owned greater than 5% of our outstanding capital stock until November 2024. The amounts paid to Avalon include support service fees or mark-ups of up to 5%. The 2021 Support Services Agreement terminated on December 31, 2024.

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 $10.6 million and $8.1 million of revenue under the Merck Agreement for the years ended December 31, 2024 and 2023, 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.

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. 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, 2024 and 2023 (in thousands)

	Year Ended December 31,		
	2024	2023	Change
Collaboration revenue	$ 10,588	$ 8,083	$ 2,505
Operating expenses:			
Research and development	68,388	54,922	13,466
General and administrative	41,047	26,140	14,907
Total operating expenses	109,435	81,062	28,373
Loss from operations	(98,847)	(72,979)	(25,868)
Other income	29,853	14,686	15,167
Net loss	$ (68,994)	$ (58,293)	$ (10,701)

Collaboration Revenue

Collaboration revenues were $10.6 million and $8.1 million for the years ended December 31, 2024 and 2023, respectively. The increase of $2.5 million was primarily due to the achievement of a developmental milestone related to the First Collaboration Target under the Merck Agreement in June 2024 offset by 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, 2024 and 2023 (in thousands):

	Year Ended December 31,		
	2024	2023	Change
Direct costs:			
JANX007	$ 15,655	$ 7,895	$ 7,760
JANX008	6,541	5,401	1,140
Preclinical stage programs and other direct unallocated costs	13,223	13,950	(727)
Total direct costs	35,419	27,246	8,173
Indirect costs	32,969	27,676	5,293
Total research and development expenses	$ 68,388	$ 54,922	$ 13,466

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, 2024 and 2023. We will further separate direct costs related to our other programs as future IND applications are cleared by the FDA.

Research and development expenses were $68.4 million and $54.9 million for the years ended December 31, 2024 and 2023, respectively. The increase of $13.5 million was primarily due to increases in direct costs related to the development of JANX007 of $7.8 million, direct costs related to the development of JANX008 of $1.1 million and indirect costs of $5.3 million, offset by decreases in preclinical stage programs and other direct unallocated costs of $0.7 million.

General and Administrative Expense

General and administrative expenses were $41.0 million and $26.1 million for the years ended December 31, 2024 and 2023, respectively. The increase of $14.9 million was primarily due to increases in stock-based compensation of $11.2 million, consulting and professional fees of $2.2 million and other general and administrative expenses of $1.5 million.

Other Income

Other income was $29.9 million and $14.7 million for the years ended December 31, 2024 and 2023, respectively. The increase of $15.2 million was due to an increased cash and cash equivalents balance 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, 2024, we had cash, cash equivalents, restricted cash and short-term investments of $1.0 billion. Inclusive in this amount is $0.8 million of restricted cash that is not available for current use.

In May 2023, we entered into an ATM Equity Offering℠ Sales Agreement (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. 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 Sale Agreement. In May 2024, we filed a shelf registration statement on Form S-3ASR which included a new prospectus which covers the offering, issuance and sale of up to a maximum aggregate offering price of $150.0 million of our common stock under the Sale Agreement. As of December 31, 2024, $150.0 million of common stock remained available for sale under the Sale Agreement.

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 at an exercise price of $0.001 per share. 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 offering expenses in the aggregate amount of $20.9 million, resulting in net proceeds of $320.1 million.

The registration statement on Form S-3ASR that we filed in May 2024 provides us with the ability to offer an unlimited amount 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 December 2024, we closed an underwritten offering of 6,150,793 shares of our common stock and pre-funded warrants to purchase 238,095 shares of common stock at an exercise price of $0.001 per share. The shares of common stock were sold at a price of $63.00 per share and the pre-funded common stock warrants were sold at a price of $62.999 per pre-funded common stock warrant, resulting in gross proceeds of $402.5 million. Fees related to the offering included underwriting discounts, commissions, and offering expenses in the aggregate amount of $24.6 million, resulting in net proceeds of $377.9 million.

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

	Year Ended December 31,	
	2024	2023
Net cash provided by (used in):		
Operating activities	$ (43,814)	$ (50,575)
Investing activities	(258,021)	(41,194)
Financing activities	713,235	59,548
Net increase (decrease) in cash, cash equivalents and restricted cash	$ 411,400	$ (32,221)

Operating Activities

Net cash used in operating activities of $43.8 million for the year ended December 31, 2024 was primarily due to our net loss of $69.0 million and a change in operating assets and liabilities and other non-cash charges of $7.8 million, adjusted for $33.0 million of stock-based compensation expense. 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.

Investing Activities

Net cash used in investing activities of $258.0 million for the year ended December 31, 2024 was primarily due to $257.7 million of net purchases of short-term investments and by our purchase of property and equipment, primarily consisting of laboratory equipment of $0.3 million. 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.

Financing Activities

Net cash provided by financing activities of $713.2 million for the year ended December 31, 2024 was primarily due to proceeds from the issuance of common stock and pre-funded common stock warrants, net of issuance costs, of $698.3 million, and exercises of common stock options and from shares issued under our 2021 Employee Stock Purchase Plan (ESPP) of $14.9 million. 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 ESPP of $3.0 million.

Funding Requirements

Based on our current operating plan, we believe that our existing cash, 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 resulting from geopolitical and macroeconomic conditions, including the military conflict in Ukraine and Russia, the war in the Middle East, epidemics and bank failures; 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 Clinical Trial and 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 clinical trial and research and

development expenses include the costs incurred for services performed by our vendors in connection with clinical trial and research and development activities for which we have not yet been invoiced.

We base our expenses related to clinical trial and research and development activities on our estimates of the services received and efforts expended pursuant to quotes and contracts with vendors that conduct clinical trials and 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 clinical trial and 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 clinical trial or 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, restricted stock units and employee stock purchase plan rights, recognized on a straight-line basis over the requisite service period for stock options and restricted stock units 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 4 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.

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

Interest rate risk

We hold certain financial instruments for which a change in prevailing interest rates may cause the principal amount of the marketable securities to fluctuate. Financial instruments that potentially subject us to significant concentrations of credit risk consist primarily of cash, cash equivalents and short-term investments. We invest our excess cash primarily in U.S. Treasury securities, U.S. agency bonds, corporate debt securities and commercial paper. The primary objectives of our investment activities are to ensure liquidity and to preserve principal while at the same time maximizing the income we receive from our marketable securities without significantly increasing risk. Additionally, we established guidelines regarding approved investments and maturities of investments, which are designed to maintain safety and liquidity. We believe that should a 10.0% change in interest rates were to have occurred on December 31, 2024, this change would not have had a material effect on the fair value of our investment portfolio as of that date. Any changes would only be realized if we sold the investments prior to maturity.

Foreign currency exchange risk

We are not currently exposed to significant market risk related to changes in foreign currency exchange rates; however, we do contract with vendors that are located outside of the United States and may be subject to fluctuations in foreign currency rates. We may enter into additional contracts with vendors located outside of the United States in the future, which may increase our foreign currency exchange risk. We believe that should a 10.0% change in foreign currency exchange rates were to have occurred on December 31, 2024, this change would not have had a material effect on our financial statements.

Inflation

Inflation generally affects us by increasing our cost of labor and preclinical and clinical development costs. We do not believe that inflation had a material effect on our business, financial condition or results of operations during the year ended December 31, 2024.

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, 2024 and 2023, the related statements of operations and comprehensive loss, stockholders' equity and cash flows for each of the three years in the period ended December 31, 2024, and the related notes (collectively referred to as the "financial statements"). In our opinion, the financial statements present fairly, in all material respects, the financial position of the Company at December 31, 2024 and 2023, and the results of its operations and its cash flows for each of the three years in the period ended December 31, 2024, in conformity with U.S. generally accepted accounting principles.

We also have audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States) (PCAOB), the Company's internal control over financial reporting as of December 31, 2024, based on criteria established in Internal Control-Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission (2013 framework), and our report dated February 27, 2025 expressed an unqualified opinion thereon.

Basis for Opinion

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

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

Critical Audit Matter

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

Clinical Trial Expenses

Description of the Matter	The Company recorded research and development expenses of $68.4 million for the year ended December 31, 2024, which includes clinical trial expenses. Clinical trial expenses are expensed as incurred. As discussed in Note 1 to the financial statements, the Company estimates expenses incurred for clinical trials and services received and maintains a prepaid or accrual based on these estimates. The Company estimates expenses based on the progress of the clinical trials and incorporates representations from service providers about study and patient activities and expected expenses for those activities based on contracted fees with contract research organizations. Auditing the Company's clinical trial expenses is complex as the information necessary to estimate the costs incurred is accumulated from multiple sources. In addition, in certain circumstances, the determination of the nature and level of services that have been received during the reporting period requires judgment because the timing and pattern of vendor invoicing does not correspond to the level of services provided and there may be delays in invoicing from contract research organizations.
How We Addressed the Matter in Our Audit	To test the Company's clinical trial expenses, we performed audit procedures that included, among other procedures, obtaining supporting evidence of the activities performed for significant clinical trials and confirming expenses with the contract research organizations. We corroborated the status of significant clinical trials through meetings with accounting and clinical project managers. We compared the costs for a sample of expenses against the related invoices and contracts and examined a sample of subsequent payments to evaluate the accuracy of the clinical trial expenses and recalculated the ending prepaid or accrual for clinical trial expenses.

/s/ Ernst & Young LLP

We have served as the Company's auditor since 2021.

San Diego, California

February 27, 2025

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

	December 31,	
Assets	**2024**	**2023**
Current assets:		
Cash and cash equivalents	$ 430,605	$ 19,205
Short-term investments	594,568	324,823
Prepaid expenses and other current assets	8,493	5,213
Total current assets	1,033,666	349,241
Restricted cash	816	816
Property and equipment, net	4,864	7,003
Operating lease right-of-use assets	19,286	20,838
Other long-term assets	2,884	2,509
Total assets	$ 1,061,516	$ 380,407
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable	$ 4,026	$ 2,424
Accrued expenses	11,684	7,387
Current portion of deferred revenue	—	1,705
Current portion of operating lease liabilities	1,749	1,517
Total current liabilities	17,459	13,033
Operating lease liabilities, net of current portion	21,276	23,025
Total liabilities	38,735	36,058
Commitments and contingencies (Note 3)		
Stockholders' equity:		
Preferred stock, $0.001 par value; authorized shares – 10,000,000 at December 31, 2024 and 2023, respectively; no shares issued and outstanding at December 31, 2024 and 2023	—	—
Common stock, $0.001 par value; authorized shares – 200,000,000 at December 31, 2024 and 2023, respectively; issued shares – 59,064,606 and 46,262,759 at December 31, 2024 and 2023, respectively; outstanding shares – 59,064,606 and 46,252,440 at December 31, 2024 and 2023, respectively	59	46
Additional paid-in capital	1,258,316	512,401
Accumulated other comprehensive income	2,163	665
Accumulated deficit	(237,757)	(168,763)
Total stockholders' equity	1,022,781	344,349
Total liabilities and stockholders' equity	$ 1,061,516	$ 380,407

See accompanying notes.

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

	Year Ended December 31,		
	2024	**2023**	**2022**
Collaboration revenue	$ 10,588	$ 8,083	$ 8,612
Operating expenses:			
Research and development	68,388	54,922	53,441
General and administrative	41,047	26,140	22,262
Total operating expenses	109,435	81,062	75,703
Loss from operations	(98,847)	(72,979)	(67,091)
Other income:			
Interest income	29,853	14,686	4,032
Total other income	29,853	14,686	4,032
Net loss	$ (68,994)	$ (58,293)	$ (63,059)
Other comprehensive gain (loss):			
Unrealized gain (loss) on available-for-sale securities, net	1,498	2,200	(1,265)
Comprehensive loss	$ (67,496)	$ (56,093)	$ (64,324)
Net loss per common share, basic and diluted	$ (1.28)	$ (1.32)	$ (1.52)
Weighted-average shares of common stock outstanding, basic and diluted	53,751,480	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 $2,495 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
Issuance of common stock and pre-funded common stock warrants, net of $45,554 of issuance costs	11,548,094	12	697,908	—	—	697,920
Exercise of common stock options	1,152,192	1	14,175	—	—	14,176
Issuance of common stock upon vesting of restricted stock units	2,500	—	—	—	—	—
Shares issued under employee stock purchase plan	99,061	—	792	—	—	792
Vesting of restricted shares	10,319	—	20	—	—	20
Stock-based compensation	—	—	33,020	—	—	33,020
Unrealized gain on available-for-sale securities, net	—	—	—	1,498	—	1,498
Net loss	—	—	—	—	(68,994)	(68,994)
Balance at December 31, 2024	59,064,606	$ 59	$ 1,258,316	$ 2,163	$ (237,757)	$ 1,022,781

See accompanying notes.

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

	Year Ended December 31,		
	2024	**2023**	**2022**
Cash flows from operating activities			
Net loss	$ (68,994)	$ (58,293)	$ (63,059)
Adjustments to reconcile net loss to net cash used in operating activities:			
Depreciation	2,060	1,955	841
Stock-based compensation	33,020	20,005	17,203
Accretion of discounts on investments, net	(10,585)	(7,688)	(2,183)
Changes in operating assets and liabilities:			
Prepaid expenses and other current assets	(3,280)	210	(3,369)
Other long-term assets	(375)	(1,119)	(1,270)
Accounts payable	1,584	277	(294)
Accrued expenses	4,426	(678)	4,156
Deferred revenue	(1,705)	(5,922)	1,764
Operating lease right-of-use assets and liabilities, net	35	678	3,289
Net cash used in operating activities	(43,814)	(50,575)	(42,922)
Cash flows from investing activities			
Purchases of property and equipment	(359)	(1,850)	(6,445)
Purchases of short-term investments	(470,577)	(317,344)	(294,389)
Maturities of short-term investments	212,915	278,000	359,100
Net cash provided by (used in) investing activities	(258,021)	(41,194)	58,266
Cash flows from financing activities			
Proceeds from exercise of common stock options and employee stock purchase plan	14,968	3,018	500
Proceeds from the issuance of common stock and pre-funded common stock warrants, net of issuance costs	698,267	56,530	—
Net cash provided by financing activities	713,235	59,548	500
Net increase (decrease) in cash, cash equivalents and restricted cash	411,400	(32,221)	15,844
Cash, cash equivalents and restricted cash – beginning of year	20,021	52,242	36,398
Cash, cash equivalents and restricted cash – end of period	$ 431,421	$ 20,021	$ 52,242
Supplemental disclosure of noncash investing and financing activities			
Unpaid property and equipment	$ 6	$ 132	$ 109
Unpaid issuance costs	$ 347	$ —	$ —
Vesting of restricted common stock	$ 20	$ 149	$ 1,034
Unrealized gain (loss) on available-for-sale securities, net	$ 1,498	$ 2,200	$ (1,265)
Operating lease liabilities arising from right-of-use assets	$ —	$ —	$ 23,422

See accompanying notes.

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, 2024, 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 $237.8 million as of December 31, 2024. 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 underwritten offerings, 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 public health crises, financial conditions within the banking industry, including the effects of failures of financial institutions and liquidity levels, as well as 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 believes the Company has sufficient capital to fund its operations for at least 12 months from the issuance date of these financial statements.

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 clinical trials and other research and development arrangements, 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, 2024:				
Assets:				
Cash equivalents:				
Money market funds	$ 427,959	$ 427,959	$ —	$ —
Total cash equivalents	427,959	427,959	—	—
Short-term investments:				
U.S. Treasury securities	95,474	95,474	—	—
U.S. agency bonds	300,845	—	300,845	—
Corporate debt securities	161,997	—	161,997	—
Commercial paper	36,252	—	36,252	—
Total short-term investments	594,568	95,474	499,094	—
Restricted cash:				
Money market account	816	816	—	—
Total restricted cash	816	816	—	—
Total assets measured at fair value on a recurring basis	$ 1,023,343	$ 524,249	$ 499,094	$ —

	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, 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	$ —

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, 2024	December 31, 2023
Cash and cash equivalents	$ 430,605	$ 19,205
Restricted cash	816	816
Total cash and cash equivalents and restricted cash	$ 431,421	$ 20,021

Short-Term Investments

Short-term investments consist of U.S. Treasury securities, U.S. agency bonds, 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, 2024			
	Amortized Cost	Unrealized Gains	Unrealized Losses	Estimated Fair Value
U.S. Treasury securities	$ 94,984	$ 490	$ —	$ 95,474
U.S. agency bonds	299,831	1,209	(195)	300,845
Corporate debt securities	161,336	696	(35)	161,997
Commercial paper	36,254	20	(22)	36,252
Total	$ 592,405	$ 2,415	$ (252)	$ 594,568

	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

The amortized cost and estimated fair value in the tables above exclude $5.4 million and $2.2 million of accrued interest receivable as of December 31, 2024 and 2023, 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, 2024	
	Due in 1 Year or Less	Due Between 1 and 3 Years
U.S. Treasury securities	$ 57,858	$ 37,616
U.S. agency bonds	78,135	222,710
Corporate debt securities	—	161,997
Commercial paper	36,252	—
Total	$ 172,245	$ 422,323

	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, 2024, 14 out of 65 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, 2024 or December 31, 2023.

There were no available-for-sale debt securities in a continuous unrealized loss position for 12 months or longer at December 31, 2024.

The following table summarizes our available-for-sale debt securities in an aggregate gross unrealized loss position at December 31, 2023, 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)

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, 2024, 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. Impairment losses recognized through December 31, 2024 were not material.

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.

Clinical Trial Expenses

The Company makes payments in connection with its clinical trials under contracts with contract research organizations that support conducting and managing clinical trials. The financial terms of these agreements are subject to negotiation and vary from contract to contract and may result in uneven payment flows. Generally, these agreements set forth the scope of work to be performed at a fixed fee, unit price or on a time and materials basis. A portion of the Company's obligation to make payments under these contracts depends on factors such as the successful enrollment or treatment of patients or the completion of other clinical trial milestones.

Expenses related to clinical trials are accrued based on the progress of the clinical trials. The Company incorporates in the expenses representations from service providers regarding work performed, including actual level of patient enrollment, completion of patient studies and progress of the clinical trials. Other incidental costs related to patient enrollment or treatment are accrued when reasonably certain. If the amounts the Company is obligated to pay under clinical trial agreements are modified (for instance, as a result of changes in the clinical trial protocol or scope of work to be performed), the Company adjusts the accruals accordingly. Revisions to the contractual payment obligations are charged to expense in the period in which the facts that give rise to the revision become reasonably certain.

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

Stock-based compensation expense represents the grant date fair value of equity awards, consisting of stock options, restricted stock units and employee stock purchase plan rights, recognized on a straight-line basis over the requisite service period for stock options and restricted stock units, and over the respective offering period for employee stock purchase plan rights. The Company estimates the fair value of stock options and employee stock purchase plan rights using the Black-Scholes option pricing model. The fair value of restricted stock units is based on the closing price of the Company's common stock as reported on The Nasdaq Global Market on the date of grant. The Company recognizes forfeitures for all awards 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 gain (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 ("CODM"), 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, which is engaged in the research and development of a broad pipeline of novel immunotherapies. The accounting policies of the novel immunotherapies segment are the same as those described in the summary of significant accounting policies. The measure of segment profit or loss is reported on the statement of operations and comprehensive loss as net loss. The Company monitors its cash and cash equivalents and short-term investments as reported on the Company's balance sheets to determine funding for its research and development. In order to allocate resources and assess performance, the Company's CODM, or President and Chief Executive Officer, regularly reviews scientific data from clinical and pre-clinical studies as well as forecasted expenses for clinical and pre-clinical programs and other projected operational expenses. No product revenue has been generated since inception and all assets are held in the United States. All revenue recognized to date has been derived from the Company's existing collaboration agreement with Merck (as defined and described in Note 5).

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 underwritten offerings (Note 4), 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 3,645 shares, 27,458 shares and 182,194 shares from the weighted-average number of shares of common stock outstanding for the years ended December 31, 2024, 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):

	As of December 31,		
	2024	2023	2022
Common stock options outstanding	8,873,071	7,989,192	7,345,444
Restricted stock units outstanding	341,847	—	—
Unvested common stock	—	10,319	68,406
Employee stock purchase plan shares	19,140	13,796	10,423
Total potentially dilutive shares	9,234,058	8,013,307	7,424,273

Recent Accounting Pronouncements

In August 2020, the Financial Accounting Standards Board ("FASB") issued Accounting Standards Update ("ASU") No. 2020-06, Debt - Debt with Conversion and Other Options (Subtopic 470-20) and Derivatives and Hedging - Contracts in Entity's Own Equity (Subtopic 815-40) - Accounting for Convertible Instruments and Contracts in an Entity's Own Equity, which simplifies the

accounting for certain financial instruments with characteristics of liabilities and equity, including convertible instruments and contracts on an entity's own equity. The Company adopted ASU 2020-06 on January 1, 2024 and the adoption of the standard had no material impact on its financial statements and related disclosures.

In November 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. 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 adopted ASU 2023-07 on January 1, 2025 and the adoption of the standard had no material impact on its financial statements and related disclosures.

Accounting Pronouncements Pending Adoption

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

Prepaid expenses and other current assets consist of the following (in thousands):

	As of December 31,	
	2024	2023
Interest receivable	$ 5,381	$ 2,161
Prepaid research and development	2,354	2,318
Other prepaid expenses	758	734
Prepaid expenses and other current assets	$ 8,493	$ 5,213

Property and equipment, net consist of the following (in thousands):

	As of December 31,	
	2024	2023
Laboratory equipment	$ 8,360	$ 8,454
Furniture and fixtures	792	792
Computer equipment and software	658	628
Assets not placed in service	6	43
Total property and equipment	9,816	9,917
Less: accumulated depreciation	(4,952)	(2,914)
Property and equipment, net	$ 4,864	$ 7,003

Accrued expenses consist of the following (in thousands):

	As of December 31,	
	2024	2023
Accrued research and development	$ 6,200	$ 3,535
Accrued compensation	4,566	3,303
Other accrued expenses	918	549
Accrued expenses	$ 11,684	$ 7,387

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, 2024 are as follows (in thousands):

2025	$	3,505
2026		3,611
2027		3,719
2028		3,830
2029		3,945
Thereafter		12,927
Total minimum lease payments		31,537
Less: Imputed interest		(8,512)
Total operating lease liabilities		23,025
Less: Current portion of operating lease liabilities		(1,749)
Operating lease liabilities, net of current portion	$	21,276

The Torrey Plaza lease has a remaining lease term of 8.1 years and a discount rate of 8% as of December 31, 2024. Operating lease expense included in the measurement of lease liabilities for years ended December 31, 2024, 2023 and 2022 was $3.4 million, $3.4 million and $2.8 million, respectively. Cash paid for amounts included in the measurement of lease liabilities for the years ended December 31, 2024, 2023 and 2022 was $3.4 million, $2.8 million and $0.2 million, respectively.

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, 2024, the Company is not currently party to any material legal proceedings.

4. Stockholders' Equity

Shelf Registration Statement

In May 2023, the Company entered into an ATM Equity Offering℠ Sales Agreement ("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. 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 Sale Agreement. In May 2024, the Company filed a shelf registration statement on Form S-3ASR which included a new prospectus which covers the offering, issuance and sale of up to a maximum aggregate offering price of $150.0 million of the Company's common stock under the Sale Agreement. There was no activity from the Sale Agreement during the year ended December 31, 2024. As of December 31, 2024, $150.0 million of common stock remained available for sale under the Sale Agreement.

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.

