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, 2023

OR

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

Commission File Number 001-40881

Pyxis Oncology, Inc.
(Exact name of Registrant as specified in its Charter)

Delaware	**83-1160910**
(State or other jurisdiction of incorporation or organization)	**(I.R.S. Employer Identification No.)**
321 Harrison Avenue Boston, Massachusetts	**02118**
(Address of principal executive offices)	**(Zip Code)**

Registrant's telephone number, including area code: (617) 221-9059

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

Title of each class	**Trading Symbol(s)**	**Name of each exchange on which registered**
Common Stock, par value $0.001 per share	PYXS	Nasdaq Global Select Market

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

Indicate by check mark if the Registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act. YES ☐ NO ☒

Indicate by check mark if the Registrant is not required to file reports pursuant to Section 13 or 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, 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 Registrant's common stock held by non-affiliates as of June 30, 2023 the last business day of the Registrant's most recently completed second fiscal quarter, was approximately $97.0 million, as computed by reference to the closing price of the common stock on the Nasdaq Global Select Market on that date.

As of March 20, 2024, the Registrant had 58,133,375 shares of common stock, $0.001 par value per share, outstanding.

DOCUMENTS INCORPORATED BY REFERENCE

None.

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CAUTIONARY NOTE REGARDING FORWARD-LOOKING STATEMENTS

This Annual Report on Form 10-K contains forward-looking statements concerning our business, operations and financial performance and condition, as well as our plans, objectives and expectations for our business, operations and financial performance and condition. Any statements contained herein that are not statements of historical facts may be deemed to be forward-looking statements. These statements involve known and unknown risks and other important factors that are in some cases beyond our control and may cause our actual results, performance or achievements to be materially different from any future results, performance or achievements expressed or implied by the forward-looking statements.

Unless the context requires otherwise, references in this Annual Report on Form 10-K to "Pyxis Oncology," the "Company," "we," "us," and "our" refer to Pyxis Oncology, Inc. and its subsidiaries. In some cases, you can identify forward-looking statements by terms such as "anticipate," "believe," "can," "continue," "could," "estimate," "expect," "intend," "likely," "may," "might," "objective," "ongoing," "plan," "potential," "predict," "project," "should," "to be," "will," "would," or the negative or plural of these words, or similar expressions or variations, although not all forward-looking statements contain these words. The forward-looking statements in this Annual Report on Form 10-K are only predictions. We have based these forward-looking statements largely on our current expectations and projections about future events and financial trends that we believe may affect our business, financial condition and results of operations. These forward-looking statements speak only as of the date of this Annual Report on Form 10-K and are subject to a number of risks, uncertainties and assumptions described in the section titled "Risk Factors" and elsewhere in this Annual Report on Form 10-K. Because forward-looking statements are inherently subject to risks and uncertainties, some of which cannot be predicted or quantified, you should not rely on these forward-looking statements as predictions of future events. The events and circumstances reflected in our forward-looking statements may not be achieved or occur and actual results could differ materially from those projected in the forward-looking statements. Some of the key factors that could cause actual results to differ from our expectations include:

- our ability to develop and advance our current or future product candidates and programs, and to successfully initiate and complete clinical trials;
- the ability of our clinical trials to demonstrate the safety, purity and potency of our product candidates and other positive results;
- the size of the market opportunity for our product candidates, including our estimates of the number of patients who suffer from the cancers we are targeting;
- our manufacturing, commercialization and marketing capabilities and strategy;
- our plans to expand our pipeline of product candidates and further develop the FACT Platform and APXiMAB Platform (as defined herein);
- the timing or likelihood of regulatory filings and approvals for our product candidates;
- regulatory developments in the United States and Europe and other foreign jurisdictions:
- our expectations and plans to obtain funding for our operations, including from our existing and potential future collaboration and licensing agreements;
- our ability to receive milestone or royalty payments under existing or future agreements;
- our expectations regarding our ability to obtain and maintain intellectual property protection for our product candidates:
- our continued reliance on third parties to manufacture our product candidates for preclinical studies, and, in the future, to conduct clinical trials and manufacture product candidates for such clinical trials; and
- our estimates regarding expenses, future revenue, capital requirements and needs for additional financing.

In addition, statements such as "we believe" and similar statements reflect our beliefs and opinions on the relevant subject. These statements are based upon information available to us as of the date of this Annual Report on Form 10-K and, although we believe such information forms a reasonable basis for such statements, such information may be limited or incomplete, and our statements should not be read to indicate that we have conducted a thorough inquiry into, or review of, all potentially available relevant information. Furthermore, if our forward-looking statements prove to be inaccurate, the inaccuracy may be material. In light of the significant uncertainties in these forward-looking statements, you should not regard these statements as a representation or warranty by us or any other person that we will achieve our objectives and plans in any specified time frame, or at all. Except as required by applicable law, we do not plan to publicly update or revise any forward-looking statements contained herein, whether as a result of any new information, future events or otherwise.

SUMMARY RISK FACTORS

You should consider carefully the risks described under “Risk Factors” in Part II, Item 1A of this Annual Report on Form 10-K. References to “Pyxis Oncology,” the “Company,” “we,” “us,” and “our” in this section titled “Summary Risk Factors” refer to Pyxis Oncology, Inc. and its wholly owned subsidiaries. A summary of the risks that could materially and adversely affect our business, financial condition, operating results and prospects include the following:

- We are a clinical stage biopharmaceutical company with a limited operating history and have incurred significant losses since our inception. We expect to incur losses over at least the next several years and may never achieve or maintain profitability.
- We will require substantial additional capital to finance our operations, obtain regulatory approval for our product candidates, and commercialize our product candidates. If we are unable to raise such capital when needed, or on acceptable terms, we may be forced to delay, reduce or eliminate one or more of our research and product development programs or future commercialization efforts.
- We are heavily dependent on the success of PYX-201, PYX-106 and PYX-107, which are in the early stages of development, and if PYX-201, PYX-106 and/or PYX-107 are not successful in clinical trials or do not receive regulatory approval or licensure or are not successfully commercialized, our business will be materially and adversely affected.
- Our product candidates may fail in development or suffer delays that materially and adversely affect their commercial viability. If we or our existing or future collaborators are unable to initiate and complete clinical development of, obtain regulatory approval or licensure for or commercialize our product candidates or experience significant delays in doing so, our business will be materially harmed.
- Our preclinical studies and clinical trials may fail to demonstrate adequately the safety, purity and potency of any of our product candidates, which would prevent or delay development, regulatory approval or licensure and commercialization.
- Our preclinical programs may experience delays or may never advance to clinical trials, which would adversely affect our ability to obtain regulatory approval or licensure or commercialize these programs on a timely basis or at all.
- We face competition from entities that have developed or may develop product candidates for cancer treatment, including companies developing novel treatments and technology platforms. If these companies develop technologies or product candidates more rapidly than we do or if their technologies are more effective, our ability to develop and successfully commercialize product candidates may be adversely affected.
- Clinical testing and product development is a lengthy and expensive process with an uncertain outcome. We may incur unexpected costs or experience delays in completing, or ultimately be unable to complete, the clinical testing and the development of our product candidates and may never achieve commercialization for any of our product candidates.
- The regulatory licensure and approval processes of the FDA and other comparable regulatory authorities are lengthy, time-consuming and inherently unpredictable and, if we are ultimately unable to obtain marketing licensure or approval for our product candidates, our business will be substantially harmed.
- If we fail to attract and retain qualified senior management and key scientific personnel, our business may be materially and adversely affected.
- We rely on third parties to manufacture our product candidates. Any failure by a third party manufacturer to produce acceptable raw materials or product candidates for us or to obtain authorization from the FDA or comparable foreign regulatory authorities relating thereto may delay or impair our ability to initiate or complete our clinical trials, obtain regulatory licensure or approvals or commercialize approved products.
- We face substantial competition, which may result in others discovering, developing or commercializing products more quickly or marketing them more successfully than we do.
- If we are unable to obtain and maintain patent protection for our product candidates, or if the scope of the patent protection obtained is not sufficiently broad, or if our patents are insufficient to protect our product candidates for an adequate amount of time, or if we are unable to obtain adequate protection for our proprietary know-how, we may not be able to compete effectively in our markets.
- If we fail to comply with our obligations under any license, collaboration or other agreements, we may be required to pay damages and could lose intellectual property rights that are necessary for developing and protecting our product candidates or we could lose certain rights to grant sublicenses.