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 at an exercise price of $0.001 per share. 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 offering expenses in the aggregate amount of $20.9 million, resulting in net proceeds of $320.1 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 registration statement on Form S-3ASR that the Company filed in May 2024 provides the Company with the ability to offer an unlimited amount 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 December 2024, the Company closed an underwritten offering of 6,150,793 shares of its common stock and pre-funded warrants to purchase 238,095 shares of common stock at an exercise price of $0.001 per share. The shares of common stock were sold at a price of $63.00 per share and the pre-funded common stock warrants were sold at a price of $62.999 per pre-funded common stock warrant, resulting in gross proceeds of $402.5 million. Fees related to the offering included underwriting discounts, commissions, and offering expenses in the aggregate amount of $24.6 million, resulting in net proceeds of $377.9 million.

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 a certain percentage 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. 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, 2024, there were 10,867,540 shares authorized for issuance under the 2021 Plan, inclusive of shares added from 2017 Plan cancellations.

Stock Options

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 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		
Outstanding at December 31, 2023	7,989,192	$ 12.08	7.8	$ 16,733
Granted	2,359,363	$ 15.07		
Exercised	(1,152,192)	$ 12.30		
Forfeited or cancelled	(323,292)	$ 13.10		
Outstanding at December 31, 2024	8,873,071	$ 12.81	7.2	$ 361,595
Vested and expected to vest at December 31, 2024	8,873,071	$ 12.81	7.2	$ 361,595
Exercisable at December 31, 2024	5,401,003	$ 11.21	6.6	$ 228,619

The weighted-average grant date fair value of option grants for the years ended December 31, 2024, 2023 and 2022 was $11.30, $10.02 and $12.35, respectively. The total intrinsic value of stock options exercised for the years ended December 31, 2024, 2023 and 2022 was $45.6 million, $1.9 million and $0.1 million, respectively. As of December 31, 2024, total unrecognized stock-based compensation cost associated with option grants was $33.9 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,		
	2024	2023	2022
Risk-free interest rate	3.6% – 4.6%	3.5% – 4.7%	1.5% – 4.2%
Expected volatility	83% – 106%	82% – 87%	81% – 85%
Expected term (in years)	5.3 – 6.1	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. For options granted in the initial years following the Company's IPO, 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. As sufficient historical data is now available for the Company's stock price, the Company is currently applying and will continue to apply the volatility of its own stock price in determining volatility.

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 and nonemployee directors, 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.

Restricted Stock Units

A summary of the Company's restricted stock unit ("RSU") activity under the 2021 Plan is as follows:

	Number of Restricted Stock Units	Weighted-Average Grant Date Fair Value per Share
Outstanding at December 31, 2023	—	$ —
Granted	344,347	$ 58.95
Vested	(2,500)	$ 39.80
Forfeited or cancelled	—	$ —
Outstanding at December 31, 2024	341,847	$ 59.09

RSU awards are share awards that, upon vesting, will deliver to the holder shares of the Company's common stock. The grant-date fair value is recognized as compensation expense over the vesting period. As of December 31, 2024, total unrecognized stock-based compensation cost associated with RSUs was $19.3 million, which is expected to be recognized over a remaining weighted-average period of approximately 3.7 years. The Company did not have any RSU activity during the year ended December 31, 2023.

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. 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). For the years ended December 31, 2024, 2023 and 2022, stock-based compensation expense related to the ESPP was $0.8 million, $0.9 million and $0.6 million, respectively. As of December 31, 2024, total unrecognized stock-based compensation expense related to the ESPP was $0.6 million, which is expected to be recognized over a remaining weighted-average period of approximately 1.3 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,		
	2024	2023	2022
Research and development	$ 9,718	$ 7,873	$ 7,235
General and administrative	23,302	12,132	9,968
Total	$ 33,020	$ 20,005	$ 17,203

Modification of Equity Awards

In July 2024, and in connection with the resignation of a former director, the board of directors approved the following modifications to the terms of the former director's outstanding equity awards: (a) acceleration of the vesting of all unvested stock options and awards in full, effective as of the former director's resignation date; and (b) extension of the post-termination exercise period for outstanding options until the earlier of the third anniversary of such resignation date or the original expiration date of such

options, subject to the Company's ability to take any actions permitted under the 2021 Plan. The incremental stock-based compensation expense resulting from these modifications recognized during the year ended December 31, 2024 was $0.7 million.

In August 2024, and in connection with the resignation of a former executive officer, the compensation committee of the board of directors approved the following modifications to the terms of the former officer's outstanding equity awards as defined within a transition and consulting agreement with the former officer (the "Transition Agreement"): (a) acceleration of the vesting of unvested stock options such that the number of options that would have vested through June 30, 2026, are vested and exercisable, with such acceleration deemed effective as of December 31, 2024, subject to service conditions described within the Transition Agreement; and (b) extension of the post-termination exercise period for outstanding options until the earlier of December 31, 2027 or the original expiration date of such options, subject to the Company's ability to take any actions permitted under the Plans, as applicable. The incremental stock-based compensation expense resulting from these modifications recognized during the year ended December 31, 2024 was $8.7 million.

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
Vested shares	(10,319)	$ 1.57	(20)
Balance at December 31, 2024	—	$ —	$ —

Common Stock Reserved for Future Issuance

Common stock reserved for future issuance consists of the following:

	December 31,		
	2024	2023	2022
Common stock options outstanding	8,873,071	7,989,192	7,345,444
RSUs outstanding	341,847	—	—
Shares available for issuance under the Plans	5,131,660	5,198,941	4,012,001
Shares available for issuance under the ESPP	1,506,316	1,142,750	816,478
Pre-funded common stock warrants outstanding	2,676,804	503,226	—
Total	18,529,698	14,834,109	12,173,923

5. 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 has 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 Collaboration Targets were completed as of December 31, 2024.

In June 2024, a developmental milestone of $7.5 million related to the First Collaboration Target was achieved, at which time the Company recognized the associated revenue. All other future potential milestone payments are considered constrained as of December 31, 2024 as they are uncertain in nature and highly dependent on factors outside of the Company's control until the underlying events occur or the associated approvals are received.

The Company recognized $10.6 million, $8.1 million and $8.6 million of revenue under the Merck Agreement for the years ended December 31, 2024, 2023 and 2022, respectively. The Company's performance obligations related to the Collaboration Targets were completed as of December 31, 2024.

6. Income Taxes

The Company has not recorded a current or deferred tax expense or benefit for the years ended December 31, 2024, 2023 or 2022. The net losses for the years ended December 31, 2024, 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,		
	2024	2023	2022
Expected tax benefit computed at federal statutory rate	$ (14,489)	$ (12,242)	$ (13,242)
State income taxes, net of federal tax benefit	(3,437)	(2,827)	(3,754)
Permanent differences	111	86	(48)
Equity compensation	(6,448)	1,289	686
Officer's compensation	6,449	2,192	1,261
Research and development credits	(6,251)	(4,300)	(2,930)
Reserve for uncertain tax positions	1,534	1,058	715
Other	385	124	80
Change in valuation allowance	22,146	14,620	17,232
Income tax expense (benefit)	$ —	$ —	$ —

Significant components of the Company's net deferred tax assets are summarized as follows (in thousands):

	December 31,	
	2024	2023
Deferred tax assets:		
Net operating loss carryforwards	$ 25,676	$ 18,745
Capitalized research and development	26,615	15,698
Lease liability	5,961	6,868
Research and development credit carryforwards	11,286	6,597
Stock-based compensation	3,712	4,005
Other	152	713
Total deferred tax assets	73,402	52,626
Valuation allowance	(66,740)	(44,981)
Net deferred tax assets	6,662	7,645
Deferred tax liabilities:		
ROU asset	(4,993)	(5,831)
Property and equipment	(1,008)	(1,498)
Unrealized gains	(560)	(186)
Other	(101)	(130)
Total gross deferred tax liabilities	(6,662)	(7,645)
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, 2024 and 2023. During the year ended December 31, 2024, the valuation allowance increased by $21.8 million.

At December 31, 2024, the Company had federal and state net operating loss ("NOL") carryforwards of $66.2 million and $167.6 million, respectively. Federal NOL carryforwards totaling $0.5 million begin to expire in 2037, unless previously utilized, and federal NOL carryforwards of $65.7 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 $167.6 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 $10.9 million and $5.3 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 common 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 and therefore has established a full valuation allowance as the realization of such deferred tax assets has not met the more likely than not threshold requirement. If ownership changes have occurred or occurs 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, 2024, 2023 and 2022 (in thousands):

	Year Ended December 31,		
	2024	2023	2022
Balance at beginning of year	$ 2,389	$ 1,273	$ 510
Increases related to prior year tax positions	—	126	—
Increases related to current year tax positions	1,642	990	763
Balance at end of year	$ 4,031	$ 2,389	$ 1,273

The Company had no accrual for interest or penalties on the Company's balance sheets at December 31, 2024 or 2023, and has not recognized interest and/or penalties in the statement of operations and comprehensive loss for the years ended December 31, 2024, 2023 and 2022. As of December 31, 2024 and 2023, the Company had unrecognized tax benefits of $4.0 million and $2.4 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.

7. 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, 2024, 2023 and 2022 were $0.4 million, $0.4 million and $0.2 million, respectively.

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 (principal executive and financial officer), evaluated the effectiveness of our disclosure controls and procedures as of December 31, 2024. The term "disclosure controls and procedures" as defined in Rules 13a-15(e) and 15d-15(e) under the 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 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, 2024, our Chief Executive Officer (principal executive and 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, 2024, our internal control over financial reporting was effective.

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

The effectiveness of our internal control over financial reporting as of December 31, 2024 has been audited by Ernst & Young LLP, an independent registered public accounting firm, as stated in its report, which is included herein.

Changes in Internal Control over Financial Reporting

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

REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

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

Opinion on Internal Control Over Financial Reporting

We have audited Janux Therapeutics Inc.'s internal control over financial reporting as of December 31, 2024, based on criteria established in Internal Control—Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission (2013 framework) (the COSO criteria). In our opinion, Janux Therapeutics, Inc. (the Company) maintained, in all material respects, effective internal control over financial reporting as of December 31, 2024, based on the COSO criteria.

We also have audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States) (PCAOB), the balance sheets of the Company as of December 31, 2024 and 2023, the related statements of operations and comprehensive loss, stockholders' equity and cash flows for each of the three years in the period ended December 31, 2024, and the related notes and our report dated February 27, 2025 expressed an unqualified opinion thereon.

Basis for Opinion

The Company's management is responsible for maintaining effective internal control over financial reporting and for its assessment of the effectiveness of internal control over financial reporting included in the accompanying Management's Report on Internal Control over Financial Reporting. Our responsibility is to express an opinion on the Company's internal control over financial reporting based on our audit. We are a public accounting firm registered with the PCAOB and are required to be independent with respect to the Company in accordance with the U.S. federal securities laws and the applicable rules and regulations of the Securities and Exchange Commission and the PCAOB.

We conducted our audit in accordance with the standards of the PCAOB. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether effective internal control over financial reporting was maintained in all material respects.

Our audit included obtaining an understanding of internal control over financial reporting, assessing the risk that a material weakness exists, testing and evaluating the design and operating effectiveness of internal control based on the assessed risk, and performing such other procedures as we considered necessary in the circumstances. We believe that our audit provides a reasonable basis for our opinion.

Definition and Limitations of Internal Control Over Financial Reporting

A company's internal control over financial reporting is a process designed to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles. A company's internal control over financial reporting includes those policies and procedures that (1) pertain to the maintenance of records that, in reasonable detail, accurately and fairly reflect the transactions and dispositions of the assets of the company; (2) provide reasonable assurance that transactions are recorded as necessary to permit preparation of financial statements in accordance with generally accepted accounting principles, and that receipts and expenditures of the company are being made only in accordance with authorizations of management and directors of the company; and (3) provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use, or disposition of the company's assets that could have a material effect on the financial statements.

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

/s/ Ernst & Young LLP

San Diego, California

February 27, 2025

Item 9B. Other Information.

Trading Arrangements

During the three months ended December 31, 2024, 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), except as follows:

On December 30, 2024, Byron Robinson, Ph.D., our Chief Strategy Officer, adopted a Rule 10b5-1 trading arrangement that is intended to satisfy the affirmative defense of Rule 10b5-1(c) for the sale of up to 238,000 shares of our common stock until August 31, 2025.

On December 30, 2024, Zachariah McIver, D.O., Ph.D., our Chief Medical Officer, adopted a Rule 10b5-1 trading arrangement that is intended to satisfy the affirmative defense of Rule 10b5-1(c) for the sale of up to 76,587 shares of our common stock until April 1, 2026.

On December 30, 2024, Tommy DiRaimondo, Ph.D., our Chief Scientific Officer, modified an existing Rule 10b5-1 trading arrangement that is intended to satisfy the affirmative defense of Rule 10b5-1(c). The modified trading arrangement terminates on August 29, 2025 and provides for the sale of up to 91,100 shares of our common stock.

In addition, our officers (as defined in Rule 16a-1(f) under the Exchange Act) have entered into sell-to-cover arrangements adopted pursuant to Rule 10b5-1 authorizing the pre-arranged sale of shares to satisfy our tax withholding obligations arising exclusively from the vesting of restricted stock units. The amount of shares to be sold to satisfy our tax withholding obligations under these arrangements is dependent on future events which cannot be known at this time, including the future trading price of our shares. The expiration date relating to these arrangements is dependent on future events which cannot be known at this time, including the final vesting date of the applicable shares of restricted stock and the officer's termination of service.

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, 2024 (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 and financial officer and principal accounting officer. 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 Exhibit 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).
4.6	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 February 29, 2024).
4.7	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 December 5, 2024).
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, Forms of Option Grant Notice, Option Agreement and Notice of Exercise thereunder, and Forms of RSU Award Grant Notice and RSU Award Agreement. (incorporated by reference to Exhibit 10.1 to the Registrant's Quarterly Report on Form 10-Q, filed with the SEC on August 7, 2024).
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 (incorporated by reference to Exhibit 10.2 to the Registrant's Quarterly Report on Form 10-Q, filed with the SEC on August 7, 2024).
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*	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).
10.10+	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).
10.11+	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).
10.12+	Employment Agreement, by and between the Registrant and Zachariah McIver, D.O., Ph.D., dated April 24, 2023.
10.13+	Employment Agreement, by and between the Registrant and Tommy DiRaimondo, Ph.D., dated January 1, 2021 (incorporated by reference to Exhibit 10.14 to the Registrant's Annual Report on Form 10-K, filed with the SEC on March 8, 2024).
10.14+	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).
10.15	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).
10.16	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).
10.17	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).
10.18	Underwriting Agreement, dated February 28, 2024, by and among Janux Therapeutics, Inc. and BofA Securities, Inc., Cowen and Company, LLC, Cantor Fitzgerald & Co. and William Blair & Company, L.L.C. as representatives of the several underwriters named therein (incorporated by reference to Exhibit 1.1 of the Registrant's Current Report on Form 8-K, filed February 29, 2024).
10.19+	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).
10.20	Underwriting Agreement, dated December 4, 2024, by and among Janux Therapeutics, Inc. and BofA Securities, Inc., TD Securities (USA) LLC, Stifel, Nicolaus & Company, Incorporated, Cantor Fitzgerald & Co. and William Blair & Company, L.L.C. as representatives of the several underwriters named therein (incorporated by reference to Exhibit 1.1 of the Registrant's Current Report on Form 8-K, filed December 5, 2024).
10.21+	Transition and Consulting Agreement, by and between the Registrant and Tighe Reardon, dated August 2, 2024 (incorporated by reference to Exhibit 10.1 to the Registrant's Quarterly Report on Form 10-Q, filed with the SEC on November 6, 2024).
19.1	Janux Therapeutics, Inc. Insider Trading Policy
23.1	Consent of Independent Registered Public Accounting Firm.
24.1	Power of Attorney (see signature page).
31.1	Certification of Principal Executive and 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 and Financial Officer Pursuant to 18 U.S.C. Section 1350, as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
97.1	Janux Therapeutics, Inc. Incentive Compensation Recoupment Policy (incorporated by reference to Exhibit 10.22 to the Registrant's Annual Report on Form 10-K, filed with the SEC on March 8, 2024).
101.INS	Inline XBRL Instance Document – the instance document does not appear in the Interactive Data File because XBRL tags are embedded within the Inline XBRL document.
101.SCH	Inline XBRL Taxonomy Extension Schema 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: February 27, 2025

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 Maria Dobek, 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 and Financial Officer)	February 27, 2025
/s/ Maria Dobek Maria Dobek	Vice President, Accounting (Principal Accounting Officer)	February 27, 2025
/s/ Ron Barrett, Ph.D. Ron Barrett, Ph.D.	Chairperson of the Board of Directors	February 27, 2025
/s/ Vickie Capps Vickie Capps	Director	February 27, 2025
/s/ Eric Dobmeier Eric Dobmeier	Director	February 27, 2025
/s/ Sheila Gujrathi, M.D. Sheila Gujrathi, M.D.	Director	February 27, 2025
/s/ Natasha Hernday Natasha Hernday	Director	February 27, 2025
/s/ Winston Kung Winston Kung	Director	February 27, 2025
/s/ Alana McNulty Alana McNulty	Director	February 27, 2025
/s/ Jake Simson, Ph.D. Jake Simson, Ph.D.	Director	February 27, 2025

10955 Vista Sorrento Parkway, Suite 200
San Diego, California 92130

NOTICE OF ANNUAL MEETING OF STOCKHOLDERS
TO BE HELD ON JUNE 11, 2025

Dear Stockholder:

You are cordially invited to attend the 2025 Annual Meeting of Stockholders (the "Annual Meeting") of Janux Therapeutics, Inc., a Delaware corporation, which will be held virtually over the internet, on Wednesday, June 11, 2025 at 1:30 p.m. Pacific Time. The Annual Meeting is being held for the following purposes:

1. To elect the three nominees for Class I director named in the accompanying proxy statement to serve for three-year terms until the 2028 Annual Meeting of Stockholders.
2. To ratify the selection by the Audit Committee of the Board of Directors of Ernst & Young LLP as our independent registered public accounting firm for our fiscal year ending December 31, 2025.
3. To approve, on an advisory basis, the compensation of our named executive officers, as disclosed in the proxy statement.
4. To indicate, on an advisory basis, the preferred frequency of holding future stockholder votes to approve the compensation of our named executive officers.
5. To conduct any other business properly brought before the Annual Meeting.

These items of business are more fully described in the proxy statement accompanying this Notice.

To participate, vote or submit questions during the Annual Meeting via live webcast, you must register in advance at www.proxydocs.com/JANX prior to the deadline of Tuesday, June 10, 2025 at 5:00 p.m. Eastern Time. **You will not be able to attend the Annual Meeting in person.**

Our Board of Directors recommends a vote "**FOR**" for the election of all nominees for Class I director to our Board of Directors, "**FOR**" the ratification of the selection by the Audit Committee of the Board of Directors of Ernst & Young LLP as our independent registered public accounting firm for our fiscal year ending December 31, 2025, "**FOR**" the advisory approval of the compensation of our named executive officers, as disclosed in the proxy statement, and for a "**ONE YEAR**" frequency of holding future stockholder votes to approve the compensation of our executive officers. The accompanying proxy statement contains additional information and should be carefully reviewed by stockholders.

The record date for the Annual Meeting is April 17, 2025. Only stockholders of record at the close of business on that date may vote at the Annual Meeting or any adjournment or postponement thereof.

By Order of the Board of Directors,

/s/ David Campbell, Ph.D.
David Campbell, Ph.D.
President and Chief Executive Officer

San Diego, California
April 25, 2025

You are cordially invited to attend the Annual Meeting. Whether or not you expect to attend the Annual Meeting, you are urged to cast your vote as soon as possible. You may vote your shares via the internet or via a toll-free telephone number by following the instructions on the Notice of Internet Availability of Proxy Materials or the proxy card. In addition, if you received paper copies of the proxy materials by mail, you can also vote by mail by following the instructions on the proxy card. Submitting a proxy card will not prevent you from attending the Annual Meeting and voting at the Annual Meeting if you so desire. Please note, however, that if your shares are held of record by a broker, bank, or other nominee and you wish to vote at the Annual Meeting, you must obtain from the record holder a proxy issued in your name.

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10955 Vista Sorrento Parkway, Suite 200
San Diego, California 92130

PROXY STATEMENT
FOR THE 2025 ANNUAL MEETING OF STOCKHOLDERS

To be held on June 11, 2025

QUESTIONS AND ANSWERS ABOUT THESE PROXY MATERIALS AND VOTING

Why did I receive a notice regarding the availability of proxy materials on the internet?

We have sent you a Notice of Internet Availability of Proxy Materials (the "Notice") because the Board of Directors (sometimes referred to as the "Board") of Janux Therapeutics, Inc. (sometimes referred to as "we," "us," the "Company" or "Janux") is soliciting your proxy to vote at the 2025 Annual Meeting of Stockholders, including at any adjournments or postponements of the meeting (the "Annual Meeting"). Pursuant to rules adopted by the Securities and Exchange Commission (the "SEC"), we have elected to provide access to our proxy materials over the internet. Accordingly, we have sent the Notice to our stockholders of record. All stockholders will have the ability to access the proxy materials on the website referred to in the Notice or request to receive a printed set of the proxy materials. Instructions on how to access the proxy materials over the internet or to request a printed copy may be found in the Notice.

We intend to mail the Notice on or about April 25, 2025 to all stockholders of record entitled to vote at the Annual Meeting.

Will I receive any other proxy materials by mail?

We may send you a proxy card, along with a second notice, on or after May 7, 2025.

What is the format of the Annual Meeting?

The Annual Meeting will be held in a virtual meeting format only with no physical in person meeting. A summary of the information you need to attend the Annual Meeting is provided below:

- To participate, vote or submit questions during the Annual Meeting via live webcast, you must register in advance at www.proxydocs.com/JANX prior to the deadline of Tuesday, June 10, 2025 at 5:00 p.m. Eastern Time and provide the control number as set forth in the Notice, or proxy card, or voting instruction form at www.proxydocs.com/JANX. Upon completing your registration, you will receive further instructions via email, including unique links to access the Annual Meeting and to submit questions in advance of the Annual Meeting.
- Any stockholder may listen to the Annual Meeting and participate live via webcast at www.proxydocs.com/JANX. The webcast will begin at 1:30 p.m. Pacific Time on June 11, 2025.
- To enter the Annual Meeting, please have your control number which is available on your Notice, your proxy card or the instructions that accompanied your proxy materials.

- Instructions on how to connect to and participate in the Annual Meeting via the internet, including how to demonstrate proof of stock ownership, are posted at www.proxydocs.com/JANX.

Can I attend the Annual Meeting?

We will be hosting the Annual Meeting via live webcast on the internet. **You will not be able to attend the Annual Meeting in person. Any stockholder can listen to and participate in the Annual Meeting live via the internet at www.proxydocs.com/JANX. The webcast will start at 1:30 p.m. Pacific Time on June 11, 2025. Stockholders may vote and submit questions while connected to the Annual Meeting on the internet.**

What do I need to be able to participate in the Annual Meeting online?

To participate, vote or submit questions during the Annual Meeting via live webcast, you must register in advance at www.proxydocs.com/JANX prior to the deadline of Tuesday, June 10, 2025 at 5:00 p.m. Eastern Time and provide the control number as provided described in the Notice, or proxy card, or voting instruction form at www.proxydocs.com/JANX. Upon completing your registration, you will receive further instructions via email, including unique links to access the Annual Meeting and to submit questions in advance of the Annual Meeting.