•Licensing of intellectual property is of critical importance to our business and involves complex legal, business and scientific issues. If we breach our University of Chicago, Pfizer Inc., or Pfizer, or Biosion USA, Inc., or Biosion, license agreements or any of the other agreements under which we acquired, or will acquire, intellectual property rights covering our product candidates, we could lose the ability to continue the development and commercialization of the related product candidate(s).

•We are subject to stringent and changing obligations related to data privacy and cybersecurity. Our actual or perceived failure to comply with such obligations could lead to regulatory investigations or actions, litigation, fines and penalties, a disruption of our business operations, including our clinical trials, harm to our reputation, and other adverse effects on our business or prospects.

•Our internal computer systems, or those of any of our existing or future contract research organizations, or CROs, manufacturers, other contractors, consultants, or collaborators, may fail or suffer security or data privacy breaches or other unauthorized or improper access to, use of or destruction of our proprietary and confidential data, employee data or personal data, which could result in additional costs, significant liabilities, harm to our reputation and material disruption of our operations.

•If we achieve commercialization and the market opportunities for any product that we develop are smaller than we believe they are, our revenue may be adversely affected, and our business may suffer.

PART I

Item 1. Business.

Overview

We are a clinical stage company focused on defeating difficult-to-treat cancers. We are efficiently building next generation therapeutics that hold the potential for mono and combination therapies. We develop our product candidates with the objective to kill tumor cells, and to address the underlying pathologies created by cancer that enable its uncontrollable proliferation and immune evasion. Since our launch in 2019, we have developed a broad portfolio that includes antibody-drug conjugates, or ADC, product candidates, and immuno-oncology, or IO, product candidates. Our ADC and IO programs employ novel and emerging strategies to target a broad range of solid tumors resistant to current standards of care.

Our pipeline is balanced across programs with an emphasis on solid tumors. We in-licensed two ADC programs in March 2021 from Pfizer and one IO program from Biosion in March 2022. Additionally, upon the acquisition of Apexigen Inc., or Apexigen, in August 2023, we added another IO program to our pipeline. We have additional preclinical monoclonal antibody, or mAb, discovery programs derived from the work at the laboratory of Dr. Thomas Gajewski. We retain full worldwide development and commercialization rights to all our product candidates, with the exception of PYX-106 in Greater China (mainland China, Hong Kong, Macau and Taiwan).

Our clinical development pipeline focused on multiple difficult-to-treat tumors is displayed below:

Our Clinical Program Portfolio

PYX-201

Our lead ADC product candidate is PYX-201, an investigational, novel ADC consisting of human Immunoglobulin G1, or IgG1, site-specifically conjugated with a next generation auristatin derivative via proteases-cleavable linker. PYX-201 is an ADC that uniquely targets Extradomain-B Fibronectin, or EDB+FN, in the tumor stroma. EDB+FN regulates blood vessel morphogenesis, which provides the tumor access to nutrition and oxygen, a means to remove waste, and a pathway for metastasizing cells.

We believe EDB+FN within the tumor stroma may be an ideal target to address in many cancers with high unmet need. The stroma plays a major role in the initiation, growth, survival, invasion and drug-resistance of solid tumors, yet few therapeutics specifically target tumor-associated stroma. By targeting EDB+FN and specifically attacking the stroma, our goal is to destabilize the barrier that protects, feeds and provides structure to the tumor in addition to killing tumor cells directly. EDB+FN is overexpressed in many malignancies and is minimally expressed in most normal adult tissues, making it a potentially attractive means to target tumors while sparing healthy cells.

In preclinical models of patient-derived xenograft, or PDX models, we observed tumor regression with single agent PYX-201 in a dose-dependent manner. In addition, we observed that the treatment of preclinical syngeneic tumor models with PYX-201 resulted in enhanced T-cell infiltration into the tumor microenvironment, or TME, suggesting that PYX-201 may have caused immunogenic cell death, or ICD, and could potentially trigger downstream anti-tumor immune response.

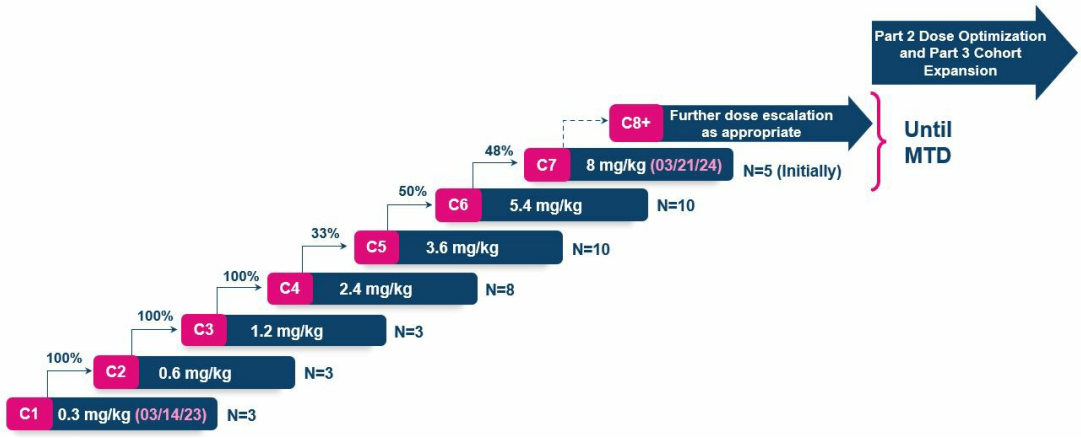
In December 2022, we announced clearance of our investigational new drug application, or IND, by the U.S. Food and Drug Administration, or FDA, to initiate a Phase 1 clinical trial. During the first quarter of 2023, we announced dosing of the first subject in a Phase 1 trial of PYX-201, referred to as PYX-201-101. PYX-201-101 is an open-label, multicenter, dose-escalation trial designed to evaluate the safety, tolerability, pharmacokinetics, or PK, pharmacodynamics, or PD, and preliminary efficacy of PYX-201 and identify recommended doses for further study. Patients with relapsed or refractory solid tumors, including non-small cell lung cancer, or NSCLC, locally advanced/metastatic breast cancer, hormone receptor and human epidermal growth factor receptor 2 positive and negative, or HR+ HER- and HR- HER2+, breast cancers, triple negative breast cancer, or TNBC, ovarian cancer, thyroid cancer, pancreatic ductal adenocarcinoma, or PDAC, soft tissue sarcoma, or STS, hepatocellular carcinoma, or HCC, head and neck squamous cell carcinoma, or HNSCC, and kidney cancer are eligible to enroll in this study. In May 2023, the FDA granted Orphan Drug Designation, or ODD, for use of PYX-201 in the treatment of pancreatic cancer.

In the Phase 1 portion of the trial, the starting dose of PYX-201 was 0.3 mg/kg. The Dose Escalation Steering Committee, or DESC, approved escalating the dose after each cohort. PYX-201 is administered once every three weeks. Dose escalation follows the Bayesian Optimal Interval, or BOIN, design until the recommended Part 2 dose(s), or RP2D, is determined.

To date, 37 subjects in six cohorts have been dosed with PYX-201 in this Phase 1 trial. PYX-201 recently cleared the 21-day Dose Limiting Toxicity, or DLT, observation period for ten subjects in Cohort 6 at a dose of 5.4 mg/kg. The DESC met on March 19, 2024, and voted to escalate dosing into Cohort 7 at a dose of 8 mg/kg and we are now enrolling subjects in Cohort 7 at this dose. PYX-201 has been well tolerated to date, with no significant evidence of target mediated toxicities experienced by the 37 subjects enrolled and dosed to date. Approximately 54% of subjects have experienced grade 2, and 6% of subjects have experienced grade 3 treatment emergent adverse events, or TEAEs. No subjects have reported TEAEs leading to dosing delay or study drug discontinuation. We anticipate enrolling and dosing another 10-15 subjects at Cohort 7 with a dose of 8 mg/kg or future higher dose level cohorts, should PYX-201's profile continue to support further dose escalation.