You will need the control number included on your Notice, your proxy card or the instructions that accompanied your proxy materials to be able to vote your shares or submit questions during the Annual Meeting. **Instructions on how to connect and participate in the Annual Meeting via the internet, including how to demonstrate proof of stock ownership, are posted at www.proxydocs.com/JANX.**

Will a list of record stockholders as of the record date be available?

For the ten days ending the day prior to the Annual Meeting, a list of our record stockholders as of the close of business on the record date will be available for examination by any stockholder of record for a legally valid purpose at our corporate headquarters during regular business hours. To access the list of record stockholders, stockholders should email investors@januxrx.com.

Who can vote at the Annual Meeting?

Only stockholders of record at the close of business on April 17, 2025 will be entitled to vote at the Annual Meeting. On this record date, there were 59,168,490 shares of common stock outstanding and entitled to vote.

Stockholder of Record: Shares Registered in Your Name

If on April 17, 2025 your shares were registered directly in your name with the Company's transfer agent, Equiniti Trust Company, LLC, then you are a stockholder of record. As a stockholder of record, you may vote at the Annual Meeting or vote by proxy. Whether or not you plan to attend the Annual Meeting, we urge you to fill out and return the proxy card that may be mailed to you, or vote by proxy over the telephone or on the internet as instructed below, to ensure your vote is counted.

Beneficial Owner: Shares Registered in the Name of a Broker or Bank

If on April 17, 2025 your shares were held, not in your name, but rather in an account at a brokerage firm, bank, dealer, or other similar organization, then you are the beneficial owner of shares held in "street name" and the Notice is being forwarded to you by that organization. The organization holding your account is considered to be the stockholder of record for purposes of voting at the Annual Meeting. As a beneficial owner, you have the right to direct your broker or other agent regarding how to vote the shares in your account(s). You are also invited to attend the Annual Meeting by registering in advance at www.proxydocs.com/JANX. However, since you are not the stockholder of record, you may be required to

obtain a valid proxy from your broker or other agent in order to vote your shares at the Annual Meeting. Follow the instructions you receive from your brokerage firm, bank, dealer, or other similar organization.

What am I voting on?

There are four matters scheduled for a vote:

- Election of the three nominees for Class I director named in this proxy statement to serve for three-year terms until the 2028 Annual Meeting of Stockholders (Proposal 1);
- Ratification of the selection by the Audit Committee of the Board of Directors of Ernst & Young LLP as our independent registered public accounting firm for our fiscal year ending December 31, 2025 (Proposal 2);
- The advisory approval of the compensation of our named executive officers ("Say-on-Pay"), as disclosed in the proxy statement (Proposal 3); and
- The advisory indication of the preferred frequency of holding future Say-on-Pay advisory votes on executive compensation (Proposal 4).

What if another matter is properly brought before the Annual Meeting?

The Board of Directors knows of no other matters that will be presented for consideration at the Annual Meeting. If any other matters are properly brought before the Annual Meeting, it is the intention of the persons named in the proxy to vote on those matters in accordance with their best judgment.

How do I vote?

For Proposal 1, the election of directors, you may either vote "For" all of the nominees to the Board of Directors or you may "Withhold" your vote for any nominee you specify. For Proposals 2 and 3, you may vote "For" or "Against" or you may abstain from voting. For Proposal 4, the advisory vote on how frequently we should solicit stockholder advisory approval of executive compensation, you may vote for any one of the following: one year, two years or three years, or you may abstain from voting on that matter. The procedures for voting are as follows:

Stockholder of Record: Shares Registered in Your Name

If you are a stockholder of record, you may vote at the Annual Meeting, vote by proxy over the telephone, vote by proxy through the internet, or vote by proxy using the proxy card that you may request or that we may elect to deliver at a later time. Whether or not you plan to attend the Annual Meeting, we urge you to vote by proxy to ensure your vote is counted. You may still attend the Annual Meeting and vote even if you have already voted by proxy.

- To vote during the Annual Meeting, follow the instructions posted at www.proxydocs.com/JANX. You must register in advance at www.proxydocs.com/JANX prior to the deadline of Tuesday, June 10, 2025 at 5:00 p.m. Eastern Time to be able to vote during the Annual Meeting.
- To vote over the telephone, dial toll-free (866) 428-0096 using a touch-tone phone and follow the recorded instructions. You will be asked to provide the company number and control number from the Notice or the proxy card that we may deliver. Your telephone vote must be received by 11:59 p.m. Pacific Time on June 10, 2025 to be counted.
- To vote through the internet, go to *www.proxypush.com/JANX* to complete an electronic proxy card. You will be asked to provide the company number and control number from the Notice or the proxy card that we may deliver. Your internet vote must be received by 11:59 p.m. Pacific Time on June 10, 2025 to be counted.

- To vote using the proxy card, simply complete, sign and date the proxy card that may be delivered to you and return it promptly in the envelope provided. If you return your signed proxy card to us before the Annual Meeting, we will vote your shares as you direct.

Beneficial Owner: Shares Registered in the Name of Broker or Bank

If you are a beneficial owner of shares registered in the name of your broker, bank, or other agent, you should have received a Notice containing voting instructions from that organization rather than from Janux. Simply follow the voting instructions in the Notice to ensure that your vote is counted. Alternatively, you may vote by telephone or over the internet as instructed by your broker, bank, or other agent. To vote at the Annual Meeting, you may be required to obtain a valid proxy from your broker, bank, or other agent. Follow the instructions from your broker, bank, or other agent included with these proxy materials, or contact that organization to request a proxy form, and you also must register in advance at www.proxydocs.com/JANX prior to the deadline of Tuesday, June 10, 2025 at 5:00 p.m. Eastern Time.

We provide internet proxy voting to allow you to vote your shares online, with procedures designed to ensure the authenticity and correctness of your proxy vote instructions. However, please be aware that you must bear any costs associated with your internet access, such as usage charges from internet access providers and telephone companies.

How many votes do I have?

On each matter to be voted upon, you have one vote for each share of common stock you own as of April 17, 2025.

What happens if I do not vote?

Stockholder of Record: Shares Registered in Your Name

If you are a stockholder of record and do not vote by completing a proxy card, by telephone, through the internet, or at the Annual Meeting, your shares will not be voted.

Beneficial Owner: Shares Registered in the Name of Broker or Bank

If you are a beneficial owner and do not instruct your broker, bank, or other agent how to vote your shares, the question of whether your broker or nominee will still be able to vote your shares depends on whether the proposal is deemed to be a “routine” matter. Brokers and nominees can use their discretion to vote “uninstructed” shares with respect to matters that are considered “routine,” but not with respect to “non-routine” matters. Under the relevant rules and interpretations, “non-routine” matters are matters that may substantially affect the rights or privileges of stockholders, such as mergers, stockholder proposals, elections of directors (even if not contested), executive compensation (including any advisory stockholder votes on executive compensation and on the frequency of stockholder votes on executive compensation), and certain corporate governance proposals, even if management-supported. Accordingly, without your instructions, your broker or nominee may not vote your shares on Proposal 1, 3 or 4, but may vote your shares on Proposal 2.

What if I return a proxy card or otherwise vote but do not make specific choices?

If you return a signed and dated proxy card or otherwise vote without marking voting selections, your shares will be voted, as applicable, “For” the election of all nominees for director named in this proxy statement, “For” the ratification of the selection by the Audit Committee of the Board of Directors of Ernst & Young LLP as our independent registered public accounting firm for our fiscal year ending December 31, 2025, “For” the advisory approval of the compensation of our named executive officers, as disclosed in the proxy statement, and for a “One Year” frequency of holding future Say-on-Pay advisory votes on executive compensation. If any other matter is properly presented at the Annual Meeting, your proxy

holder (one of the individuals named on your proxy card) will vote your shares using his or her best judgment.

Who is paying for this proxy solicitation?

We will pay for the entire cost of soliciting proxies. In addition to these proxy materials, our directors and employees may also solicit proxies in person, by telephone, or by other means of communication. Directors and employees will not be paid any additional compensation for soliciting proxies. We may reimburse brokerage firms, banks, and other agents for the cost of forwarding proxy materials to beneficial owners.

What does it mean if I receive more than one Notice?

If you receive more than one Notice, your shares may be registered in more than one name or in different accounts. Please follow the voting instructions on the Notices to ensure that all your shares are voted.

Can I change my vote after submitting my proxy?

Stockholder of Record: Shares Registered in Your Name

Yes. You can revoke your proxy at any time before the final vote at the Annual Meeting. If you are the record holder of your shares, you may revoke your proxy in any one of the following ways:

- You may submit another properly completed proxy card with a later date.
- You may grant a subsequent proxy by telephone or through the internet.
- You may send a timely written notice that you are revoking your proxy to our Corporate Secretary at 10955 Vista Sorrento Parkway, Suite 200, San Diego, California 92130. To be timely, a written notice revoking your proxy must be received by 11:59 p.m. Pacific Time on June 10, 2025.
- You may attend and vote during the Annual Meeting, which will be hosted via the internet. Simply attending the Annual Meeting will not, by itself, revoke your proxy.

Your most current proxy card or telephone or internet proxy is the one that is counted.

Beneficial Owner: Shares Registered in the Name of Broker or Bank

If your shares are held by your broker, bank or other agent, you should follow the instructions provided by your broker, bank, or other agent with respect to changing your vote.

When are stockholder proposals and director nominations due for the 2026 Annual Meeting of Stockholders?

To be considered for inclusion in next year's proxy materials, your proposal must be submitted in writing by December 26, 2025, to the attention of our Corporate Secretary at 10955 Vista Sorrento Parkway, Suite 200, San Diego, California 92130. If you wish to submit a proposal (including a director nomination) at the 2026 Annual Meeting of Stockholders that is not to be included in next year's proxy materials, your written request must be received by our Corporate Secretary between February 11, 2026 and March 13, 2026. You are also advised to review our Amended and Restated Bylaws ("Bylaws"), which contain additional requirements about advance notice of stockholder proposals and director nominations. In addition, to comply with the universal proxy rules, stockholders who intend to solicit proxies in support of director nominees other than our Board of Director's nominees must provide notice that sets forth any additional information required by Rule 14a-19 promulgated under the Securities Exchange Act of 1934, as amended (the "Exchange Act"), no later than April 12, 2026.

How are votes counted?

Votes will be counted by the inspector of election appointed for the Annual Meeting, who will separately count, for the proposal to elect directors, votes "For," "Withhold," and broker non-votes; with respect to Proposal 2, votes "For" and "Against," abstentions and, if applicable, broker non-votes; with respect to Proposal 3, votes "For" and "Against," abstentions and, if applicable, broker non-votes; and, with respect to Proposal 4, votes "One Year," "Two Years" " and "Three Years," abstentions and, if applicable, broker non-votes. Abstentions will have no effect on Proposal 1. Abstentions will be counted towards the vote total for Proposals 2 and 3 and will have the same effect as "Against" votes. Abstentions will be counted towards the vote total for Proposal 4 and will have the effect of a vote against each of the proposed frequencies. Broker non-votes will be counted towards the presence of a quorum but will not be counted towards the vote total for any proposal.

What are "broker non-votes"?

As discussed above, when a beneficial owner of shares held in "street name" does not give instructions to the broker or nominee holding the shares as to how to vote on matters deemed to be "non-routine," the broker or nominee cannot vote the shares. These un-voted shares are counted as "broker non-votes."

As a reminder, if you are a beneficial owner of shares held in street name, in order to ensure your shares are voted in the way you would prefer, you must provide voting instructions to your broker, bank, or other agent by the deadline provided in the materials you receive from your broker, bank, or other agent.

How many votes are needed to approve each proposal?

- For the election of directors, the three nominees receiving the most "For" votes from the holders of shares present at the Annual Meeting or represented by proxy and entitled to vote on the election of directors will be elected. Only votes "For" will affect the outcome.
- To be approved, the ratification of the selection by the Audit Committee of the Board of Directors of Ernst & Young LLP as our independent registered public accounting firm for the fiscal year ending December 31, 2025 must receive "For" votes from the holders of a majority of shares present at the Annual Meeting or represented by proxy and entitled to vote on the matter. If you mark your proxy to "Abstain" from voting, it will have the same effect as an "Against" vote. Broker non-votes will have no effect.
- To be approved on an advisory basis, the vote on the compensation of our named executive officers must receive "For" votes from the holders of a majority of shares present at the Annual Meeting or represented by proxy and entitled to vote on the matter. If you mark your proxy to "Abstain" from voting, it will have the same effect as an "Against" vote. Broker non-votes will have no effect. Since this proposal is an advisory vote, the result will not be binding on our Board of Directors. However, our Board of Directors values our stockholders' opinions, and our Board of Directors and the Compensation Committee will take into account the outcome of the advisory vote when considering future executive compensation decisions.
- For the advisory vote on the frequency of future advisory stockholder votes to approve the compensation of our named executive officers, the frequency receiving votes from the holders of a majority of shares present at the Annual Meeting or represented by proxy and entitled to vote on the matter will be determined to be the preferred frequency with which the Company is to hold an advisory stockholder vote to approve the compensation paid to the Company's named executive officers. If you mark your proxy to "Abstain" from voting, it will have the effect of a vote against each of the proposed frequencies. Broker non-votes will have no effect. Since this proposal is an advisory vote, the result will not be binding on our Board of Directors. However, our Board of Directors values our stockholders' opinions, and our Board of Directors

and the Compensation Committee will take into account the outcome of the advisory vote when considering future executive compensation decisions.

What is the quorum requirement?

A quorum of stockholders is necessary to hold a valid meeting. A quorum will be present if stockholders holding a majority of the outstanding shares entitled to vote are present at the Annual Meeting or represented by proxy. On the record date, there were 59,168,490 shares outstanding and entitled to vote. Thus, the holders of at least 29,584,246 shares must be present or represented by proxy at the Annual Meeting to have a quorum.

Your shares will be counted towards the quorum only if you submit a valid proxy (or one is submitted on your behalf by your broker, bank, or other nominee) or if you vote at the Annual Meeting. Abstentions and broker non-votes will be counted towards the quorum requirement. If there is no quorum, the holders of a majority of shares present at the Annual Meeting or represented by proxy may adjourn the Annual Meeting to another date.

How can I find out the results of the voting at the Annual Meeting?

Preliminary voting results will be announced at the Annual Meeting. In addition, final voting results will be published in a current report on Form 8-K that we expect to file within four business days after the Annual Meeting. If final voting results are not available to us in time to file a Form 8-K within four business days after the Annual Meeting, we intend to file a Form 8-K to publish preliminary results and, within four business days after the final results are known to us, file an additional Form 8-K to publish the final results.

PROPOSAL 1

ELECTION OF DIRECTORS

Our Board of Directors is divided into three classes. Each class consists, as nearly as possible, of one-third of the total number of directors, and each class has a three-year term. Vacancies on the Board of Directors may be filled only by persons elected by a majority of the remaining directors. A director elected by the Board of Directors to fill a vacancy in a class, including vacancies created by an increase in the number of directors, shall serve for the remainder of the full term of that class and until the director's successor is duly elected and qualified.

Our Board of Directors currently consists of nine members. There are three directors in Class I, the class whose term of office expires at this Annual Meeting: David Campbell, Ph.D., Ron Barrett, Ph.D., and Winston Kung. The three nominees for Class I director were nominated for re-election to the Board of Directors at the Annual Meeting by the Nominating and Corporate Governance Committee of the Board of Directors. If elected at the Annual Meeting, each of these nominees for director would serve for a three-year term until our 2028 Annual Meeting of Stockholders, and until his successor is duly elected and qualified, or until his earlier death, resignation or removal. It is our policy to invite directors and nominees for director to attend the Annual Meeting. All of our then active directors attended the 2024 Annual Meeting of Stockholders other than Sheila Gujrathi, M.D. Proxies cannot be voted for a greater number of persons than the number of nominees named in this proxy statement.

Directors are elected by a plurality of the votes of the holders of shares present or represented by proxy and entitled to vote at the Annual Meeting. Accordingly, the three nominees receiving the most "For" votes (among votes properly cast at the Annual Meeting or by proxy) will be elected. If no contrary indication is made, shares represented by executed or authenticated proxies will be voted "For" the election of the three nominees named above or, if any nominee becomes unavailable for election as a result of an unexpected occurrence, "For" the election of a substitute nominee designated by our Board of Directors. Each nominee has agreed to serve as a director if elected and we have no reason to believe that any nominee will be unable to serve.

The Nominating and Corporate Governance Committee seeks to assemble a Board of Directors that, as a whole, possesses the appropriate balance of professional and industry knowledge, financial expertise, and high-level management experience necessary to oversee and direct the Company's business. The Nominating and Corporate Governance Committee and the Board of Directors also seek to attain diversity and balance among directors of race, gender, geography, thought, viewpoints, and backgrounds. To those ends, the Nominating and Corporate Governance Committee has identified and evaluated nominees in the broader context of the Board of Directors' overall composition, with the goal of recruiting members who complement and strengthen the skills of other members through diversity and who also exhibit integrity, collegiality, sound business judgment, and other qualities that the Nominating and Corporate Governance Committee views as critical to effective functioning of the Board of Directors. The brief biographies below include information, as of the date of this proxy statement, regarding the specific and particular experience, qualifications, attributes or skills of each director/nominee that led the Nominating and Corporate Governance Committee to recommend that person as a nominee. However, each of the members of the Nominating and Corporate Governance Committee may have a variety of reasons why he or she believes a particular person would be an appropriate nominee for the Board of Directors, and these views may differ from the views of other members.

Nominees for Election for a Three-year Term Expiring at the 2028 Annual Meeting

David Campbell, Ph.D., 66, is our founder and has served as President and Chief Executive Officer and as a member of our Board of Directors since our inception in June 2017. Prior to founding Janux, Dr. Campbell was an Entrepreneur in Residence at Avalon Ventures from March 2013 to December 2019. Dr. Campbell served as the Chief Scientific Officer for Sitari Pharmaceuticals, Inc. from November 2013 through August 2019 and for Iron Horse Therapeutics, Inc. from November 2015 to June 2019. Dr.

Campbell served as the President and Chief Executive Officer of Enlibirum from November 2015 through December 2017. Dr. Campbell received a B.S. in Chemistry from Harvey Mudd College and a Ph.D. in Organic Chemistry from Cornell University, and received post-doctoral training under then University of California, Berkeley professor Dr. Peter Schultz.

The Nominating and Corporate Governance Committee and the Board of Directors believe that Dr. Campbell's extensive experience as a senior executive officer of biotechnology companies and his educational background provide him with the qualifications and skills to serve as a member of our Board of Directors.

Ron Barrett, Ph.D., 69, has served as a member of our Board of Directors since September 2021. Dr. Barrett also serves as a member of the board of directors of Quadriga Biosciences, a private oncology company. Dr. Barrett served as Executive Chairman of Medikine, Inc., a biopharmaceutical company, from January 2023 to July 2023 and previously served as its Chief Executive Officer and Chairman of the board of directors from June 2017 until January 2023, and as its Executive Chair from December 2016 to June 2017. Dr. Barrett was a founder of XenoPort, Inc. ("XenoPort"), a biopharmaceutical company, and served as its Chief Executive Officer from 2001 to October 2015, its Chief Scientific Officer from 1999 to 2001 and as a member of its board of directors from 1999 to October 2015. Prior to XenoPort, Dr. Barrett held various positions at Affymax Research Institute, a drug discovery company now owned by GlaxoSmithKline plc, and Abbott Laboratories, a healthcare company. Dr. Barrett received a B.S. from Bucknell University and a Ph.D. in Pharmacology from Rutgers University.

The Nominating and Corporate Governance Committee and the Board of Directors believe that Dr. Barrett's extensive experience with pharmaceutical and biotechnology companies and his educational background provide him with the qualifications and skills to serve as a member of our Board of Directors.

Winston Kung, 49, has served as a member of our Board of Directors since September 2022. Mr. Kung has served as the Chief Financial Officer and Treasurer of ArriVent BioPharma, Inc., a biopharmaceutical company, since January 2024. From December 2017 to January 2024, Mr. Kung served as the Chief Operating Officer and Chief Financial Officer of PMV Pharmaceuticals, Inc., a public precision oncology company. From April 2013 to November 2017, Mr. Kung held multiple positions at Celgene Corporation, a global biopharmaceutical company (acquired by Bristol-Myers Squibb), including Vice President of Business Development and Global Alliances, and Chief Business Officer at Celgene Cellular Therapeutics (a wholly-owned subsidiary of Celgene Corporation). Prior to Celgene, Mr. Kung worked at Citigroup from June 2010 to April 2013 in its Global Healthcare Investment Banking group and at Lehman Brothers (which was subsequently acquired by Barclays) from May 2007 to June 2010 in its Global Mergers and Acquisition Group. From August 2004 to May 2007, Mr. Kung worked at Amgen, Inc. ("Amgen"), a public biopharmaceutical company, as a co-founder of the Alliance Management group, and served as the deal lead on multiple acquisitions as part of the Corporate Development group. Mr. Kung also worked at Genentech Inc., a biotechnology company (acquired by Roche Holding AG), from November 1999 to September 2002 as part of the Business and Corporate Development group. Mr. Kung received a B.A. in Biology and International Relations from Brown University and a M.B.A. from Harvard Business School.

The Nominating and Corporate Governance Committee and the Board of Directors believe that Mr. Kung's experience in corporate finance, accounting, operations, investor relations, capital markets and strategic business development provide him with the qualifications and skills to serve as a member of our Board of Directors.

THE BOARD OF DIRECTORS RECOMMENDS A VOTE "FOR" THE ELECTION OF EACH NAMED NOMINEE.

Directors Continuing in Office Until the 2026 Annual Meeting

Sheila Gujrathi, M.D., 54, has served as a member of our Board of Directors since March 2021. Dr. Gujrathi also serves as the Chairperson of the board of directors of Immpact Bio, a biopharmaceutical company, and as the Executive Chair of the board of directors of Ventyx Biosciences, a public biopharmaceutical company. Dr. Gujrathi previously served as Chair of the board of directors of ADARx Pharmaceuticals, Inc., a biopharmaceutical company, from June 2020 to January 2025, and on the board of directors of Turning Point Therapeutics, Inc., a public biopharmaceutical company, from November 2017 to March 2021, and as Chair of the board of directors from April 2019 to March 2021. Dr. Gujrathi also previously served on the board of directors of Five Prime Therapeutics, Inc. (acquired by Amgen in April 2021) from December 2015 to June 2019 and Ambrx, Inc. from February 2014 until its acquisition in June 2015. Dr. Gujrathi is a Co-Founder of Gossamer Bio, Inc., a public biopharmaceutical company, and served as President and Chief Executive Officer from July 2018 to November 2020 and as President and Chief Operating Officer from October 2015 to June 2018 and as a member of its board of directors from October 2015 to November 2020. Previously, Dr. Gujrathi was the Chief Medical Officer of Receptos, Inc., a biopharmaceutical company, a position she held from June 2011 until its acquisition by Celgene Corporation in August 2015. Dr. Gujrathi joined Receptos, Inc. from Bristol-Myers Squibb Company ("Bristol-Meyers Squibb"), where she was Vice President of the Global Clinical Research Group in Immunology from 2008 until 2011. Prior to joining Bristol-Myers Squibb, Dr. Gujrathi worked at Genentech, Inc., where she held roles of increasing responsibility in the Immunology, Tissue Growth and Repair clinical development group from 2002 until 2008. From 1999 until 2002, Dr. Gujrathi was a management consultant at McKinsey & Company in the healthcare practice, where she provided strategic advice on a variety of projects in the healthcare and pharmaceutical industry. Dr. Gujrathi received her B.S. in Biomedical Engineering and an M.D. from Northwestern University in Medical Education. Dr. Gujrathi completed her internal medicine internship and residency at Brigham and Women's Hospital, Harvard Medical School and is board certified in internal medicine. Dr. Gujrathi received additional training at the University of California, San Francisco and Stanford University in their Allergy and Immunology Fellowship Program.