The dose escalation and number of subjects enrolled and dosed to date with PYX-201 in the PYX-201-101 trial, for each cohort since initiating the trial in March 2023, are provided in Figure 1 below.

Figure 1



As we continue to analyze the data generated, we anticipate that the data from the dose finding studies will guide the selection for the RP2D for subsequent multi-dosing and potential combination studies. We believe the encouraging PYX-201 safety profile observed to date likely reflects the specificity of target expression within tumor tissue and the potential for a wider therapeutic index, or TI, given the novel mechanism of action within the TME. We anticipate reporting efficacy, safety, and PK/PD data from this Phase 1 clinical trial, in the fall of 2024. We also anticipate reporting pre-clinical insights along with the plan for the next phase of development at that time.

PYX-106

Our lead IO product candidate is PYX-106, an investigational, fully human IgG1 Siglec-15-targeting antibody designed to block Siglec-15 mediated suppression of T-cell proliferation and function. PYX-106 has high binding affinity to a unique epitope and high potency. Overall, by binding and blocking Siglec-15 activity on myeloid cells and tumors, our Siglec-15 targeting antibody is designed to enhance immune cell mediated tumor cell killing. We are developing this asset for the treatment of solid tumors and believe that PYX-106 has the potential to provide additional benefit to patients either alone or in combination with other therapies, including other immuno-therapies.

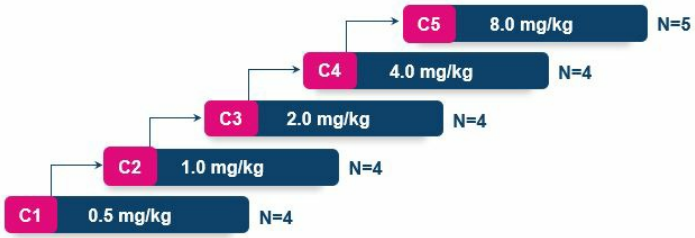
Preclinical studies provided us sufficient scientific rationale about the effect of blocking Siglec-15 in various animal models. PYX-106 was observed as well tolerated with no evidence of anti-drug antibodies. Further, PYX-106 was observed to have 7 days of half-life in monkeys in our preclinical studies. If the half-life of 7 days were observed in humans, it would allow for less frequent dosing, maintain exposure and target engagement.

In December 2022, we announced clearance of our IND by the FDA for PYX-106 to initiate a Phase 1 clinical trial. During the second quarter of 2023, we announced dosing of the first subject in a Phase 1 trial of PYX-106, referred to as PYX-106-101. PYX-106-101 is a first-in-human, Phase 1, multicenter, open-label dose escalation trial designed to evaluate the safety, tolerability, PK, PD, and preliminary efficacy of PYX-106 and identify recommended doses for further study. Patients with relapsed or refractory solid tumors, including non-small cell lung cancer without driver mutations/translocations, breast cancer, endometrial cancer, thyroid cancer, kidney cancer, cholangiocarcinoma, bladder cancer, colorectal cancer, and HNSCC are eligible to enroll in this study.

In the Phase 1 portion of the trial, the starting dose of PYX-106 was 0.5 mg/kg. The DESC approved escalating the dose after each cohort. We are currently dosing subjects in Cohort 5 at a dose of 8 mg/kg and Cohort 5 is fully enrolled. To date, 21 subjects have been dosed with PYX-106 in this Phase 1 trial. PYX-106 is administered once every two weeks. Dose escalation will follow the BOIN design until the RP2D is determined.

The dose escalation and number of subjects enrolled and dosed to date with PYX-106 in the PYX-106-101 trial, for each cohort since initiating the trial in May 2023, are provided in Figure 2 below.