The Nominating and Corporate Governance Committee and the Board of Directors believe that Dr. Gujrathi's extensive experience as a senior executive officer at multiple biotechnology companies and educational background provide her with the qualifications and skills to serve as a member of our Board of Directors.

Natasha Hernday, 53, has served as a member of our Board of Directors since July 2024. Ms. Hernday brings extensive experience in business development, corporate strategy and alliance management, having served as Chief Business Officer and a member of the Executive Committee at Seagen Inc. ("Seagen") from December 2022 until its acquisition by Pfizer in December 2023, and previously as Executive Vice President, Corporate Development from October 2020 until December 2022. Ms. Hernday joined Seagen in 2011 where she built and led the business development team responsible for licensing deals, acquisitions and strategic alliances. Prior to her role at Seagen, Ms. Hernday spent 16 years at Amgen, where she began her career in discovery research, then held various leadership positions in corporate development and corporate strategy, including as Director, Mergers & Acquisitions and as Director, Out-Partnering, playing a key role in numerous high-value transactions. Ms. Hernday has served on the boards of directors of Xoma Corp. since June 2019 and Firefly Biologics, Inc. since September 2024 and on the Knight Campus External Advisory Board for the University of Oregon. Ms. Hernday previously served on the boards of directors of Alpine Immune Sciences, Inc., from December 2020 until its acquisition by Vertex Pharmaceuticals Incorporated in May 2024, and PDL BioPharma, Inc., from June 2019 until January 2021. Ms. Hernday received a B.A. in microbiology from the University of California, Santa Barbara and an M.B.A. from Pepperdine University.

The Nominating and Corporate Governance Committee and the Board of Directors believe that Ms. Hernday's extensive experience as a senior executive officer at multiple biotechnology companies and educational background provide her with the qualifications and skills to serve as a member of our Board of Directors.

Alana McNulty, 62, has served as a member of our Board of Directors since September 2021. Ms. McNulty served as Chief Business Officer of Effector Therapeutics, Inc. ("Effector") from July 2019 to July

2022. Previously, Ms. McNulty served as Chief Financial Officer of Effector from July 2012 until December 2020 (in a consulting capacity until October 2015). Ms. McNulty served as Chief Financial Officer of Lumena Pharmaceuticals Inc. from July 2012 until its acquisition by Shire plc in November 2014, and as Chief Financial Officer of Excaliard Pharmaceuticals, Inc. from March 2011 through its acquisition by Pfizer Inc. in November 2011. Prior to that, Ms. McNulty was acting Chief Financial Officer at BrainCells, Inc. from 2004 until 2011 and Chief Financial Officer of Elitra Pharmaceuticals Inc. from 1998 to 2003. Prior to that, Ms. McNulty was head of Corporate Development and a General Manager of a business unit at Advanced Tissue Sciences. Ms. McNulty has served on the board of directors of Lipidio Pharmaceuticals, a biopharmaceutical company, since February 2023. Ms. McNulty received a B.A. in Biology from the University of California, Santa Barbara and an M.B.A. from the Anderson School of Business at the University of California, Los Angeles.

The Nominating and Corporate Governance Committee and the Board of Directors believe that Ms. McNulty's experience in corporate finance, accounting, operations, investor relations, capital markets and strategic business development provide her with the qualifications and skills to serve as a member of our Board of Directors.

Directors Continuing in Office Until the 2027 Annual Meeting

Vickie Capps, 63, has served as a member of our Board of Directors since March 2021. Ms. Capps has also served as a member of the board of directors of Amedisys, Inc., a public healthcare company, since October 2019, and is the Chair of its audit committee and a member of its compensation committee. Ms. Capps has also served as a member of the board of directors of Orthofix Medical, Inc., a public medical technology company, since March 2025. In addition, Ms. Capps serves as a member of the boards of directors of Enable Injections, Inc. and Breg, Inc., both private medical device companies, a member of the senior advisory board of Consonance Capital Partners, a healthcare investment firm, and is also a member of the board of directors of the San Diego State University Research Foundation and a member of its audit committee and its finance and investment committee. Ms. Capps previously served on the board of directors of NuVasive, Inc., a public medical device company, from June 2015 until the closing of its merger with Globus Medical, Inc. in September 2023, of Otonomy, Inc., a public biotechnology company, from March 2014 until February 2023, of Silverback Therapeutics, Inc., a public biotechnology company, from June 2020 until the closing of its merger with ARS Pharmaceuticals, Inc. in November 2022, of Synthorx, Inc., a public biotechnology company, from April 2018 until its sale to Sanofi in January 2020, and of Connecture, Inc., a healthcare IT company, from October 2014 to April 2018. Ms. Capps has also previously served on the boards of directors of several other public and private companies, including OmniGuide Holdings, Inc., RF Surgical Systems, Inc., Eagle Rx, Inc. and SenoRx, Inc. From July 2002 to December 2013, Ms. Capps was the Chief Financial Officer of DJO Global, Inc., a medical device company. Prior to joining DJO Global, Inc., Ms. Capps served as the Chief Financial Officer of several other public and private companies. Earlier in her career, Ms. Capps was a senior audit and accounting professional at Ernst & Young LLP. Ms. Capps is a California Certified Public Accountant and was recognized as a CFO of the Year Honoree by the San Diego Business Journal in 2009 and 2010 and as a Director of the Year Honoree by the Corporate Directors Forum in 2022. Ms. Capps received a B.A. in Business Administration/Accounting from San Diego State University.

The Nominating and Corporate Governance Committee and the Board of Directors believe that Ms. Capps's experience in corporate finance, accounting, operations, investor relations, capital markets and strategic business development provide her with the qualifications and skills to serve as a member of our Board of Directors.

Eric Dobmeier, 56, has served as a member of our Board of Directors since July 2024. Mr. Dobmeier is an executive and board member with more than 20 years of experience in the biotechnology industry. Most recently, he served as president and CEO of Chinook Therapeutics, Inc. ("Chinook") from April 2019 until its acquisition by Novartis AG in August 2023. Prior to Chinook, Mr. Dobmeier served as president and CEO of Silverback Therapeutics, Inc., a private biotechnology company. Previously, Mr. Dobmeier spent 16 years in a series of positions of increasing responsibility at Seagen, Inc., a public

biotechnology company, including Chief Operating Officer, during the company's growth from 60 to 1,200 employees, from a market cap of $150 million to over $8 billion and through its transition to a commercial company with FDA approval and launch of Adcetris, a novel lymphoma drug. Mr. Dobmeier is currently a venture partner at Samsara Biocapital and has served on the board of directors of Structure Therapeutics, Inc., a public biotechnology company, since December 2022, as well as several private biotechnology companies. He previously served on the boards of directors of Atara Biotherapeutics, Inc. from 2015 to May 2024 and Adaptive Biotechnologies, Inc. from 2016 to March 2021, both public biotechnology companies. Mr. Dobmeier earned his J.D. from the University of California, Berkeley School of Law and his undergraduate degree from Princeton University.

The Nominating and Corporate Governance Committee and the Board of Directors believe that Mr. Dobmeier's experience in venture capital in the biopharmaceutical industry and his educational background provide him with the qualifications and skills to serve as a member of our Board of Directors.

Jake Simson, Ph.D., 39, has served as a member of our Board of Directors since March 2021. Dr. Simson has served as a Partner at RA Capital Management, L.P. ("RA Capital") since December 2020. Previously, Dr. Simson served as an associate, analyst and principal at RA Capital from July 2013 to December 2020. Dr. Simson also serves as a member of the board of directors of Tyra Biosciences, a public biotechnology company, and each of Bicara Therapeutics, Convergent Therapeutics and Septerna, each a private biotechnology company. Dr. Simson received an S.B. in Materials Science and Engineering from the Massachusetts Institute of Technology and a Ph.D. in Biomedical Engineering from the Johns Hopkins University.

The Nominating and Corporate Governance Committee and the Board of Directors believe that Dr. Simson's experience in venture capital in the biopharmaceutical industry and his educational background provide him with the qualifications and skills to serve as a member of our Board of Directors.

INFORMATION REGARDING THE BOARD OF DIRECTORS AND CORPORATE GOVERNANCE

Independence of the Board of Directors

As required under the Nasdaq Stock Market ("Nasdaq") listing standards, a majority of the members of a listed company's Board of Directors must qualify as "independent," as affirmatively determined by the Board of Directors of such company. Our Board of Directors consults with our counsel to ensure that the Board of Directors' determinations are consistent with relevant securities and other laws and regulations regarding the definition of "independent," including those set forth in pertinent listing standards of Nasdaq, as in effect from time to time.

Consistent with these considerations, after review of all relevant identified transactions or relationships between each director, or any of his or her family members, and our company, our senior management and our independent auditors, the Board of Directors has affirmatively determined that all of our directors, other than Dr. Campbell, are independent within the meaning of the applicable Nasdaq listing standards. In making this determination, the Board of Directors found that none of these directors had a material or other disqualifying relationship with our company.

Board Leadership Structure

Our Board of Directors is currently chaired by Dr. Barrett. Our Chair has the authority, among other things, to call and preside over Board of Directors meetings, to set meeting agendas and to determine materials to be distributed to the Board of Directors. Accordingly, our Chair has substantial ability to shape the work of our Board of Directors. We believe that separation of the positions of Chair and Chief Executive Officer reinforces the independence of our Board of Directors in its oversight of our business and affairs. In addition, we have a separate Chair for each committee of our Board of Directors. The Chair of each committee is expected to report annually to our Board of Directors on the activities of their committee in fulfilling their responsibilities as detailed in their respective charters or specify any shortcomings should that be the case.

Stockholder Communications with the Board of Directors

Our Board of Directors has adopted a formal process by which stockholders may communicate with the Board of Directors or any of its directors. Stockholders who wish to communicate with the Board of Directors may do so by sending written communications addressed to the Corporate Secretary of Janux Therapeutics, Inc. at 10955 Vista Sorrento Parkway, Suite 200, San Diego, California 92130. Each communication must set forth: the name and address of the stockholder on whose behalf the communication is sent and the number of our shares that are owned beneficially by such stockholder as of the date of the communication. Each communication will be reviewed by our Corporate Secretary to determine whether it is appropriate for presentation to the Board of Directors or such director. Communications determined by our Corporate Secretary to be appropriate for presentation to the Board of Directors or such director will be submitted to the Board of Directors or such director on a periodic basis.

Code of Ethics

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. The Code of Business Conduct and Ethics is available on our website at *www.januxrx.com*. If we make any substantive amendments to the Code of Business Conduct and Ethics or grant any waiver from a provision of the Code of Business Conduct and Ethics to any principal executive officer, principal financial officer, principal accounting officer or controller or persons performing similar functions or our directors, we will promptly disclose the nature of the amendment or waiver on our website.

Role of the Board of Directors in Risk Oversight

Our Audit Committee is primarily responsible for overseeing our risk management processes on behalf of the full Board of Directors. The Audit Committee receives reports from management at least annually regarding our assessment of risks. In addition, the Audit Committee reports regularly to the full Board of Directors, which also considers our risk profile. The Audit Committee and the full Board of Directors focus on the most significant risks we face, including major financial, operational, regulatory and cybersecurity risks, and our general risk management strategies. While the Board of Directors oversees our risk management, company management is responsible for day-to-day risk management processes. Our Board of Directors expects company management to consider risk and risk management in each business decision, to proactively develop and monitor risk management strategies and processes for day-to-day activities and to effectively implement risk management strategies adopted by the Audit Committee and the Board of Directors. In addition, the Compensation Committee evaluates and monitors whether any of our compensation policies and practices has the potential to encourage excessive risk-taking or is likely to have a material adverse effect on the Company. We believe this division of responsibilities is the most effective approach for addressing the risks we face and that our Board of Directors leadership structure, which also emphasizes the independence of the Board of Directors in its oversight of our business and affairs, supports this approach.

Meetings of the Board of Directors

The Board of Directors held eight meetings and acted by unanimous written consent without a meeting five times during 2024. Each Board member attended 80% or more of the aggregate number of meetings of the Board of Directors and of the committees on which he or she served, held during the portion of the last fiscal year for which he or she was a director or committee member, respectively.

Information Regarding Committees of the Board of Directors

The Board of Directors has three standing committees: an Audit Committee, a Compensation Committee, and a Nominating and Corporate Governance Committee. The following table provides membership for each of the committees of the Board of Directors:

Name	Audit	Compensation	Nominating and Corporate Governance
David Campbell, Ph.D.			
Ron Barrett, Ph.D.[1]		X [2]	
Vickie Capps[3]	X [2]		
Eric Dobmeier[4]		X	
Sheila Gujrathi, M.D.			
Natasha Hernday[5]			X
Winston Kung	X		
Alana McNulty	X		
Jake Simson, Ph.D.[6]			X [2]

(1) Dr. Barrett served as a member of the Nominating and Corporate Governance Committee in fiscal year 2024.
(2) Committee Chairperson
(3) Financial Expert, as defined by section 407 of the Sarbanes-Oxley Act of 2002
(4) Mr. Dobmeier became a member of the Board of Directors in July 2024 and a member of the Compensation Committee in March 2025.
(5) Ms. Hernday became a member of the Board of Directors in July 2024 and a member of the Nominating and Corporate Governance Committee in March 2025.
(6) Dr. Simson served as a member of the Compensation Committee in fiscal year 2024.

Each of the committees has authority to engage legal counsel or other experts or consultants, as it deems appropriate to carry out its responsibilities. The Board of Directors has determined that each member of each committee meets the applicable Nasdaq rules and regulations regarding “independence” and that each member is free of any relationship that would impair his or her individual exercise of independent judgment with regard to us.

Below is a description of each committee of the Board of Directors.

Audit Committee

The Audit Committee of the Board of Directors was established by the Board of Directors in accordance with Section 3(a)(58)(A) of the Exchange Act, to oversee our corporate accounting and financial reporting processes and audits of our financial statements. For this purpose, the Audit Committee performs several functions which include, among other things:

- evaluating the performance, independence and qualifications of our independent auditors and determining whether to retain our existing independent auditors or engage new independent auditors;
- reviewing and approving the engagement of our independent auditors to perform audit services and any permissible non-audit services;
- monitoring the rotation of partners of our independent auditors on our engagement team as required by law;
- prior to engagement of any independent auditor, and at least annually thereafter, reviewing relationships that may reasonably be thought to bear on their independence, and assessing and otherwise taking the appropriate action to oversee the independence of our independent auditor;

- reviewing our annual and quarterly financial statements and reports, including the disclosures contained under the caption “Management’s Discussion and Analysis of Financial Condition and Results of Operations,” and discussing the statements and reports with our independent auditors and management;
- reviewing, with our independent auditors and management, significant issues that arise regarding accounting principles and financial statement presentation and matters concerning the scope, adequacy and effectiveness of our financial controls;
- reviewing with management and our independent auditors any earnings announcements and other public announcements regarding material developments;
- establishing procedures for the receipt, retention and treatment of complaints received by us regarding financial controls, accounting or auditing matters and other matters;
- preparing the report that the SEC requires in our annual proxy statement;
- reviewing and providing oversight of any related-person transactions in accordance with our related person transaction policy and reviewing and monitoring compliance with legal and regulatory responsibilities, including our code of business conduct and ethics;
- reviewing our major financial, operational, regulatory and cybersecurity risk exposures, including the guidelines and policies to govern the process by which risk assessment and risk management are implemented;
- reviewing on a periodic basis our investment policy; and
- reviewing and evaluating on an annual basis the performance of the Audit Committee and the Audit Committee charter.

The current members of the Audit Committee are Ms. Capps, Ms. McNulty and Mr. Kung, with Ms. Capps serving as the Chair. The Audit Committee met six times during 2024 and acted by unanimous written consent without a meeting five times during 2024. Our Board of Directors has determined that each member of the Audit Committee is an independent director under Rule 5605(c)(2)(A)(i) and (ii) of the Nasdaq listing standards and under Rule 10A-3 under the Exchange Act. Each member of our Audit Committee can read and understand fundamental financial statements in accordance with Nasdaq audit committee requirements. In arriving at this determination, the Board of Directors has examined each Audit Committee member’s scope of experience and the nature of their employment in the corporate finance sector.

Our Board of Directors has determined that Ms. Capps qualifies as an Audit Committee financial expert within the meaning of SEC regulations and meets the financial sophistication requirements of the Nasdaq Listing Rules. In making this determination, our Board of Directors has considered Ms. Capps’ formal education and the nature and scope of her experience with public companies. Both our independent registered public accounting firm and management periodically meet privately with our Audit Committee.

The Audit Committee charter can be found on our website at *www.januxrx.com* in the Corporate Governance section.

Report of the Audit Committee of the Board of Directors

The material in this report is not “soliciting material,” is not deemed “filed” with the SEC, and is not to be incorporated by reference in any filing of the Company under the Securities Act of 1933, as amended (the “Securities Act”) or the Exchange Act, whether made before or after the date hereof and irrespective of any general incorporation language in any such filing.

The Audit Committee has reviewed and discussed the audited financial statements for the fiscal year ended December 31, 2024 with management of the Company. The Audit Committee has discussed with the independent registered public accounting firm the matters required to be discussed by Auditing Standard No. 1301, Communications with Audit Committees, as adopted by the Public Company

Accounting Oversight Board ("PCAOB"). The Audit Committee has also received the written disclosures and the letter from the independent registered public accounting firm required by applicable requirements of the PCAOB regarding the independent registered public accounting firm's communications with the Audit Committee concerning independence, and has discussed with the independent registered public accounting firm the accounting firm's independence. Based on the foregoing, the Audit Committee has recommended to the Board of Directors that the audited financial statements be included in the Company's Annual Report on Form 10-K for the fiscal year ended December 31, 2024.

Audit Committee
Vickie Capps, *Chair*
Winston Kung
Alana McNulty

Compensation Committee

Our Compensation Committee currently consists of Dr. Barrett and Mr. Dobmeier, with Dr. Barrett serving as the Chair. Our Board of Directors has determined that each of the members of our Compensation Committee is a non-employee director, as defined in Rule 16b-3 promulgated under the Exchange Act and satisfies the Nasdaq independence requirements. The Compensation Committee met three times during 2024 and acted by unanimous written consent without a meeting three times during 2024. The Compensation Committee has a charter that is reviewed and updated annually, or as may be warranted from time to time. The functions of the Compensation Committee include, among other things:

- reviewing, modifying and approving (or if it deems appropriate, making recommendations to the full Board of Directors regarding) our overall compensation strategy and policies;
- reviewing and making recommendations to the full Board of Directors regarding the compensation and other terms of employment of our executive officers;
- reviewing and approving (or if it deems it appropriate, making recommendations to the full Board of Directors regarding) performance goals and objectives relevant to the compensation of our executive officers and assessing their performance against these goals and objectives;
- reviewing and approving (or if it deems it appropriate, making recommendations to the full Board of Directors regarding) the equity incentive plans, compensation plans and similar programs advisable for us, as well as modifying, amending or terminating existing plans and programs;
- evaluating risks associated with our compensation policies and practices and assessing whether risks arising from our compensation policies and practices for our employees are reasonably likely to have a material adverse effect on us;
- reviewing and making recommendations to the full Board of Directors regarding the type and amount of compensation to be paid or awarded to our non-employee directors;
- establishing policies with respect to votes by our stockholders to approve executive compensation as required by Section 14A of the Exchange Act and determining our recommendations regarding the frequency of advisory votes on executive compensation, to the extent required by law;
- reviewing and assessing the independence of compensation consultants, legal counsel and other advisors as required by Section 10C of the Exchange Act;
- administering our equity incentive plans;
- establishing policies with respect to equity compensation arrangements;
- reviewing the competitiveness of our executive compensation programs and evaluating the effectiveness of our compensation policy and strategy in achieving expected benefits to us;

- reviewing and making recommendations to the full Board of Directors regarding the terms of any employment agreements, severance arrangements, change in control protections and any other compensatory arrangements for our executive officers;
- reviewing with management and approving our disclosures under the caption “Compensation Discussion and Analysis” in our periodic reports or proxy statements to be filed with the SEC, to the extent such caption is included in any such report or proxy statement;
- preparing the report that the SEC requires in our annual proxy statement; and
- reviewing and assessing on an annual basis the performance of the Compensation Committee and the Compensation Committee charter.

The agenda for each Compensation Committee meeting is usually developed by the Chair of the Compensation Committee, in consultation with the Chief Executive Officer or General Counsel. The Compensation Committee meets regularly in executive session. However, from time to time, various members of management and other employees as well as outside advisors or consultants may be invited by the Compensation Committee to make presentations, to provide financial or other background information or advice or to otherwise participate in Compensation Committee meetings. The Chief Executive Officer may not participate in, or be present during, any deliberations or determinations of the Compensation Committee regarding his compensation or individual performance objectives. The charter of the Compensation Committee grants the Compensation Committee full access to all our books, records, facilities, and personnel. In addition, under the charter, the Compensation Committee has the authority to obtain, at our expense, advice and assistance from internal and external legal, accounting or other advisors and other external resources that the Compensation Committee considers necessary or appropriate in the performance of its duties. The Compensation Committee has direct responsibility for the oversight of the work of any advisers engaged for the purpose of advising the Compensation Committee. In particular, the Compensation Committee has the authority, in its sole discretion, to retain compensation consultants to assist in its evaluation of executive and director compensation, including the authority to approve the consultant’s reasonable fees and other retention terms. Under its charter, the Compensation Committee may select, or receive advice from, a compensation consultant, legal counsel, or other adviser to the Compensation Committee, other than in-house legal counsel and certain other types of advisers, only after taking into consideration six factors, prescribed by the SEC and Nasdaq, that bear upon the adviser’s independence; however, there is no requirement that any adviser be independent.

The Compensation Committee or the Board of Directors upon recommendation from the Compensation Committee, makes the significant adjustments to annual compensation, determines bonus and equity awards, and establishes new performance objectives at one or more meetings held during the first quarter of the year. Generally, the Compensation Committee’s process comprises two related elements: the determination of compensation levels and the establishment of performance objectives for the current year. For executives other than the Chief Executive Officer, the Compensation Committee solicits and considers evaluations and recommendations submitted to the Compensation Committee by the Chief Executive Officer. In the case of the Chief Executive Officer, the evaluation of his performance is conducted by the Board of Directors upon recommendation from the Compensation Committee, which determines any adjustments to his compensation as well as awards to be granted. For all executives, as part of its deliberations, the Compensation Committee may review and consider, as appropriate, materials such as financial reports and projections, operational data, tax and accounting information, tally sheets that set forth the total compensation that may become payable to executives in various hypothetical scenarios, executive and director stock ownership information, company stock performance data, analyses of historical executive compensation levels and current Company-wide compensation levels and recommendations of the Compensation Committee’s compensation consultant, including analyses of executive compensation paid at other companies identified by the consultant.

Our Compensation Committee is authorized to retain the services of one or more executive compensation advisors, as it sees fit, in connection with the establishment of our executive compensation programs and related policies. The Compensation Committee engaged Frederic W. Cook & Co., Inc., or FW Cook, as its independent compensation consultant to provide objective analysis, advice and

recommendations on executive officer pay in connection with the Compensation Committee's decision-making process for 2024. During 2024, FW Cook did not provide services to us other than the services to our Compensation Committee described herein. Our Compensation Committee performs an annual assessment of its compensation consultants' independence to determine whether the consultants are independent. Based on its evaluation, the Compensation Committee has determined that FW Cook is independent and that its work has not raised any conflicts of interest.

Under its charter, the Compensation Committee may form, and delegate authority to, subcommittees as appropriate. In 2021, the Compensation Committee formed a Non-Officer Stock Award Committee, currently composed of Dr. Campbell, to which it delegated authority to grant, without any further action required by the Compensation Committee, stock options and restricted stock units ("RSUs") to employees who are not officers of the Company. The purpose of this delegation of authority is to enhance the flexibility of equity awards administration within the Company and to facilitate the timely grant of equity awards to non-officer employees, particularly new employees, within specified limits approved by the Compensation Committee. In particular, the subcommittee may grant equity awards only within pre-approved guidelines and not to any employee who has a title that is above vice president. Typically, as part of its oversight function, the Compensation Committee will review on a regular basis the list of grants made by the subcommittee. During fiscal year 2024, the subcommittee exercised its authority to grant options to purchase an aggregate of 1,140,791 shares of the Company's common stock and 75,385 RSUs to non-officer employees.

The Compensation Committee charter can be found on our website at *www.januxrx.com* in the Corporate Governance section.

Nominating and Corporate Governance Committee

Our Nominating and Corporate Governance Committee currently consists of Dr. Simson and Ms. Hernday, with Dr. Simson serving as the Chair. Our Board of Directors has determined that each of the members of this committee satisfies the Nasdaq independence requirements. The Nominating and Corporate Governance Committee met three times during 2024 and acted by unanimous written consent without a meeting one time during 2024. The Nominating and Corporate Governance Committee has a charter that is reviewed and updated annually, or as may be warranted from time to time. The functions of this committee include, among other things:

- identifying, reviewing and evaluating candidates to serve on our Board of Directors consistent with criteria approved by our Board of Directors;
- determining the minimum qualifications for service on our Board of Directors;
- evaluating director performance on the Board of Directors and applicable committees of the Board of Directors and determining whether continued service on our Board of Directors is appropriate;
- evaluating, nominating and recommending individuals for membership on our Board of Directors;
- evaluating nominations by stockholders of candidates for election to our Board of Directors;
- considering and assessing the independence of members of our Board of Directors;
- developing a set of corporate governance policies and principles, including a code of business conduct and ethics, periodically reviewing and assessing these policies and principles and their application and recommending to our Board of Directors any changes to such policies and principles;
- considering questions of possible conflicts of interest of directors as such questions arise; and
- reviewing and assessing on an annual basis the performance of the Nominating and Corporate Governance Committee and the Nominating and Corporate Governance Committee charter.

The Nominating and Corporate Governance Committee believes that the candidates for director, both individually and collectively, have the integrity, experience, judgment, commitment (including having sufficient time to devote to us and level of participation), skills, diversity, and expertise appropriate for us. In assessing the directors, both individually and collectively, the Nominating and Corporate Governance Committee considers our current needs and the needs of the Board of Directors, to maintain a balance of knowledge, experience, capability, race, gender, geography, thought, viewpoints, backgrounds, skills, and expertise. However, the Nominating and Corporate Governance Committee retains the right to modify these qualifications from time to time. Candidates for director nominees are reviewed in the context of the current composition of the Board of Directors, our operating requirements, and the long-term interests of stockholders. In conducting this assessment, the Nominating and Corporate Governance Committee typically considers diversity (including with respect to race, gender, geography, thought, viewpoints, and backgrounds), age, skills, and such other factors as it deems appropriate given our current needs and the needs of the Board of Directors, to maintain a balance of knowledge, experience and capability. In the case of incumbent directors whose terms of office are set to expire, the Nominating and Corporate Governance Committee reviews these directors' overall service to us during their terms, including the number of meetings attended, level of participation, quality of performance and any other relationships and transactions that might impair the directors' independence. In the case of new director candidates, the Nominating and Corporate Governance Committee also determines whether the nominee is independent for Nasdaq purposes, which determination is based upon applicable Nasdaq listing standards, applicable SEC rules and regulations, and the advice of counsel, if necessary. The Nominating and Corporate Governance Committee then uses its network of contacts to compile a list of potential candidates, but may also engage, if it deems appropriate, a professional search firm. Any search firm retained to assist the Nominating and Corporate Governance Committee in seeking candidates for the Board of Directors will be instructed to seek to include diverse candidates in terms of race, gender, geography, thought, viewpoints, backgrounds, skills, experience, and expertise from, among other areas, professional and academic areas relevant to the Company's area of focus. In addition, the Nominating and Corporate Governance Committee conducts any appropriate and necessary inquiries into the backgrounds and qualifications of possible candidates after considering the function and needs of the Board of Directors. The Nominating and Corporate Governance Committee meets to discuss and consider the candidates' qualifications and then selects a nominee for recommendation to the Board of Directors by majority vote.

The Nominating and Corporate Governance Committee will consider director candidates recommended by stockholders. The Nominating and Corporate Governance Committee does not intend to alter the way it evaluates candidates, including the minimum criteria set forth above, based on whether or not the candidate was recommended by a stockholder. Stockholders who wish to recommend individuals for consideration by the Nominating and Corporate Governance Committee to become nominees for election to the Board of Directors may do so by delivering a written recommendation to the Nominating and Corporate Governance Committee at the following address: 10955 Vista Sorrento Parkway, Suite 200, San Diego, California 92130, Attn: Corporate Secretary, no later than the 90th day and no earlier than the 120th day prior to the one year anniversary of the preceding year's Annual Meeting. Submissions must include, among other things, (1) the name and address of the stockholder on whose behalf the submission is made; (2) number of our shares that are owned beneficially by such stockholder and the nominee as of the date of the submission; (3) the full name, age, business address and residence address of the proposed candidate; (4) description of the proposed candidate's business experience for at least the previous five years; (5) complete biographical information for the proposed candidate; (6) a description of the proposed candidate's qualifications as a director; and (7) any other information required by our Bylaws. We may require any proposed nominee to furnish such other information as we may reasonably require to determine the eligibility of such proposed nominee to serve as our independent director or that could be material to a reasonable stockholder's understanding of the independence, or lack thereof, of such proposed nominee.

The Nominating and Corporate Governance Committee charter can be found on our website at *www.januxrx.com* in the Corporate Governance section.

Hedging Policy*

As part of our Insider Trading Policy and Code of Business Conduct and Ethics, all employees, including our officers, directors and consultants are prohibited from engaging in short sales, transactions in put or call options, hedging transactions or other inherently speculative transactions with respect to our securities at any time. In addition, no employee, including any officer, director, or consultant may margin, or make any offer to margin, any of our securities, including without limitation, borrowing against such securities, at any time.

* “The disclosure under the caption “Hedging Policy” is not to be incorporated by reference in any filing of the Company under the Securities Act or the Exchange Act, whether made before or after the date hereof and irrespective of any general incorporation language in any such filing.”

PROPOSAL 2

RATIFICATION OF SELECTION OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

The Audit Committee has selected Ernst & Young LLP as our independent registered public accounting firm for the fiscal year ending December 31, 2025 and has further directed that management submit the selection of independent registered public accounting firm for ratification by the stockholders at the Annual Meeting.

Representatives of Ernst & Young LLP are expected to be present at the Annual Meeting. They will have an opportunity to make a statement if they so desire and will be available to respond to appropriate questions.

Neither our Bylaws nor other governing documents or law require stockholder ratification of the selection of Ernst & Young LLP as our independent registered public accounting firm. However, the Audit Committee is submitting the selection of Ernst & Young LLP to the stockholders for ratification as a matter of good corporate practice. If the stockholders fail to ratify the selection, the Audit Committee will reconsider whether to retain that firm. Even if the selection is ratified, the Audit Committee in its discretion may direct the appointment of different independent auditors at any time during the year if they determine that such a change would be in our best interests and the best interests of our stockholders.

The affirmative vote of the holders of a majority of the shares present at the Annual Meeting or represented by proxy and entitled to vote at the Annual Meeting will be required to ratify the selection of Ernst & Young LLP. Abstentions will be counted toward the tabulation of votes on proposals presented to the stockholders and will have the same effect as negative votes. Broker non-votes (if any) are counted towards a quorum but are not counted for any purpose in determining whether this matter has been approved.

THE BOARD OF DIRECTORS RECOMMENDS A VOTE "FOR" PROPOSAL 2.

Principal Accountant Fees and Services

The following table shows the aggregate fees for services provided for the fiscal year ended December 31, 2024 and 2023, by Ernst & Young LLP, our independent registered public accounting firm for those periods. All fees described below were pre-approved by the Audit Committee.

	Year Ended December 31,	
	2024	2023
Audit Fees[1]	$ 1,143,037	$ 551,500
Audit Related Fees	—	—
Tax Fees	—	—
All Other Fees[2]	3,600	3,600
Total Fees	$ 1,146,637	$ 555,100

(1) Audit fees consist of fees billed for professional services by Ernst & Young LLP for audit and quarterly review of our financial statements and review of our registration statements and related issuances of consents, and related services that are normally provided in connection with statutory and regulatory filings or engagements.

(2) All other fees consist of fees paid to Ernst & Young LLP for access to its proprietary accounting research database.

In connection with the audit of each of the 2024 and 2023 financial statements, we entered into engagement agreements with Ernst & Young LLP, which set forth the terms under which Ernst & Young LLP performed audit services for us. Such agreements are subject to alternative dispute resolution procedures.

Pre-Approval Policies and Procedures

The Audit Committee must pre-approve the audit and non-audit services rendered by our independent registered public accounting firm. The Audit Committee has adopted a policy and procedures for the pre-approval of such audit and non-audit services. The policy generally pre-approves specified services in the defined categories of audit services, audit-related services and tax services up to specified amounts. Pre-approval may also be given as part of the Audit Committee's approval of the scope of the engagement of the independent auditor or on an individual, explicit, case-by-case basis before the independent auditor is engaged to provide such service. The pre-approval authority may be delegated to one or more of the Audit Committee's members, but any pre-approval decisions must be reported to the full Audit Committee at its next scheduled meeting. Pursuant to the policy, the Audit Committee has delegated pre-approval authority to its Chair.

The Audit Committee has determined that the rendering of services other than audit services by Ernst & Young LLP is compatible with maintaining the principal accountant's independence.

PROPOSAL 3

ADVISORY VOTE ON THE COMPENSATION OF OUR NAMED EXECUTIVE OFFICERS

In accordance with the requirements of Section 14A of the Exchange Act and the related rules of the SEC, our stockholders are being asked to approve, in an advisory, non-binding vote, the compensation of our named executive officers as disclosed pursuant to Item 402 of Regulation S-K, including the compensation tables and narrative discussion. In considering their vote, we urge stockholders to review the information on our compensation policies and decisions regarding the named executive officers presented in the section below titled "Executive Compensation."

This advisory resolution, commonly referred to as a "say-on-pay" resolution, is non-binding. Although this resolution is non-binding, the Board and the Compensation Committee value the opinions of our stockholders and will review and consider the voting results when making future compensation decisions for our named executive officers. If stockholders approve the "One Year" option as the frequency of future say-on-pay votes under Proposal 3, we expect that we will conduct our next say-on-pay vote at the 2026 annual meeting of stockholders.

We believe that our compensation components provide a reasonable balance of base compensation and long-term equity-based incentive compensation that is closely aligned with the Company's overall performance. The Company aims to provide executive officers with a reasonable level of security through base salary and benefits, while rewarding them through cash and equity-based incentive compensation to achieve business objectives and create stockholder value. We believe that each of our compensation components is integral to attracting, retaining, and rewarding qualified named executive officers.

The text of the resolution in respect of Proposal no. 3 is as follows:

"RESOLVED, that the compensation paid to the Company's named executive officers as disclosed pursuant to Item 402 of Regulation S-K, including the compensation tables and narrative discussion, is hereby approved."

THE BOARD OF DIRECTORS RECOMMENDS A VOTE "FOR" PROPOSAL 3.

PROPOSAL 4

ADVISORY VOTE ON THE FREQUENCY OF FUTURE ADVISORY STOCKHOLDER VOTES TO APPROVE THE COMPENSATION OF OUR NAMED EXECUTIVE OFFICERS

In accordance with the requirements of Section 14A of the Exchange Act and the related rules of the SEC, our stockholders are also entitled to vote, on an advisory basis, on whether the "say-on-pay" vote, as required by Section 14A of the Exchange Act, should occur every one, two, or three years. The vote on the frequency of the say-on-pay vote, just as with the say-on-pay vote itself, is advisory only, and it also is not binding on the Company or on our Board of Directors. Although the vote is non-binding, the Compensation Committee and the Board will carefully consider the outcome of the vote when determining the frequency of future stockholder advisory votes to approve the compensation of our named executive officers.

After careful consideration, the Board has determined that a say-on-pay vote that occurs every year is the most appropriate alternative for our Company at this time. Therefore, the Board recommends that you vote for a "One Year" frequency for the say-on-pay vote.

Although the Board recommends a say-on-pay vote be held every year, you may vote one of four choices for this Proposal 4 on the proxy card: "One Year", "Two Years", "Three Years", or "Abstain." The text of the resolution in respect of Proposal no. 4 is as follows:

"RESOLVED, that the option of once every one year, two years, or three years that receives the affirmative vote of the majority of shares present at the Annual Meeting or represented by proxy and entitled to vote on the matter for this resolution will be determined to be the preferred frequency with which the Company is to hold an advisory stockholder vote to approve the compensation paid to the Company's named executive officers, as disclosed pursuant to Item 402 of Regulation S-K, including the compensation tables and narrative discussion."

The Board and the Compensation Committee value the opinions of the stockholders in this matter and, to the extent there is any significant vote in favor of one frequency over the other options, even if less than a majority, the Board will consider the stockholders' concerns and evaluate any appropriate next steps. However, because this vote is advisory and, therefore, not binding on the Board or the Company, the Board may decide that it is in the best interests of the stockholders that we hold a say-on-pay vote more or less frequently than the option preferred by the stockholders. The vote will not be construed to create or imply any change or addition to the fiduciary duties of the Company or the Board.

THE BOARD OF DIRECTORS RECOMMENDS A VOTE OF "ONE YEAR" ON PROPOSAL 4.

EXECUTIVE OFFICERS

The following table sets forth information regarding our executive officers as of the date of this proxy statement.

Executive Officer	Age	Position(s)
David Campbell, Ph.D.	66	President and Chief Executive Officer
Thomas DiRaimondo, Ph.D.	39	Chief Scientific Officer
Zachariah McIver, D.O., Ph.D.	55	Chief Medical Officer
Andy Meyer	41	Chief Business Officer
Byron Robinson, Ph.D. JD.	60	Chief Strategy Officer
Charles Winter	56	Chief Technical Officer

The following is biographical information for our executive officers other than Dr. Campbell, whose biographical information is included under Proposal 1.

Thomas DiRaimondo, Ph.D. is one of our co-founders and has served as our Chief Scientific Officer since January 2024 and had previously served as our Executive Director, Head of Research and Development from January 2023 through December 2023, Senior Director of Therapeutics Discovery from January 2022 through December 2022, and Director of Research from January 2018 through December 2021. Previously, Dr. DiRaimondo served at Sitari Pharma, Inc., which he co-founded, as Director of Research from January 2020, and Principal Scientist from December 2013. Dr. DiRaimondo received a B.S.E in chemical engineering and M.Eng in pharmaceutical engineering from the University of Michigan, Ann Arbor as well as a M.S. and Ph.D. in chemical engineering from Stanford University.

Zachariah McIver, D.O., Ph.D. has served as our Chief Medical Officer since January 1, 2025 and had previously served as our Vice President, Clinical Development from May 2023 to December 2024. Previously, Dr. McIver served as Executive Medical Director at Amgen from 2018 to April 2023, leading cross-functional teams in the design, implementation, and execution of clinical and correlative study strategies. From 2013 to 2018, Dr. McIver served as an attending physician at Wake Forest in the hematology/oncology department. From 2011 to 2013, Dr. McIver served as an attending physician and a research investigator in the department of hematology/oncology at Tulane University School of Medicine. Dr. McIver received a B.S. in Physics and General Sciences from the University of Oregon, a Medical Doctorate (D.O.) from Ohio University College of Osteopathic Medicine and a Ph.D. in Molecular Medicine and Translational Sciences from Wake Forest University School of Medicine. He completed his internal medicine residency at the Cleveland Clinic, and his clinical fellowship in hematology and oncology at the National Heart, Lung, and Blood Institute at the National Institutes of Health.

Andy Meyer has served as our Chief Business Officer since March 2021. Previously, Mr. Meyer served at Evercore as a Managing Director on the Life Sciences Investment Banking team from March 2019 to March 2021 and as a Vice President on the Life Sciences Investment Banking team from May 2015 to March 2019. Prior to Evercore, Mr. Meyer served at Bank of America Merrill Lynch as a Vice President on the Life Sciences Investment Banking team from December 2014 through April 2015 and as an Associate on the Life Sciences Investment Banking team from July 2011 to December 2014. Mr. Meyer received a B.A. in Finance from Georgetown University and an MBA from the University of Southern California Marshall School of Business.

Byron Robinson, Ph.D., J.D. has served as our Chief Strategy Officer since February 2022. Previously, Dr. Robinson served as Senior Vice President, Global Head of Clinical Development Strategy and Innovation from June 2020 to February 2022 and as Senior Vice President, Global Program Leader (Avelumab) from May 2016 to February 2022 at Merck KGaA (EMD Serono) (“Merck”). Prior to Merck, Dr. Robinson served as Vice President, Senior Global Program Head, Oncology at Bayer from April 2015 to May 2016, and as Senior Director Global Program Head from 2012 to 2015. Prior to Bayer, Dr. Robinson served as Director, R&D Program Management and Strategic Operations; Global Program Manager at Amgen from 2002 to 2012. Dr. Robinson received a B.S. (Hon I) and Ph.D. from the University of New England (Australia) and a J.D. from Santa Barbara College of Law.

Charles Winter has served as our Chief Technical Officer since January 2023 and had previously served as our Senior Vice President of Chemistry, Manufacturing and Controls from March 2021 through December 2022. Previously, Mr. Winter served at AnaptysBio as Vice President of Chemistry, Manufacturing and Controls from August 2020 to March 2021, at Sanofi as Vice President of Chemistry, Manufacturing and Controls from January 2020 to August 2020, at Synthorx (acquired by Sanofi in January 2020) as Vice President of Chemistry, Manufacturing and Controls from June 2018 to January 2020, at Denali Therapeutics as Head of Biologics from November 2016 to June 2018, at JHL Biotech as Vice President of Manufacturing and Technology, running its cGMP contract manufacturing plant, from July 2015 to August 2016, at Gilead as Director of Biologics Development from September 2011 to June 2015 and at Genentech from 1994 to September 2011, most recently as Senior Group Leader and Principal Engineer. Mr. Winter received a B.S. in chemical engineering from the University of Wisconsin-Madison.

EXECUTIVE COMPENSATION

In 2024, the Company was a “smaller reporting company” under Item 10 of Regulation S-K promulgated under the Exchange Act, and the following compensation disclosure is intended to comply with the requirements applicable to smaller reporting companies. Although the rules for smaller reporting companies allow the Company to provide less detail about its executive compensation program, we are committed to providing information necessary to help our investors understand how we compensate, motivate and retain our executive officers. Accordingly, this section includes supplemental narratives that describe our executive compensation program.

Named Executive Officers

This supplemental discussion provides additional context with respect to our 2024 compensation program for the following named executive officers that are required to be included in the Company’s Summary Compensation Table:

- David Campbell, Ph.D., our President and Chief Executive Officer
- Tighe Reardon, our former Chief Financial Officer
- Thomas DiRaimondo, our Chief Scientific Officer; and
- Byron Robinson, Ph.D., J.D., our Chief Strategy Officer.

Compensation Philosophy and Objectives

We believe that a strong executive team is critical to our ability to deliver on our long-term objectives. Our executive compensation program is designed to achieve a variety of goals, including:

- attracting, retaining and motivating exceptional executive talent;
- providing incentives that reward the achievement of performance goals that we believe directly correlate to the enhancement of stockholder value, as well as to facilitate executive retention; and
- align our executives’ interests with those of our stockholders through long-term incentives linked to specific performance

The Compensation Committee evaluates our executive compensation program on a regular basis to ensure that it is consistent with our short-term and long-term goals given the dynamic nature of our

business and the market in which we compete for executive talent. The following table summarizes our executive compensation and related policies and practices:

What We Do	What We Don't Do
• Tie performance bonus opportunities to defined corporate objectives	• Allow hedging or pledging of Company stock
• "Double-trigger" change in control severance payments, requiring both a change in control and an involuntary termination for payout	• Reprice stock options
• Maintain a clawback policy	• Provide excessive perquisites
• Maintain a Compensation Committee comprised entirely of independent directors	• Provide supplemental executive retirement plans
• Retain an independent compensation consultant	• Provide "single-trigger" change in control severance
• Reevaluate and adjust our compensation program annually based on market developments	• Provide contracts guaranteeing excise-tax gross ups

Say-on-Pay Vote on Executive Compensation

In prior years, we qualified as an "emerging growth company" as defined in the Jumpstart Our Business Startups Act of 2012 and were not required to hold a Say-on-Pay vote. At the 2025 Annual Meeting of Stockholders, we will be conducting our first Say-on-Pay vote as described in Proposal 3 of this proxy statement, as well as conducting a non-binding advisory vote on the frequency by which we will conduct a Say-on-Pay vote (the "Say-on-Frequency" vote). Because we value the opinions of our stockholders, the Board and our Compensation Committee will consider the outcome of the Say-on-Pay vote, and the related Say-on-Frequency vote when making compensation decisions for our named executive officers in the future.

Role of the Independent Compensation Consultant

The Compensation Committee has the authority under its charter to engage the services of outside legal counsel, compensation consultants and other advisors. The Compensation Committee engaged FW Cook to serve as its independent compensation consultant to advise the Compensation Committee on matters related to executive and non-management director compensation.

Our Compensation Committee's annual compensation review for 2024 included an analysis of data, comparing the Company's executive and director compensation levels and practices against a peer group pre-commercial biopharmaceuticals companies. FW Cook provided our Compensation Committee with advice, counsel and recommendations with respect to the composition of the peer group and competitive data used for assessing our compensation program. Our Compensation Committee used this and other information provided by FW Cook to reach an independent recommendation regarding compensation to be paid to our Executive Chairman, CEO, directors and other executives. FW Cook also provides written and verbal advice at Compensation Committee meetings and attends executive sessions of the Compensation Committee.

The Compensation Committee reviews compensation for peer group companies and other market data in order to gain a better understanding of current compensation practices for similarly situated companies and to provide a reference point when assessing executive compensation at competitive levels.

The companies in our compensation peer group are selected based on the industry in which they operate, the size of their business and similarities in certain qualitative factors such as geography, stock

performance and business model. These companies are also representative of the types of companies with which we compete for executive talent. The Compensation Committee used the following peer group, developed in consultation with FW Cook in September 2023, to conduct comparative pay analysis of our pay levels and compensation program structures for 2024.