Figure 2



We anticipate reporting preliminary data from this Phase 1 clinical trial, including PK/PD data and early signs of potential clinical activity, in the second half of 2024.

PYX-107

On August 23, 2023, we completed the acquisition contemplated by that Agreement and Plan of Merger, or the Merger Agreement, by and among the Company, Ascent Merger Sub Corp., a Delaware corporation and wholly-owned subsidiary of the Company, or the Merger Sub, and Apexigen, a Delaware corporation and a clinical-stage biopharmaceutical company focused on discovering and developing innovative antibody therapeutics for oncology.

Pursuant to the Merger Agreement, Merger Sub merged with and into Apexigen, with Apexigen surviving as a wholly owned subsidiary of the Company, or the Merger. As consideration for the Merger, we delivered to Apexigen common stockholders 4,344,435 shares of our common stock and replaced stock options, restricted stock units and warrants to Apexigen's former employees and warrant-holders, for an aggregate purchase price of $10.7 million.

The Merger expanded our existing pipeline with the addition of sotigalimab (now PYX-107), a CD40 agonist with demonstrated anti-cancer activity in patients who previously progressed on PD-(L)1 inhibitors. PYX-107 has been evaluated in more than 500 patients in clinical trials and demonstrated strong activity, including rapid, deep and durable responses and a favorable tolerability profile, across multiple difficult-to-treat tumor types. In a Phase II trial, PYX-107 in combination with nivolumab has demonstrated strong activity in melanoma patients who are refractory to anti-PD-(L)1, with a 15.2% partial response rate and a 30.3% stable disease rate along with a favorable tolerability profile. Opportunity to advance clinical development of PYX-107 will be further assessed as part of portfolio evaluation.

Our Technology Platforms

We are capitalizing on years of industry innovation and advancement in ADC platforms to develop and design our product candidates. Our PYX-201 product candidate was built utilizing the Flexible Antibody Conjugation Technology, or FACT Platform, initially licensed from Pfizer in December 2020, before securing an exclusive license to the FACT Platform in October 2022. The FACT Platform leverages over a decade of investment refining the technical components of ADCs to improve the clinical properties of ADCs. Using our expertise in site-specific antibody conjugation, we are developing next-generation ADCs with customized linker-payload combinations aimed at increasing stability and, consequently, a reduced off target side-effect profile potentially enhancing the TI.

The Merger enhanced our ADC capabilities with the addition of Apexigen's antibody-discovery platform, or the APXiMAB Platform, to use with our FACT Platform to support and potentially accelerate our existing ADC initiatives and the combined company's end-to-end capabilities to design and produce novel next-generation ADC candidates with improved potency, stability and tolerability.

The APXiMAB Platform was used to enable the discovery of multiple protein therapeutic product candidates against a variety of molecular targets, including targets that are difficult to generate antibodies with conventional antibody technologies. In addition to certain product candidates that we wholly own, several product candidates that were discovered through the use of the APXiMAB Platform are in clinical development by our licensees. The most advanced of these programs is Novartis' Beovu® (brolucizumab-dbll) product, which received FDA approval in 2019 and is marketed in over 70 countries. Two other programs being developed by our licensees are in later-stage development; Simcere's Phase 3 clinical trial of suvemcitug (BD0801) for injection combined with chemotherapy in patients with recurrent, platinum-resistant epithelial ovarian, fallopian tube or primary peritoneal cancer, which met the primary endpoints in January 2024, and Mabwell's Phase 3 clinical trial of 9MW0211 in wet age-related macular degeneration, or AMD. Other than already approved programs (i.e. Novartis' Beovu®) there is no guarantee that any of the other product candidates discovered using our APXiMAB Platform, whether developed by us or our licensees, will receive regulatory approval.

Our Team

Our company was founded in 2018, and launched operations in 2019, with a mission to defeat difficult-to-treat cancers. We have a highly qualified team with deep experience and proficiency in oncology research and development and plan to leverage our team's decades of experience in drug development to bring a variety of innovative therapies through the clinic. The collective experience across our team spans the spectrum of both pharmaceuticals and biotechnology.