Alaunos Therapeutics, Inc (TCRT)	CytomX Therapeutics, Inc. (CTMX)	Replimune Group, Inc. (REPL)
Arcus BioSciences, Inc. (RCUS)	Inhibrx Biosciences, Inc. (INBX)	Sutro Biopharma, Inc. (STRO)
Arvinas, Inc. (ARVN)	Kura Oncology, Inc. (KURA)	Syndax Pharmaceuticals, Inc. (SNDX)
BioAtla, Inc. (BCAB)	Mersana Therapeutics, Inc. (MRSN)	Xencor, Inc. (XNCR)
Cue Biopharma, Inc. (CUE)	Poseida Therapeutics, Inc. (PSTX)	Zymeworks Inc. (ZYME)

Elements of Executive Officer Compensation

Overview

The compensation packages for the Company's named executive officers have both performance-based and fixed elements. Total target compensation paid to our named executive officers is divided among three principal components:

- Base salary, which is fixed and does not vary based on our financial and other performance;
- Cash incentive compensation, which is paid annually and is variable based on company performance; and
- Equity-based awards, which are variable and the value of which depends on stock price performance

For 2024, our overall mix of executive compensation continued to include a balance of salary, cash incentive, and equity-based compensation.

Annual Base Salary

We believe that a competitive base salary is a necessary element of any compensation program. We set base salary compensation for our executive officers at a level we believe enables us to retain and motivate and, as needed, hire individuals in a competitive environment.

An executive officer's initial base salary is established pursuant to the terms of the executive's employment agreement. Employment agreements for executive officers are negotiated at arms-length and approved by our Compensation Committee, taking into account the individual's qualifications and experience, the strategic importance of the role, market and peer company data, as well as internal pay equity considerations.

Our Compensation Committee reviews base salaries for all of our executive officers on an annual basis, generally in connection with our annual performance review process. However, the compensation of Dr. Campbell is determined and approved by our Board based on recommendations from our Compensation Committee. In determining whether to adjust an executive's base salary, the Compensation Committee considers a number of factors, including individual and company performance during the prior year, historic salary levels and length of time in the role, risk to retention, and internal parity among executive team members. In addition, as noted above, the Compensation Committee also considers competitive market data, including data with respect to base salaries paid to similarly situated executive officers at peer group companies.

In reviewing and adjusting base salaries for 2024, the Compensation Committee considered the factors listed above. The Compensation Committee approved increases to the base salaries of our named executive officers, other than Dr. DiRaimondo and Mr. Reardon, ranging from approximately 3.4% to 10.5%, which the Compensation Committee felt represented the appropriate increase because the executive officer's base salaries fell well below the median levels for such positions at our peers. In connection with Dr. DiRaimondo's promotion to Chief Scientific Officer in January 2024 and based on the recommendations and market data presented to our Compensation Committee by our independent compensation consultant, our Compensation Committee approved an increase to Dr. DiRaimondo's annual base salary from $380,000 to $420,000. Mr. Reardon served as our Acting Chief Financial Officer from our inception in June 2017 until August 2024. As part of his responsibilities as Chief Financial Officer of Avalon Ventures, LLC he provided Chief Financial Officer services to a number of Avalon Ventures portfolio companies including us. Mr. Reardon was not party to an employment or consulting agreement with us and was not entitled to any cash compensation in 2024, including the payment of base salary. The named executive officers' base salaries and increases from each of their 2023 base salaries, if applicable, are reflected in the table below.

Executive Officer	2023 Base Salary ($)	2024 Base Salary ($)	% Change
David Campbell, Ph.D.	625,000	646,000	3.4%
Tighe Reardon	—	—	—
Thomas DiRaimondo, Ph.D.	380,000	420,000	10.5%
Byron Robinson, Ph.D., J.D.	450,000	485,000	7.8%

Annual Cash Incentive Compensation

Consistent with our emphasis on a pay-for-performance incentive compensation program, executive officers are eligible to receive annual cash bonuses based upon company performance during the fiscal year. As with base salaries, the target annual bonus opportunity for each of our executive officers was established initially through arm's-length negotiations at the time each individual was hired. In addition, target bonus opportunities are reviewed annually by the Compensation Committee concurrently with their review of base salaries. In determining the ratio of an executive's base salary and cash bonus opportunity, the Compensation Committee considers the specific role of each executive.

Each of our named executive officers (other than Mr. Reardon) participates in our annual bonus plan and has a target bonus represented as a percentage of base salary, or a target bonus percentage, each of which is set forth below. As noted above, Mr. Reardon was not eligible to participate in our annual bonus plan during 2024.

Executive Officer	2024 Target Bonus as a Percent of Base Salary
David Campbell, Ph.D.	60%
Tighe Reardon	—
Thomas DiRaimondo, Ph.D.[(1)]	40%
Byron Robinson, Ph.D., J.D.	40%

(1) In connection with Dr. DiRaimondo's promotion to Chief Scientific Officer in January 2024 and based on a review of market data and on the recommendations presented to our Compensation Committee by FW Cook, our Compensation Committee approved an increase to Dr. DiRaimondo's target bonus from 35% to 40% effective beginning with calendar year 2024.

The Compensation Committee, in consultation with our Chief Executive Officer, establishes the objectives for the annual bonus plan, the relative weight of each objective, and the respective targets for each objective, considering the Company's growth objectives, internal budget, and publicly disclosed financial guidance. Generally, these objectives are tied to achievement of research, clinical and regulatory milestones related to our drug development programs as well as other general corporate objectives.

The corporate goals established and achieved for 2024 included various research and development and corporate governance activities and objectives primarily related to our drug development programs, including:

- JANX007 (PSMA): Optimize dose and dose frequency that provides a durable response, with developable safety profile;
- JANX008 (EGFR): Exhibit early anti-tumor activity while maintaining a developable safety profile;
- Research and development activities to enable future IND milestones and achieve key collaboration milestones; and
- Appropriately grow the organization, manage the approved budget, and facilitate future success.

The Compensation Committee and the Board review the Company's achievement of the corporate goals in their totality, taking into account the Company's overall performance for the year. The Compensation Committee and the Board determine which corporate goals it believes are essential to building long-term stockholder value and that it will use to assess our annual corporate performance. The 2024 corporate goals aimed to incentivize performance related to achievement of research, clinical and regulatory milestones related to our drug development programs. In setting these goals, the Compensation Committee and the Board balance the consideration of the likelihood of achievement of these corporate goals with the effectiveness of such goals in incentivizing our named executive officers' performance. The relative weightings of the 2024 corporate goals are based upon our assessment of the importance of each goal in creating long-term value for the Company and our stockholders.

In December 2024, the Compensation Committee and the Board reviewed our 2024 performance and determined that we met each of our corporate goals based on our achievements, which resulted in an overall 2024 corporate goal achievement of 125% due to the strong outcome achieved in respect of the goals and facilitating significant growth in Company value. The table below sets forth the payments under the 2024 bonus plan for our named executive officers.

Executive Officer	Target Bonus ($)	Actual Bonus ($)	Actual as % of Target
David Campbell, Ph.D.	387,600	484,500	125%
Tighe Reardon	—	—	—
Thomas DiRaimondo, Ph.D.	168,000	210,000	125%
Byron Robinson, Ph.D., J.D.	194,000	242,500	125%

Equity-Based Compensation

The long-term equity-based compensation grants to our named executive officers directly align their compensation with the goals and financial returns of our stockholders. Because vesting is generally subject to continued service over a period of several years following the date of grant, our equity-based incentives also serve as a retention device for named executive officers and other service providers. We generally provide initial equity-based incentive awards in connection with the commencement of employment of our named executive officers and we award annual refresher equity-based incentive awards, which typically are approved at the end of each year with grant dates to follow early in the beginning of the following year, each of which are subject to vesting over a period of multiple years in order to facilitate retention.

We have historically granted equity compensation in the form of stock options. Our Compensation Committee views stock options as performance-based compensation that are intended to create a direct link between our named executive officers' compensation and our stock price appreciation. Because the executive must pay a cash exercise price equal to the value of the stock on the date the option is granted, the executive will only receive value from the option grant if the value of our stock increases following the option grant date. Consistent with past practice, in January 2024, the Compensation Committee decided

to grant the named executive officers one hundred percent of their 2024 long-term equity incentive compensation in the form of stock options. Based on a review of competitive peer practices of similarly-sized pre-commercial biotechnology companies conducted by FW Cook and equity programs in 2024 and discussion of attraction and retention of the executive team, the Compensation Committee determined and approved, in December 2024, to introduce restricted stock units ("RSUs") into our long-term equity compensation program for our named executive officers. We believe that RSUs are a strong retention vehicle, particularly during periods of stock price volatility, and can allow us to reduce share usage and manage our available equity pool more efficiently. We also believe that if our executives hold unvested awards covering share of our common stock with a value that is significant to them, but which value cannot be immediately realized, they will have an incentive to act to maximize longer-term stockholder value instead of short-term gain. We believe that equity compensation is an integral component of our efforts to attract and retain exceptional executives, senior management and other employees.

The authority to make equity-based awards rests with our Compensation Committee, which is required to approve all equity grants (other than with respect to our Chief Executive Officer, in which case the Compensation Committee makes a recommendation for full Board approval). The Compensation Committee generally considers equity awards in the context of setting overall compensation packages for executives; accordingly, determinations with respect to equity awards are generally made in connection with the hiring or appointment of an executive officer or as part of the annual compensation review process. Options generally vest, 25% on the first anniversary date of the vesting start date and the remainder vest in 36 equal monthly installments thereafter. All options have an exercise price set at the closing market price of our common stock on the grant date. RSUs generally vest, 25% on the first anniversary of the vesting start date and 25% vest on each anniversary thereafter.

In December 2023, as part of its annual review of executive compensation, the Compensation Committee and Board (with respect to our Chief Executive Officer) approved the following option grants to our named executive officers as part of their 2024 compensation package. The grant date for these options was in January 2024.

Executive Officer	Stock Options
David Campbell, Ph.D.	356,500
Tighe Reardon	157,000
Thomas DiRaimondo, Ph.D.	147,000
Byron Robinson, Ph.D., J.D.	151,500

In December 2024, as part of its annual review of executive compensation, the Compensation Committee and Board (with respect to our Chief Executive Officer) approved the following equity awards for our named executive officers as part of their 2025 compensation package.

Executive Officer	RSUs[(1)]	Stock Options[(2)]
David Campbell, Ph.D.	81,000	283,500
Tighe Reardon[(3)]	—	—
Thomas DiRaimondo, Ph.D.	24,000	84,000
Byron Robinson, Ph.D., J.D.	28,000	98,000

(1) RSUs were approved in December 2024 but with an intended grant date of January 2, 2025. However, for purposes of FASB's Accounting Standards Codification 718, Compensation – Stock Compensation ("ASC 718") the grant date is deemed to be in December 2024 (the date of the applicable board approval). So, the RSUs appear in the Summary Compensation Table below as 2024 stock awards.

(2) Stock options were approved in December 2024 but have a grant date in January 2025 and will appear in next year's Summary Compensation Table.

(3) Mr. Reardon's consulting services to the company terminated on December 31, 2024 and as a result he was not awarded any RSUs or stock options.

SUMMARY COMPENSATION TABLE

The following table shows, for the fiscal years ended December 31, 2024 and December 31, 2023, compensation awarded to, paid to, or earned by, the named executive officers.

Executive Officer and Principal Position	Fiscal Year	Salary ($)	Bonus ($)	Option Awards ($)[1]	Stock Awards ($)[2]	Non-Equity Incentive Plan Compensation ($)[3]	All Other Compensation ($)	Total ($)
David Campbell, Ph.D.	2024	646,000	—	2,862,873	4,981,500	484,500	—	8,974,873
President and Chief Executive Officer	2023	625,000	—	3,155,769	—	412,500	—	4,193,269
Tighe Reardon[4]	2024	—	—	7,913,496[5]	—	—	—	7,913,496
Former Acting Chief Financial Officer								
Thomas DiRaimondo, Ph.D.	2024	420,000	—	1,180,484	1,604,160	210,000	—	3,414,644
Chief Scientific Officer								
Byron Robinson, Ph.D., J.D.	2024	485,000	—	1,216,621	1,871,520	242,500	—	3,815,641
Chief Strategy Officer	2023	450,000	75,000[6]	1,017,990	—	198,000	—	1,740,990

(1) In accordance with SEC rules, this column reflects the aggregate grant date fair value of the awards computed in accordance with ASC 718. Assumptions used in the calculation of these amounts are included in Note 4 to our financial statements in our Annual Report on Form 10-K for the year ended December 31, 2024. These amounts do not reflect the actual economic value that will be realized by our named executive officers upon the vesting, exercise, or the sale of the shares of common stock underlying such awards.

(2) The amounts shown in this column represent the aggregate grant date fair value of all time-based RSUs for the years indicated, computed in accordance with ASC 718. Assumptions used in the calculation of these amounts are included in Note 4 to our financial statements in our Annual Report on Form 10-K for the fiscal year ended December 31, 2024. The grant date fair value for time-based RSUs is measured in accordance with ASC 718 and based on the closing price of our common stock on the date of grant. The amounts shown in this column do not necessarily correspond to the actual value recognized or that may be recognized by our named executive officers. For further information regarding such equity awards, please see the “Outstanding Equity Awards at Fiscal Year End” tables and related footnotes below in our CD&A above. The amounts shown in this column relate to RSUs granted on January 2, 2025, but for which the ASC 718 grant date is deemed to be in December 2024 (the date of applicable approval).

(3) The amounts disclosed represent annual performance-based bonuses earned in 2024 and 2023.

(4) Mr. Reardon's service as our Acting Chief Financial Officer ended in August 2024, but he continued service with us as a consultant to the Company through December 31, 2024.

(5) In August 2024, and in connection with the resignation of Mr. Reardon, the Compensation Committee of the Board of Directors approved the following modifications to the terms of Mr. Reardon’s outstanding equity awards as defined within a transition and consulting agreement with Mr. Reardon (the “Transition Agreement”): (a) acceleration of the vesting of unvested stock options such that the number of options that would have vested through June 30, 2026, are vested and

exercisable, with such acceleration deemed effective as of December 31, 2024, subject to service conditions described within the Transition Agreement; and (b) extension of the post-termination exercise period for outstanding options until the earlier of December 31, 2027 or the original expiration date of such options, subject to the Company's ability to take any actions permitted under the Plans, as applicable. Of the amount reported in this column, $6,652,707 represents the increase in grant date fair value to these awards under ASC 718 due to the modifications.

(6) Amount consists of a $75,000 one-time discretionary bonus paid in January 2024 for 2023 services performed.

Other Compensation and Benefits

All of our named executive officers are eligible to participate in our employee benefit plans, including our medical, dental, vision and life plans, in each case on the same basis as all of our other employees. We pay the premiums for the life, disability, accidental death and dismemberment insurance for all of our employees, including our named executive officers. We generally provide limited perquisites or personal benefits to our named executive officers.

Compensation Recovery Policies

As a public company, if we are required to restate our financial results due to our material noncompliance with any financial reporting requirements under the federal securities laws as a result of misconduct, our executive officers may be legally required to reimburse our Company for any bonus or other incentive-based or equity-based compensation they receive in accordance with the provisions of section 304 of the Sarbanes-Oxley Act of 2002, as amended. Additionally, we have implemented a Dodd-Frank Act-compliant clawback policy, as required by SEC rules.

401(k) Plan

We maintain a 401(k) plan that provides eligible U.S. employees with an opportunity to save for retirement on a tax advantaged basis. Eligible employees are able to defer eligible compensation up to certain Code limits, which are updated annually. We have the ability to make matching and discretionary contributions to the 401(k) plan. Currently, we do not make matching contributions or discretionary contributions to the 401(k) plan; however, the 401(k) plan is a "safe harbor" plan under which the Company makes a mandatory annual contribution of up to 3% of eligible employees' compensation. These non-elective contributions, as well as employee elective deferrals, are always 100% vested at all times. The 401(k) plan is intended to be qualified under Section 401(a) of the Internal Revenue Code of 1986, as amended (the "Code"), with the related trust intended to be tax exempt under Section 501(a) of the Code. Contributions to the 401(k) plan are deductible by us when made, and contributions and earnings on those amounts are not generally taxable to the employees until withdrawn or distributed from the 401(k) plan.

Pension Benefits

Other than with respect to tax-qualified defined contribution plans such as our 401(k) plan, our named executive officers did not participate in any plan that provides for retirement payments and benefits, or payments and benefits that will be provided primarily following retirement.

Nonqualified Deferred Compensation

Our named executive officers did not participate in, or earn any benefits under, a non-qualified deferred compensation plan sponsored by us during the fiscal year ended December 31, 2024. The Compensation Committee may elect to adopt qualified or nonqualified defined benefit plans in the future if it determines that doing so is in our best interests.

Outstanding Equity Awards at Fiscal Year End

The following table presents the outstanding equity incentive plan awards held by each named executive officer as of December 31, 2024, including one former executive officer who departed from the Company during the fiscal year.

		Option Awards[1]				Stock Awards[3]	
Executive Officer	Grant Date	Number of Securities Underlying Unexercised Options Exercisable (#)	Number of Securities Underlying Unexercised Options Unexercisable (#)	Option Exercise Price Per Share ($)[2]	Option Expiration Date	Number of Shares or Units of Stock that Have Not Vested (#)[4]	Market Value of Shares or Units of Stock that Have Not Vested($)[5]
David Campbell, Ph.D.	1/16/2020	64,050	—	0.11	1/15/2030		
	9/1/2020	448,350	—	0.59	8/31/2030		
	3/10/2021	704,550[6]	—	4.21	3/9/2031		
	5/14/2021	727,608[7]	—	10.59	5/13/2031		
	1/3/2022	258,307	95,943	20.24	1/2/2032		
	1/3/2023	148,541	161,459	14.02	1/2/2033		
	1/2/2024		356,500[8]	11.02	1/1/2034		
	12/12/2024					81,000[9]	4,336,740
Tighe Reardon	5/14/2021	4,003	20,016[10]	10.59	5/13/2031		
	1/3/2022		31,620[10]	20.24	1/2/2032		
	1/3/2023		41,250[10]	14.02	1/2/2033		
	1/2/2024		94,854[10]	11.02	1/1/2034		
Thomas DiRaimondo, Ph.D.	9/1/2020	153,720	—	0.59	8/31/2030		
	3/10/2021	140,910[11]	—	4.21	3/9/2031		
	5/14/2021	256,200[12]	—	10.59	5/13/2031		
	1/3/2022	17,478	6,492	20.24	1/2/2032		
	1/3/2023	33,541	36,459	14.02	1/2/2033		
	1/2/2024	—	147,000[13]	11.02	1/1/2034		
	12/4/2024					24,000[14]	1,284,960
Byron Robinson, Ph.D., J.D.	3/1/2022	162,916	67,084	16.81	2/29/2032		
	1/3/2023	47,916	52,084	14.02	1/2/2033		
	1/2/2024	—	151,500[15]	11.02	1/1/2034		
	12/4/2024					28,000[16]	1,499,120

(1) Option awards with grant dates prior to June 10, 2021 were granted under the 2017 Equity Incentive Plan (the "2017 Plan"). Option awards with grant dates on or after June 10, 2021 were granted under the 2021 Plan.

(2) All of the option awards listed in the table with a grant date prior to June 10, 2021 were granted with an exercise price per share that is no less than the fair market value of our common stock on the date of grant of such award, as determined in

good faith by our Board of Directors. All of the option awards granted on or after June 10, 2021 are granted with an exercise price per share that is the closing price of our common stock on the date of grant.

(3) All of the outstanding RSU awards were granted under and subject to the terms of the 2021 Plan. Except as otherwise indicated, each RSU award vests as to one-fourth (1/4th) of the total number of shares granted on the first, second, third and fourth anniversaries of the date of grant subject to the executive's continuous service with us through the vesting dates and the potential vesting acceleration described below under "—Potential Payments upon Termination or Change in Control."

(4) The amounts shown in this column relate to RSUs granted on January 2, 2025, but for which the ASC 718 grant date is deemed to be in December 2024 (the date of applicable approval).

(5) Market value is evaluated using our December 31, 2024 closing stock price.

(6) This option is immediately exercisable, but if exercised the underlying shares would be subject to a repurchase right in favor of the company that lapses over a vesting schedule. 44,035 of these options are unvested as of December 31, 2024, one-fourth (1/4th) of the shares vest one year after March 10, 2021; the balance of the shares vest in a series of 36 successive equal monthly installments measured from the first anniversary of March 10, 2021, subject to optionholder's continuous service as of each such vesting date.

(7) This option is immediately exercisable, but if exercised the underlying shares would be subject to a repurchase right in favor of the company that lapses over a vesting schedule. 75,793 of these options are unvested as of December 31, 2024, one-fourth (1/4th) of the shares vest one year after May 14, 2021; the balance of the shares vest in a series of 36 successive equal monthly installments measured from the first anniversary of May 14, 2021, subject to optionholder's continuous service as of each such vesting date.

(8) All of the shares underlying this option are unvested as of December 31, 2024, one-fourth (1/4th) of the shares vest one year after January 2, 2024; the balance of the shares vest in a series of 36 successive equal monthly installments measured from the first anniversary of January 2, 2024, subject to optionholder's continuous service as of each such vesting date.

(9) All of the shares underlying this RSU award are unvested as of December 31, 2024, one-fourth (1/4th) of the shares vest one year after January 2, 2025; the balance of the shares vest in a series of 3 successive equal annual installments measured from the first anniversary of January 2, 2025, subject to optionholder's continuous service as of each such vesting date.

(10) Mr. Reardon's Transition Agreement as described in note five of the above Summary Compensation Table was subject to a seven-day revocation period following the date of signing. As such, the stock options that vested in accordance with the Transition Agreement remained unexercisable at December 31, 2024.

(11) This option is immediately exercisable, but if exercised the underlying shares would be subject to a repurchase right in favor of the company that lapses over a vesting schedule. 8,807 of these options are unvested as of December 31, 2024, one-fourth (1/4th) of the shares vest one year after March 10, 2021; the balance of the shares vest in a series of 36 successive equal monthly installments measured from the first anniversary of March 10, 2021, subject to optionholder's continuous service as of each such vesting date.

(12) This option is immediately exercisable, but if exercised the underlying shares would be subject to a repurchase right in favor of the company that lapses over a vesting schedule. 26,688 of these options are unvested as of December 31, 2024, one-fourth (1/4th) of the shares vest one year after May 14, 2021; the balance of the shares vest in a series of 36 successive equal monthly installments measured from the first anniversary of May 14, 2021, subject to optionholder's continuous service as of each such vesting date.

(13) All of the shares underlying this option are unvested as of December 31, 2024, one-fourth (1/4th) of the shares vest one year after January 2, 2024; the balance of the shares vest in a series of 36 successive equal monthly installments measured from the first anniversary of January 2, 2024, subject to optionholder's continuous service as of each such vesting date.

(14) All of the shares underlying this RSU award are unvested as of December 31, 2024, one-fourth (1/4th) of the shares vest one year after January 2, 2025; the balance of the shares vest in a series of 3 successive equal annual installments measured from the first anniversary of January 2, 2025, subject to the executive's continuous service as of each such vesting date.

(15) All of the shares underlying this option are unvested as of December 31, 2024, one-fourth (1/4th) of the shares vest one year after January 2, 2024; the balance of the shares vest in a series of 36 successive equal monthly installments measured from the first anniversary of January 2, 2024, subject to optionholder's continuous service as of each such vesting date.

(16) All of the shares underlying this RSU award are unvested as of December 31, 2024, one-fourth (1/4th) of the shares vest one year after January 2, 2025; the balance of the shares vest in a series of 3 successive equal annual installments measured from the first anniversary of January 2, 2025, subject to optionholder's continuous service as of each such vesting date.

Options held by our named executive officers are eligible for accelerated vesting under specified circumstances. Please see the subsection titled "—Potential Payments Upon Termination or Change in Control" below for a description of such potential acceleration.

Employment, Severance and Change in Control Agreements

Employment Agreements with Named Executive Officers

Below are descriptions of our employment agreements with our named executive officers. The employment of each of our named executive officers is at-will. For a description of the severance pay and other benefits to be provided in connection with a termination of employment and/or change in control, please see "Potential Payments Upon Termination or Change in control" below.

David Campbell, Ph.D. In January 2021 we entered into an employment agreement with Dr. Campbell, our President and Chief Executive Officer, that governs the current terms of his employment with us. Pursuant to this agreement, Dr. Campbell was initially entitled to an annual base salary of $424,408, which was most recently increased to $680,000 effective January 2025, and was initially eligible to receive an annual discretionary bonus with a target amount of 40% of his then current base salary, which was most recently increased to 60% effective January 2023, based upon the achievement of certain corporate and/or individual objectives and milestones that are determined in the sole discretion of the Board of Directors. Dr. Campbell's employment agreement also provides for severance benefits upon an involuntary termination; however, the severance terms in his employment agreement were superseded by the Change in Control and Severance Benefit Plan as described below.

Thomas DiRaimondo, Ph.D. In January 2021 we entered into an employment agreement with Dr. DiRaimondo, our Chief Scientific Officer, that governs the current terms of his employment with us. Pursuant to this agreement, Dr. DiRaimondo was initially entitled to an annual base salary of $172,414, which was most recently increased to $478,000 effective January 2025, and was initially eligible to receive an annual discretionary bonus with a target amount of 20% of his then current base salary, which was most recently increased to 40% effective January 2024, based upon the achievement of certain corporate and/or individual objectives and milestones that are determined in the sole discretion of the Board of Directors or the Compensation Committee thereof.

Byron Robinson, Ph.D., J.D. In January 2022 we entered into an employment agreement with Dr. Robinson, our Chief Strategy Officer, that governs the current terms of his employment with us. Pursuant to this agreement, Dr. Robinson was initially entitled to an annual base salary of $420,000, which was most recently increased to $504,000 effective January 2025, and is eligible to receive an annual discretionary bonus with a target amount of 40% of his then current base salary, based upon the achievement of certain corporate and/or individual objectives and milestones that are determined in the sole discretion of the Board of Directors or the Compensation Committee thereof. Dr. Robinson's employment agreement also provides for a one-time sign-on bonus of $100,000, which was subject to a prorated right of repayment in favor of the Company in the event Dr. Robinson resigned or was terminated for cause prior to the one-year anniversary of his February 2022 start date. In addition, the employment agreement provides for an initial option grant to purchase 230,000 shares of Company common stock. Dr. Robinson's employment agreement also provides that he is designated as a participant in the Change in Control and Severance Benefit Plan, as described below.

Transition and Consulting Agreement with Former Named Executive Officer

In August 2024, we entered into a transition and consulting agreement with Mr. Reardon, our former Acting Chief Financial Officer (the "Transition Agreement"). Pursuant to the Transition Agreement, Mr. Reardon received (i) continued vesting of his equity awards through December 31, 2024, and (ii) subject to satisfaction of certain conditions specified in the Transition Agreement, accelerated vesting of his unvested equity awards that would have vested through June 30, 2026 and an extension of the post-service exercise period for such equity awards until the earliest of December 31, 2027 and the original expiration date of the equity awards. Mr. Reardon is not entitled to receive any benefits under the Change in Control and Severance Benefit Plan, as described below.

Potential Payments Upon Termination or Change in Control

Regardless of the manner in which a named executive officer's service terminates, each named executive officer, other than Mr. Reardon, is entitled to receive amounts earned during their term of service, including unpaid salary and unused paid time off, as applicable. In addition, each (other than Mr.

Reardon) is entitled to certain severance benefits under the Change in Control and Severance Benefit Plan, as described below.

The following table sets forth information regarding potential payments that would have been made to our named executive officers, other than Mr. Reardon, on various termination or change in control events assuming such events occurred as of December 31, 2024, the last trading day of 2024.

	Involuntary Termination Without Cause or Resignation for Good Reason Not in Connection with a Change in Control					Involuntary Termination Without Cause or Resignation for Good Reason in Connection with a Change in Control				
Executive Officer	Salary Severance ($)	Bonus Severance ($)	Value of Continued Health Coverage ($)	Value of Accelerated Vesting ($)	Total	Salary Severance ($)	Bonus Severance ($)	Value of Continued Health Coverage ($)	Value of Accelerated Vesting ($)	Total
David Campbell, Ph.D.	646,000	—	30,705	—	676,705	1,292,000	1,162,800	61,410	34,498,829	37,015,039
Thomas DiRaimondo, Ph.D.	315,000	—	19,032	—	334,032	630,000	420,000	38,064	10,773,267	11,861,331
Byron Robinson, Ph.D., J.D.	363,750	—	39,699	—	403,449	727,500	485,000	79,397	12,463,255	13,755,152

Change in Control and Severance Benefit Plan

Each of our named executive officers, other than Mr. Reardon, is eligible to receive benefits under the terms of our Change in Control and Severance Benefit Plan (the “Severance Plan”) which was adopted by our Board of Directors in May 2021. The Severance Plan provides for severance and/or change in control benefits to the named executive officers upon a “change in control termination” or a “regular termination” (each as described below).

Upon an involuntary termination, each of our named executive officers is entitled to continued payment for a period of time of their then-current base salary (12 months for Dr. Campbell and nine months for each of Dr. DiRaimondo and Dr. Robinson) and payment of continued group health plan coverage (COBRA) premiums for a period of time (12 months for Dr. Campbell and nine months for each of Dr. DiRaimondo and Dr. Robinson). Upon a change in control termination, each of our named executive officers is entitled to (a) a lump sum payment equal to a portion of his base salary (24 months for Dr. Campbell and 18 months for each of Dr. DiRaimondo and Dr. Robinson), (b) a lump sum payment equal to a percentage his target cash bonus (200% for Dr. Campbell and 150% for each of Dr. DiRaimondo and Dr. Robinson), (c) a lump sum payment equal to a prorated portion of their target cash bonus (prorated based on their date of termination), (d) accelerated vesting of all outstanding equity awards, and (e) payment of COBRA premiums for up to 18 months, and for Dr. Campbell an additional lump sum cash payment equal to the monthly amount of his COBRA premiums for six months. All severance benefits under the Severance Plan are subject to the executive’s execution of an effective release of claims against the Company.

For purposes of the Severance Plan, an “involuntary termination” is a termination by the Company other than for cause (and not as a result of death or disability) or a resignation by the executive for good reason (each, as defined in the Severance Plan) that does not occur during the period of time beginning three months prior to, and ending 12 months following, a “change in control” (as defined in the 2021 Plan), or the “change in control period.” A “change in control termination” is an involuntary termination that occurs during the change in control period.

In addition, if any of the payments or benefits provided for under the Severance Plan or otherwise payable to a named executive officer would constitute "parachute payments" within the meaning of Section 280G of the Code and could be subject to the related excise tax, the named executive officer will receive either full payment of such payments and benefits or such lesser amount that would result in no portion of the payments and benefits being subject to the excise tax, whichever results in the greater amount of after-tax benefits to them.

Pay Versus Performance

The disclosure included in this section is prescribed by SEC rules and does not necessarily align with how the Company or the Compensation Committee view the link between the Company's performance and named executive officer ("NEO") pay. This disclosure is intended to comply with the requirements of Item 402(v) of Regulation S-K applicable to "smaller reporting companies." For further information regarding our compensation philosophy and how we seek to align executive compensation with the Company's performance, refer to "Executive Compensation."

Required Tabular Disclosure of Pay Versus Performance

The amounts set forth below under the headings "Compensation Actually Paid to PEO" and "Average Compensation Actually Paid for NEOs" have been calculated in a manner consistent with Item 402(v) of Regulation S-K. Use of the term "compensation actually paid" ("CAP") is required by the SEC's rules and as a result of the calculation methodology required by the SEC, such amounts differ from compensation actually received by the individuals and the compensation decisions described in the "*Executive* Compens*ation*" section above.

Fiscal Year	Summary Compensation Table Total for PEO ($)[1][2]	Compensation Actually Paid to PEO ($)[1][3]	Average Summary Compensation Table Total for non-PEO NEOs ($)[1][2]	Average Compensation Actually Paid to non-PEO NEOs ($)[1][3]	Value of Initial Fixed $100 Investment Based on: Total Shareholder Return ($)[4]	Net Income ($M)[5]
2024	8,974,873	55,192,709	5,047,927	16,865,449	406.53	(68.99)
2023	4,193,269	1,052,606	1,674,690	1,099,998	81.47	(58.29)

(1) The following individuals are our PEO and other non-PEO NEOs for each fiscal year:

Year	PEO	Non-PEO NEOs
2024	David Campbell, Ph.D.	Tighe Reardon, Thomas DiRaimondo, Byron Robinson Ph.D., J.D.
2023	David Campbell, Ph.D.	Byron Robinson, Ph.D., J.D., Charles Winter

(2) Represents the amount of total compensation reported for Dr. Campbell (our Chief Executive Officer) and the average total compensation for our non-PEO NEOs for each corresponding year in the "Total" column of the Summary Compensation Table. Refer to "Executive Compensation—Summary Compensation Table."

(3) Represents the amount of CAP to Dr. Campbell and the average amount of CAP to our Non-PEO NEOs, respectively, as computed in accordance with Item 402(v) of Regulation S-K. The dollar amounts do not reflect the actual amount of compensation earned by or paid to our NEOs during the applicable year. In accordance with the requirements of Item 402(v) of Regulation S-K, the following adjustments were made to the reported total compensation for each year to determine the CAP:

	PEO 2024 ($)	Average of Non-PEO NEOs 2024 ($)	PEO 2023 ($)	Average of Non-PEO NEOs 2023 ($)
Summary Compensation Table (SCT) Total	8,974,873	5,047,927	4,193,269	1,674,690
Deduct: Grant Date Fair Value of "Stock Awards" and "Option Awards" columns in the SCT for Applicable Year*	7,844,373	2,377,858	3,155,769	1,017,990
Add: Fair Value at Applicable FY End of Awards Granted during Applicable FY that Remain Unvested as of Applicable FY End*	21,848,627	5,815,636	2,188,604	706,001
Add: Change in Fair Value from the end of the Prior FY to the end of the Applicable FY of Awards Granted during Prior FY that were Outstanding and Unvested as of Applicable FY End*	15,325,254	2,671,871	(1,828,521)	(282,675)
Add: Change in Fair Value from the end of the Prior FY to the Vesting Date of Awards Granted during Prior FY that Vested During Applicable FY*	16,888,329	4,300,997	(344,978)	19,971
Add: Vesting Date Fair Value of Awards that were Granted and Vested During Applicable FY*	—	1,444,628	—	—
Deduct: Fair Value at Prior Year End of Awards Granted during Prior FY that were Forfeited during Applicable FY*	—	37,752	—	—
CAP	55,192,709**	16,865,449	1,052,606**	1,099,998**

**The fair values of stock options vested during the fiscal year or outstanding as of fiscal year end were estimated using the Black-Scholes option pricing model with the following assumptions, which may be materially different from the assumptions used for estimating the grant-date fair value as reported in the "Option Awards" columns in the Summary Compensation Table:

Expected term (in years)	1.82 – 7.67
Expected volatility	79.4 – 118.4%
Risk-free interest rate	3.36 – 4.86
Expected dividend rate	—

**Totals are rounded

(4) For the relevant fiscal year, represents the cumulative TSR of our common stock and the Nasdaq Biotechnology Index at the end of each fiscal year. In each case, assume an initial investment of $100 on December 31, 2022.

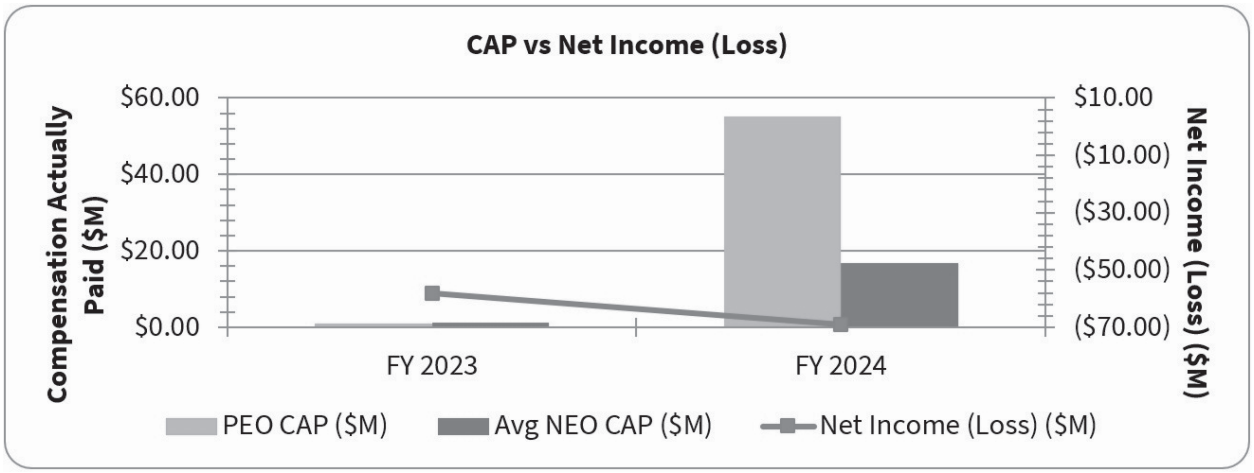
(5) The dollar amounts reported represent the amount of net loss reflected in the Company's audited financial statements for the applicable year.

Required Disclosure of the Relationship Between CAP and Financial Performance Measures

As required by Item 402(v) of Regulation S-K, we are providing the following graphs to illustrate the relationship between the pay and performance figures that are included in the pay versus performance tabular disclosure above. As noted above, CAP for purposes of the tabular disclosure and the following graphs was calculated in accordance with SEC rules and does not reflect the amount of compensation earned by or actually paid to our NEOs during the applicable years.

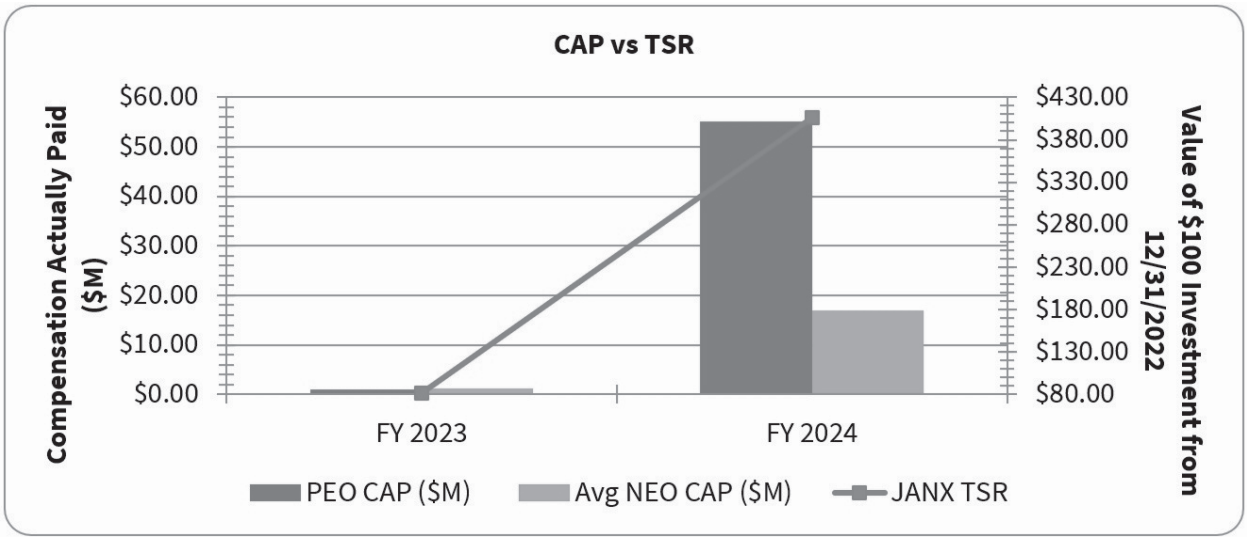
CAP and Net Income (Loss)

The chart below shows the relationship between the compensation actually paid to our PEO and the average compensation actually paid to our non-PEO NEOs, on the one hand, to the Company's Net Income (Loss) over the two years presented in the table, on the other.



CAP and Cumulative TSR

The chart below shows the relationship between the CAP to our PEO and the average CAP to our non-PEO NEOs, on the one hand, to the Company's cumulative TSR over the two years presented in the table, on the other.



All information provided above under the "Pay Versus Performance" heading will not be deemed to be incorporated by reference into any filing of the Company under the Securities Act of 1933, as amended, or

the Securities Exchange Act of 1934, as amended, whether made before or after the date hereof and irrespective of any general incorporation language in any such filing, except to the extent the Company specifically incorporates such information by reference.

Equity Compensation Plan Information

The following table provides certain information as of December 31, 2024, with respect to all of our equity compensation plans in effect on that date.

Plan Category:	Number of securities to be issued upon exercise of outstanding options, warrants and rights (a)	Weighted-average exercise price of outstanding options, warrants and rights ($) (b)	Number of securities remaining available for future issuance under equity compensation plans (excluding securities reflected in column (a)) (c)
Equity compensation plans approved by security holders			
2017 Equity Incentive Plan[1]	3,479,038	6.50	—
2021 Equity Incentive Plan[2]	5,394,033	16.87	5,473,507[3]
2021 Employee Stock Purchase Plan[4]	—	—	1,506,316
Total equity compensation plans approved by security holders	**8,873,071**	12.81	**6,979,823**
Equity compensation plans not approved by security holders[5]	—	—	—

(1) Upon adoption of our 2021 Plan, we restricted future grants from our 2017 Plan. Shares of our common stock reserved for issuance under the 2017 Plan that are repurchased, forfeited, expired, or cancelled increase the number of shares of our common stock reserved for issuance under the 2021 Plan.

(2) Under the terms of our 2021 Plan, the number of shares of our common stock reserved for issuance will automatically increase on January 1 of each calendar year, beginning on January 1, 2022 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.

(3) This amount reflects shares remaining available for issuance under the 2021 Equity Incentive Plan in the form of incentive stock options, non-statutory stock options and restricted stock unit awards.

(4) Under the terms of our ESPP, the number of shares of our common stock reserved for issuance will automatically increase on January 1 of each calendar year, beginning on January 1, 2022 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).

(5) As of December 31, 2024, we did not have any equity compensation plans that were not approved by our stockholders.

DIRECTOR COMPENSATION

The following table summarizes the compensation earned by or paid to each of the non-employee directors for the fiscal year ended December 31, 2024:

DIRECTOR COMPENSATION FOR FISCAL YEAR 2024

Name	Fees Earned or Paid in Cash ($)	Options Awards ($)[1][2]	Stock Awards ($)[1][3]	Total ($)
Ron Barrett, Ph.D.	72,038	244,532	99,500	416,070
Vickie Capps	55,000	244,532	99,500	399,032
Eric Dobmeier[4]	18,043	700,962	278,401	997,406
Sheila Gujrathi, M.D.	40,000	244,532	99,500	384,032
Natasha Hernday[4]	18,043	700,962	278,401	997,406
Winston Kung	47,500	244,532	99,500	391,532
Jay Lichter, Ph.D.[5]	41,372	244,532	99,500	385,404
Alana McNulty	47,500	244,532	99,500	391,532
Jake Simson, Ph.D.	54,500	244,532	99,500	398,532

(1) Amounts listed in the “Option Awards” and “Stock Awards” columns represent the aggregate grant date fair value amount computed as of the grant date of each option award or stock award granted in 2024 in accordance with ASC 718. Assumptions used in the calculation of these amounts are included in Note 4 to our financial statements in our Annual Report on Form 10-K for the year ended December 31, 2024. As required by SEC rules, the amounts shown exclude the impact of estimated forfeitures related to service-based vesting conditions. Our directors will only realize compensation to the extent the trading price of our common stock is greater than the exercise price of such stock awards or the sale of the common stock underlying such option awards or stock awards.

(2) The aggregate number of shares subject to outstanding stock options held as of December 31, 2024 by the non-employee directors who are listed in the table above, which includes grants made to the non-employee directors in 2024 and prior calendar years, are as follows: 63,350 shares subject to outstanding stock options for Dr. Barrett; 65,375 shares subject to outstanding stock options for Ms. Capps; 20,811 shares subject to outstanding stock options for Mr. Dobmeier; 90,995 shares subject to outstanding stock options for Dr. Gujrathi; 20,811 shares subject to outstanding stock options for Ms. Hernday; 60,225 shares subject to outstanding stock options for Mr. Kung; no shares subject to outstanding stock options for Dr. Lichter; 63,350 shares subject to outstanding stock options for Ms. McNulty and 63,350 shares subject to outstanding stock options for Dr. Simson.

(3) The aggregate number of RSUs held as of December 31, 2024 by the non-employee directors who are listed in the table above, which includes grants made to the non-employee directors in 2024, are as follows: 2,500 shares subject to outstanding stock awards for Dr. Barrett; 2,500 shares subject to outstanding stock awards for Ms. Capps; 6,231 shares subject to outstanding stock awards for Mr. Dobmeier; 2,500 shares subject to outstanding stock awards for Dr. Gujrathi; 6,231 shares subject to outstanding stock awards for Ms. Hernday; 2,500 shares subject to outstanding stock awards for Mr. Kung; no shares subject to outstanding stock awards for Dr. Lichter; 2,500 shares subject to outstanding stock awards for Ms. McNulty; and 2,500 shares subject to outstanding stock awards for Dr. Simson.

(4) Mr. Dobmeier and Ms. Hernday each joined our Board of Directors in July 2024. Amounts listed in the “Option Awards” and “Stock Awards” columns include both initial grants and prorated annual grants.

(5) Dr. Lichter resigned from our Board of Directors in July 2024. Following Dr. Lichter's resignation as a non-employee director, the Board of Directors approved the following modifications to the terms of Dr. Lichter's outstanding equity awards: (i) acceleration of the vesting in full of the stock options and RSUs granted to Dr. Lichter in 2024, and (ii) extension of the post-termination exercise period for all outstanding stock options granted to Dr. Lichter until the earlier of the third anniversary of Dr. Lichter’s resignation or the original expiration date of such options. As a result of such modifications, the grant date fair value of these equity awards computed under ASC 718 are as follows: $252,240 for stock options granted in 2021; $56,208 for stock options granted in 2022; $74,881 for stock options granted in 2023; $254,632 for stock options granted in 2024; and $110,610 for RSUs granted in 2024.

In June 2024, we granted stock options to purchase shares of our common stock to all of our then serving non-employee directors, at an exercise price of $39.80 per share, consisting of 8,350 shares to each such director. These stock options will vest in 12 equal monthly installments, subject to each such

director's continued service through each vesting date. These stock options were granted as the annual option grant provided for in our Non-Employee Director Compensation Policy, as described below.

In June 2024, we granted RSUs to all of our then serving non-employee directors, consisting of 2,500 RSUs to each such director. These RSUs will vest on the earlier of the first anniversary of the date of grant or our next annual stockholders meeting, subject to each such director's continued service through such vesting date. These RSUs were granted as the annual RSU awards provided for in our Non-Employee Director Compensation Policy, as described below.

In July 2024, in connection with the appointment of Mr. Dobmeier and Ms. Hernday to our Board of Directors, we granted each such new director the following equity awards: (i) a stock option to purchase 16,700 shares of our common stock, at an exercise price of $44.68 per share, which will vest in 36 equal monthly installments; (ii) RSUs covering 5,000 shares of our common stock, which will vest in three equal annual installments; (iii) a stock option to purchase 4,111 shares of our common stock, at an exercise price of $44.68 per share, which will vest in 12 equal monthly installments; and (iv) RSUs covering 1,231 shares of our common stock, which will vest on the first anniversary of the date of grant. The vesting of each of these equity awards is subject to the director's continued service through the applicable vesting dates. The awards described in (i) and (ii) above were granted as the initial grants and the awards described in (iii) and (iv) were granted as the prorated annual grants provided for in our Non-Employee Director Compensation Policy, as described below.

Our Board of Directors adopted a Non-Employee Director Compensation Policy in June 2021 that became effective June 10, 2021 and is applicable to all of our non-employee directors. Following review of a comprehensive assessment of our non-employee director compensation program prepared by FW Cook, and a recommendation by the Compensation Committee of our Board of Directors, the Non-Employee Director Compensation Policy was most recently amended and restated in March 2025, with changes effective April 1, 2025. The Non-Employee Director Compensation Policy, as in effect during 2024, provided that each such non-employee director is entitled to receive the following compensation for service on our Board of Directors for 2024:

- an annual cash retainer of $40,000 ($45,000 beginning in 2025);
- an additional annual cash retainer of $35,000 for service as Chair of the Board of Directors;
- an additional annual cash retainer of $7,500 ($10,000 beginning in 2025), $6,000 ($7,500 beginning in 2025) and $4,250 ($5,000 beginning in 2025) for service as a member of the Audit Committee, Compensation Committee and the Nominating and Corporate Governance Committee, respectively (not applicable to committee chairs);
- an additional annual cash retainer of $15,000 ($20,000 beginning in 2025), $12,000 ($15,000 beginning in 2025) and $8,500 ($10,000 beginning in 2025) for service as Chair of the Audit Committee, Compensation Committee and the Nominating and Corporate Governance Committee, respectively;
- an initial option grant to purchase 16,700 (23,334 beginning in 2025) shares of our common stock on the date of each such non-employee director's appointment to our Board of Directors, with the shares vesting in 36 equal monthly installments, subject to continued service as a director through each vesting date;
- an initial RSU award covering 5,000 (7,500 beginning in 2025) shares of our common stock on the date of each such non-employee director's appointment to our Board of Directors, with the shares vesting in three equal annual installments, subject to continued service as a director through each vesting date;
- an annual option grant to purchase 8,350 (11,667 beginning in 2025) shares of our common stock on the date of each of our annual stockholder meetings, with the shares vesting in 12 equal monthly installments or if earlier, fully vested as of the next annual stockholders meeting, subject to continued service as a director though each vesting date. In addition to the initial option grant described above, in the event a director is appointed prior to an annual stockholder meeting, such director will receive a prorated annual option grant; and
- an annual RSU award covering 2,500 (3,750 beginning in 2025) shares of our common stock on the date of each of our annual stockholder meetings, with the shares vesting on the earlier of the first anniversary

of the date of grant or if earlier, fully vested as of the next annual stockholders meeting, subject to continued service as a director though the applicable vesting date. In addition to the initial RSU grant described above, in the event a director is appointed prior to an annual stockholder meeting, such director will receive a prorated annual RSU grant.

Each non-employee director may elect to defer the delivery of shares in settlement of any RSU award granted under the Non-Employee Director Compensation Policy that would otherwise be delivered to such non-employee director on or following the date such award vests pursuant to the terms of a deferral election such non-employee director makes in accordance with the non-employee director compensation policy. In addition, in the event the aggregate grant date fair value of (i) the initial option grant and initial RSU grant, computed under ASC 718, would have a value in excess of $900,000, such initial equity awards will be reduced on a pro rata basis until such value is equal to $900,000 and (ii) the annual option grant (or prorated annual option grant, as applicable) and the annual RSU grant (or prorated annual RSU grant, as applicable), computed under ASC 718, would have a value in excess of $450,000, such annual equity awards (or prorated annual equity awards, as applicable), will be reduced on a pro rata basis until such value is equal to $450,000.

Each of the options granted under the Non-Employee Director Compensation Policy will be granted under our 2021 Plan. Each option and RSU awarded to directors under the Non-Employee Director Compensation Policy will be subject to accelerated vesting upon a “change in control” (as defined in the 2021 Plan). The term of each option will be ten years, subject to earlier termination as provided in the 2021 Plan.

We have reimbursed and will continue to reimburse all of our non-employee directors for their reasonable out-of-pocket expenses incurred in attending Board of Directors and committee meetings. Director’s fees are prorated to the date the director is appointed or elected.

Limitation of Liability and Indemnification

Our amended and restated certificate of incorporation and our Bylaws limit our directors’ liability, and may indemnify our directors and officers to the fullest extent permitted under Delaware General Corporation Law ("DGCL"). The DGCL provides that directors of a corporation will not be personally liable for monetary damages for breach of their fiduciary duties as directors, except for liability for any:

- transaction from which the director derives an improper personal benefit;
- act or omission not in good faith or that involves intentional misconduct or a knowing violation of law;
- unlawful payment of dividends or redemption of shares; or
- breach of a director’s duty of loyalty to the corporation or its stockholders.

These limitations of liability do not apply to liabilities arising under federal securities laws and do not affect the availability of equitable remedies such as injunctive relief or recession.

The DGCL and our Bylaws provide that we will, in certain situations, indemnify our directors and officers and may indemnify other employees and other agents, to the fullest extent permitted by law. Any indemnified person is also entitled, subject to certain limitations, to advancement, direct payment or reimbursement of reasonable expenses (including attorneys’ fees and disbursements) in advance of the final disposition of the proceeding.

In addition, we have entered, and intend to continue to enter, into separate indemnification agreements with some of our directors and officers. These indemnification agreements, among other things, require us to indemnify our directors and officers for certain expenses, including attorneys’ fees, judgments, fines and settlement amounts incurred by a director or officer in any action or proceeding arising out of their services as a director or officer, or any other company or enterprise to which the person provides services at our request.

We maintain a directors' and officers' insurance policy pursuant to which our directors and officers are insured against liability for actions taken in their capacities as directors and officers. We believe that these provisions in our amended and restated certificate of incorporation and Bylaws and these indemnification agreements are necessary to attract and retain qualified persons as directors and officers.

Insofar as indemnification for liabilities arising under the Securities Act, may be permitted to directors, officers or control persons, in the opinion of the SEC, such indemnification is against public policy, as expressed in the Securities Act and is therefore unenforceable.

SECURITY OWNERSHIP OF CERTAIN BENEFICIAL OWNERS AND MANAGEMENT

The following table sets forth certain information regarding the ownership of our common stock as of February 15, 2025, by: (i) each of our directors; (ii) each of our named executive officers in the Summary Compensation Table; (iii) all of our executive officers and directors as a group; and (iv) all those known by us to be beneficial owners of more than 5% of our common stock.

The following table is based upon information supplied by officers, directors and principal stockholders and Schedules 13D or 13G filed with the SEC. Unless otherwise indicated in the footnotes to this table and subject to community property laws where applicable, we believe that each of the stockholders named in this table has sole voting and investment power with respect to the shares indicated as beneficially owned. Applicable percentages are based on 59,096,764 shares outstanding on February 15, 2025, adjusted as required by rules promulgated by the SEC. Unless otherwise indicated, the address for the following stockholders is c/o Janux Therapeutics, Inc., 10955 Vista Sorrento Parkway, Suite 200, San Diego, California 92130.

Name of Beneficial Owner	Number of Shares Beneficially Owned (#)	Percentage of Shares Beneficially Owned (%)
5% Stockholders:		
Entities affiliated with RA Capital Healthcare Fund, L.P.[1]	12,175,165	19.99%
FMR LLC[2]	7,824,674	13.2%
Entities affiliated with Janus Henderson Group plc[3]	3,562,402	6.0%
Entities affiliated with Paradigm BioCapital Advisors GP LLC[4]	3,515,986	5.9%
Entities affiliated with Adage Capital Management, L.P.[5]	3,061,750	5.2%
Bregua Corporation[6]	2,999,990	5.1%
Named Executive Officers and Directors:		
David Campbell, Ph.D.[7]	2,730,221	4.4%
Tighe Reardon[8]	191,743	*
Thomas DiRaimondo, Ph.D.[9]	761,336	1.3%
Byron Robinson, Ph.D. JD.[10]	280,884	*
Ron Barrett, Ph.D.[11]	61,262	*
Vickie Capps[12]	131,135	*
Eric Dobmeier[13]	6,451	*
Sheila Gujrathi, M.D.[14]	201,546	*
Natasha Hernday[15]	6,451	*
Winston Kung[16]	53,137	*
Alana McNulty[17]	61,262	*
Jake Simson, Ph.D.[18]	61,262	*
All current executive officers and directors as a group (14 persons)[19]	5,174,193	8.1%

* Represents beneficial ownership of less than 1%.

Beneficial ownership is determined in accordance with SEC rules, and includes any shares to which the stockholder has sole or shares voting power or investment power, and also any shares which the stockholder has the right to acquire within 60 days of February 15, 2025, whether through the exercise or conversion of any stock option, convertible security, warrant or other right. The indication herein that shares are beneficially owned is not an admission on the part of the stockholder that he, she or it is a direct or indirect beneficial owner of those shares.

(1) Based solely on a Schedule 13D/A jointly filed on October 22, 2024 by RA Capital Management, L.P. (RA Capital), Peter Kolchinsky, Rajeev Shah, and RA Capital Healthcare Fund, L.P. (the Fund), other than with respect to the shares held by Dr. Simson. Consists of (i) 9,317,246 shares of common stock held by the Fund, (ii) pre-funded warrants exercisable for up to 503,226 shares of common stock held by the Fund (the 2023 Pre-Funded Warrants), (iii) pre-funded warrants exercisable for up to 1,245,025 shares of common stock held by the Fund (the 2024 Pre-Funded Warrants), (iv) 1,048,406 shares of common stock held by RA Capital Nexus Fund II, L.P. (the Nexus Fund II), and (v) the shares listed in footnote (18) below which are beneficially owned by Dr. Simson for the benefit of RA Capital. Each of the 2023 Pre-Funded Warrants and the 2024 Pre-Funded Warrants contains a provision which precludes exercise of the warrants to the extent that, following exercise, the Fund, together with its affiliates and other attribution parties, would own more than 19.90% and 19.99%, respectively, of the common stock outstanding. RA Capital Healthcare Fund GP, LLC is the general partner of the Fund and RA Capital Nexus Fund II GP, LLC is the general partner of the Nexus Fund II. The general partner of RA Capital is RA Capital Management GP, LLC, of which Dr. Kolchinsky and Mr. Shah are the controlling persons. RA Capital serves as investment adviser for the Fund and the Nexus Fund II and may be deemed a beneficial owner of any of the Company's securities held by the Fund or the Nexus Fund II. The Fund and the Nexus Fund II have delegated to RA Capital the sole power to vote and the sole power to dispose of all securities held in the Fund's and the Nexus Fund II's portfolio, including the shares of common stock listed here. Because the Fund and the Nexus Fund II have divested themselves of voting and investment power over the reported securities they hold and may not revoke that delegation on less than 61 days' notice, the Fund and the Nexus Fund II disclaim beneficial ownership of the securities they hold. As managers of RA Capital, Dr. Kolchinsky and Mr. Shah may be deemed beneficial owners of any of the Company's securities beneficially owned by RA Capital. RA Capital, Dr. Kolchinsky, and Mr. Shah disclaim beneficial ownership of these securities. The business address for RA Capital and the Fund is 200 Berkeley Street, 18th Floor, Boston, Massachusetts 02116.

(2) Based solely on a Schedule 13G/A filed on November 8, 2024 by FMR LLC (FMR). Consists of 7,824,674 shares of common stock beneficially owned by FMR, who reports sole voting power over 7,823,767 of such shares and sole dispositive power over all of such shares, and Abigail P. Johnson, who reports sole dispositive power over all of such shares. Abigail P. Johnson is a director, the chairman and the chief executive officer of FMR. Members of the Johnson family, including Abigail P. Johnson, are the predominant owners, directly or through trusts, of Series B voting common shares of FMR, representing 49% of the voting power of FMR. The Johnson family group and all other Series B shareholders have entered into a shareholders' voting agreement under which all Series B voting common shares will be voted in accordance with the majority vote of Series B voting common shares. Accordingly, through their ownership of voting common shares and the execution of the shareholders' voting agreement, members of the Johnson family may be deemed, under the Investment Company Act of 1940, to form a controlling group with respect to FMR. The business address for FMR is 245 Summer Street, Boston, Massachusetts 02210.

(3) Based solely on a Schedule 13G filed on February 14, 2025 by Janus Henderson Group plc (Janus). Consists of 3,562,402 shares of common stock beneficially owned by Janus, who reports shared voting and dispositive power over all of such shares. JHIUS, JHIUKL and JHIAIFML are indirect subsidiaries of Janus and are registered investment advisers furnishing investment advice to managed portfolios. The business address for Janus is 201 Bishopsgate, EC2M 3AE, United Kingdom.

(4) Based solely on a Schedule 13G jointly filed on February 14, 2025 by Paradigm BioCapital Advisors LP (the Adviser), Paradigm BioCapital Advisors GP LLC (the Adviser GP), Senai Asefaw, M.D. and Paradigm BioCapital International Fund Ltd. (the Fund). Consists of 3,515,986 shares of common stock beneficially owned by the Fund and one or more separately managed accounts managed by the Adviser (the Account). The Adviser, the Adviser GP and Dr. Asefaw each report sole voting and dispositive power over all of such shares, and the Fund reports sole voting and dispositive power over 3,030,509 of such shares. The Fund is a private investment vehicle. The Adviser is the investment manager of the Fund and the Account. The Adviser GP is the general partner of the Adviser. Dr. Asefaw is the managing member of the Adviser GP. The Adviser, the Adviser GP and Dr. Asefaw may be deemed to beneficially own the common stock directly beneficially owned by the Fund and the Account. The Adviser, the Adviser GP, Dr. Asefaw and the Fund each disclaim beneficial ownership of these securities, other than the securities directly beneficially owned by each of them. The business address of the Fund is c/o Walkers, 190 Elgin Avenue, George Town, Grand Cayman KY1-9001, Cayman Islands. The business address of the Adviser, the Adviser GP and Dr. Asefaw is 767 Third Avenue, 17th Floor, New York, New York 10017.

(5) Based solely on a Schedule 13G jointly filed on February 12, 2025 by Adage Capital Management, L.P. (ACM), Robert Atchinson and Phillip Gross. Consists of 3,061,750 shares of common stock beneficially owned by ACM, Mr. Atchinson and Mr. Gross, each of which reports shared voting and dispositive power over all of such shares. Mr. Atchinson and Mr. Gross are the (1) managing members of Adage Capital Advisors, L.L.C., managing member of Adage Capital Partners GP, L.L.C., general partner of Adage Capital Partners, L.P. (ACP) and (2) managing members of Adage Capital Partners LLC, general partner of ACM. ACM is the investment manager of ACP. The business address of each person and entity named in this footnote is 200 Clarendon Street, 52nd Floor, Boston, Massachusetts 02116.

(6) Based solely on a Schedule 13G/A filed on November 4, 2024 by Bregua Corporation (Bregua). Consists of 2,999,990 shares of common stock held by Bregua, who reports sole voting and dispositive power over all of such shares. The business address of Bregua is Wickhams Cay, P.O. Box 146, Road Town, Tortola, VG 1110, British Virgin Islands.

(7) Consists of (i) 212,054 shares of common stock held by Dr. Campbell, and (ii) 2,518,167 shares of common stock that Dr. Campbell has the right to acquire from us within 60 days of February 15, 2025 pursuant to the exercise of stock options, 15,159 of which will be unvested but exercisable as of April 16, 2025.

(8) Consists of 191,743 shares of common stock that Mr. Reardon has the right to acquire from us within 60 days of February 15, 2025 pursuant to the exercise of stock options.

(9) Consists of (i) 105,719 shares of common stock held by Dr. DiRaimondo, and (ii) 655,617 shares of common stock that Dr. DiRaimondo has the right to acquire from us within 60 days of February 15, 2025 pursuant to the exercise of stock options, 5,338 of which will be unvested but exercisable as of April 16, 2025.

(10) Consists of 280,884 shares of common stock that Dr. Robinson has the right to acquire from us within 60 days of February 15, 2025 pursuant to the exercise of stock options.

(11) Consists of 61,262 shares of common stock that Dr. Barrett has the right to acquire from us within 60 days of February 15, 2025 pursuant to the exercise of stock options.

(12) Consists of (i) 67,848 shares of common stock held by Ms. Capps, and (ii) 63,287 shares of common stock that Ms. Capps has the right to acquire from us within 60 days of February 15, 2025 pursuant to the exercise of stock options.

(13) Consists of 6,451 shares of common stock that Mr. Dobmeier has the right to acquire from us within 60 days of February 15, 2025 pursuant to the exercise of stock options.

(14) Consists of (i) 112,639 shares of common stock held by Dr. Gujrathi, and (ii) 88,907 shares of common stock that Dr. Gujrathi has the right to acquire from us within 60 days of February 15, 2025 pursuant to the exercise of stock options.

(15) Consists of 6,451 shares of common stock that Ms. Hernday has the right to acquire from us within 60 days of February 15, 2025 pursuant to the exercise of stock options.

(16) Consists of 53,137 shares of common stock that Mr. Kung has the right to acquire from us within 60 days of February 15, 2025 pursuant to the exercise of stock options.

(17) Consists of 61,262 shares of common stock that Ms. McNulty has the right to acquire from us within 60 days of February 15, 2025 pursuant to the exercise of stock options.

(18) Consists of 61,262 shares of common stock that Dr. Simson has the right to acquire from us within 60 days of February 15, 2025 pursuant to the exercise of stock options.

(19) Consists of (i) the shares described in footnotes (7) through (18) above, (ii) shares held by three executive officers who are not named in the table above, and (iii) shares of common stock that such executive officers have the right to acquire from us within 60 days of February 15, 2025 pursuant to the exercise of stock options.

CERTAIN RELATED-PERSON TRANSACTIONS

The following includes a summary of transactions since January 1, 2023 and any currently proposed transactions, to which we were a participant, in which (i) the amount involved exceeded or will exceed the lesser of $120,000 or one percent of the average of our total assets at year-end for the last two completed fiscal years; and (ii) any of our directors, executive officers or holders of more than 5% of our capital stock, or any affiliate or member of the immediate family of the foregoing persons, had or will have a direct or indirect material interest, other than compensation and other arrangements that are described in the section above titled “Executive Compensation.”

Financings

In July 2023, we completed an underwritten offering of 4,153,717 shares of our common stock at a purchase price of $12.46 per share and, in lieu of offering shares of our common stock to certain investors that so chose, pre-funded warrants to purchase 583,483 shares of our common stock. The purchase price of each pre-funded warrant was $12.459, which is equal to the price per share at which shares of common stock were sold in the offering, minus $0.001, the exercise price of each pre-funded warrant. The gross proceeds from the offering were approximately $59.0 million. RA Capital Healthcare Fund, L.P., then and now, with its affiliates, a beneficial owner of more than 5% of our common stock, purchased pre-funded warrants to purchase 503,226 shares of our common stock for an aggregate purchase price of approximately $6.3 million.

In March 2024, we completed an underwritten public offering of 5,397,301 shares of our common stock at a purchase price of $46.50 per share and, in lieu of offering shares of our common stock to certain investors that so chose, pre-funded warrants to purchase 1,935,483 shares of our common stock. The purchase price of each pre-funded warrant was $46.499, which is equal to the price per share at which shares of common stock were sold in the offering, minus $0.001, the exercise price of each pre-funded warrant. The gross proceeds from the offering were approximately $341.0 million. RA Capital Healthcare Fund, L.P., then and now, with its affiliates, a beneficial owner of more than 5% of our common stock, purchased pre-funded warrants to purchase 1,397,847 shares of our common stock for an aggregate purchase price of approximately $65.0 million.

Indemnification Agreements

We have entered into indemnification agreements with certain of our current directors and executive officers upon the completion of our initial public offering. Our amended and restated certificate of incorporation and our Bylaws provides that we will indemnify our directors and officers to the fullest extent permitted by applicable law.

Policies and Procedures for Related Party Transactions

We adopted a written related-person transactions policy upon the completion of our initial public offering that sets forth our policies and procedures regarding the identification, review, consideration and oversight of “related-person transactions.” For purposes of our policy only, a “related-person transaction” is a transaction, arrangement or relationship (or any series of similar transactions, arrangements or relationships) in which we and any “related person” are participants involving an amount that exceeds $120,000. Transactions involving compensation for services provided to us as an employee, consultant or director are not considered related-person transactions under this policy. A related person is any executive officer, director, nominee to become a director or a holder of more than five percent of our common stock, including any of their immediate family members and affiliates, including entities owned or controlled by such persons.

Under the policy, where a transaction has been identified as a related-person transaction, management must present information regarding the proposed related-person transaction to our Audit Committee (or, where review by our Audit Committee would be inappropriate, to another independent body of our Board of Directors) for review. The presentation must include a description of, among other things, all of the parties thereto, the direct and indirect interests of the related persons, the purpose of the transaction, the material facts, the benefits of the transaction to us and whether any alternative

transactions are available, an assessment of whether the terms are comparable to the terms available from unrelated third parties and management's recommendation. To identify related-person transactions in advance, we rely on information supplied by our executive officers, directors and certain significant stockholders. In considering related-person transactions, our Audit Committee or another independent body of our Board of Directors takes into account the relevant available facts and circumstances including, but not limited to:

- the risks, costs and benefits to us;
- the impact on a director's independence in the event the related person is a director, immediate family member of a director or an entity with which a director is affiliated;
- the terms of the transaction;
- the availability of other sources for comparable services or products; and
- the terms available to or from, as the case may be, unrelated third parties.

In the event a director has an interest in the proposed transaction, the director must recuse himself or herself from the deliberations and approval.

HOUSEHOLDING OF PROXY MATERIALS

The SEC has adopted rules that permit companies and intermediaries (e.g., brokers) to satisfy the delivery requirements for Notices of Internet Availability of Proxy Materials or other Annual Meeting materials with respect to two or more stockholders sharing the same address by delivering a single Notice of Internet Availability of Proxy Materials or other Annual Meeting materials addressed to those stockholders. This process, which is commonly referred to as "householding," potentially means extra convenience for stockholders and cost savings for companies.

This year, a number of brokers with account holders who are Janux stockholders will be "householding" our proxy materials. A single Notice of Internet Availability of Proxy Materials will be delivered to multiple stockholders sharing an address unless contrary instructions have been received from the affected stockholders. Once you have received notice from your broker that they will be "householding" communications to your address, "householding" will continue until you are notified otherwise or until you revoke your consent. If, at any time, you no longer wish to participate in "householding" and would prefer to receive a separate Notice of Internet Availability of Proxy Materials, please notify your broker. Stockholders who currently receive multiple copies of the Notices of Internet Availability of Proxy Materials at their addresses and would like to request "householding" of their communications should contact their brokers.

OTHER MATTERS

The Board of Directors knows of no other matters that will be presented for consideration at the Annual Meeting. If any other matters are properly brought before the meeting, it is the intention of the persons named in the accompanying proxy to vote on such matters in accordance with their best judgment.

By Order of the Board of Directors,

/s/ James Pennington
James Pennington
General Counsel and Corporate Secretary

April 25, 2025

A copy of our Annual Report to the Securities and Exchange Commission on Form 10-K for the fiscal year ended December 31, 2024 is available without charge upon written request to: Janux Therapeutics, Inc., Attn: Corporate Secretary, 10955 Vista Sorrento Parkway, Suite 200, San Diego, California 92130.