Our Strategy

Our goal is to improve the lives of patients with difficult-to-treat cancers by building a superior portfolio of biological products, including ADCs and monoclonal antibody immunotherapies.

Elements of our strategy to achieve our short and long-term goals include:

- **Building a leading ADC oncology company with opportunistic development in IO.** We believe our team, which brings deep scientific TME knowledge, functional biology expertise, expertise in ADC modality, and biologics development capabilities, position us to build a leading ADC focused oncology company with opportunistic development in IO.

- **Progress our lead product candidates, PYX-201 and PYX-106, through clinical development.** We expect preliminary data from the Phase 1 clinical trials of PYX-201 and PYX-106, including PK/PD data and early signs of potential clinical activity, in mid-2024 and the second half of 2024, respectively.

- **Pursue a multi-modality approach to cancer therapy addressing various key components of the TME.** Our approach is to leverage our capabilities to develop investigational products that target tumor cells and stromal components of the TME with ADCs as well as enhance effector cell function and overcome key mechanisms of immune-suppression with immunotherapeutic mAbs to improve response rates and/or deliver durable responses for more patients.

- **Selectively forge alliances to enhance and expand our product pipeline to further leverage our intellectual property**. We believe that the potential for single agent anti-tumor activity of our current and future products could be enhanced by incorporating potential collaborator technologies. We intend to selectively form alliances with partners to gain access to complementary technologies and expertise to develop and commercialize product candidates with increased potential for anti-tumor activity and the potential for a strong safety profile. We seek to further leverage our intellectual property portfolio through the formation of these alliances.

Unmet Need in Oncology

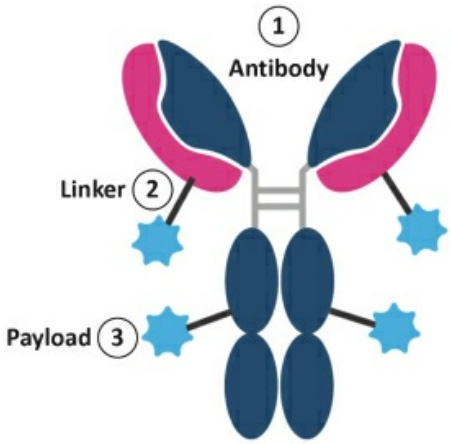
Despite the meaningful advances made in oncology with the approval of several new classes of drugs, there remains significant unmet medical need for novel treatments. According to the World Health Organization, cancer is the second leading cause of death globally, accounting for nearly 10 million deaths in 2020. The key limitations of existing oncology treatments include high toxicity, low or limited response rates, and relapse or recurrence.

Chemotherapy remains one of the most common treatments for cancer, often combined with surgery and radiotherapy depending on the stage and type of tumor. A major challenge in the development of cancer treatments has been the overall complexity and heterogeneity not only of solid tumors, but of their dynamic surrounding microenvironments. While recent advances in treatment approaches, such as targeting specific tumor mutations that contribute to carcinogenesis or redirecting a patient's immune system to eliminate tumors, have begun to address these challenges, their focus has largely been on tumor cells. We believe that targeting the TME, which has been shown to play a key role in driving tumor progression, growth and multidrug resistance, represents a novel approach for addressing unmet needs in oncology. For example, while the development of immune checkpoint inhibitors has transformed the treatment paradigm for numerous cancers, many patients who respond to these therapies ultimately develop resistance and experience disease progression. Many features of the TME have been shown to influence response and resistance to immune checkpoint inhibitors and targeting the TME has potential to overcome these limitations. Our development efforts aim to leverage our deep understanding of the TME biology with the goal of designing and developing next-generation ADCs, with site-specific conjugation and customized linker-payload combinations, and immunotherapies that target key modulators of the adaptive and innate immune system found within the TME.

Overview of Antibody-Drug Conjugates

ADCs are a therapeutic class in which cytotoxic chemotherapy molecules are linked to a targeting mAb to effectively deliver the tumor killing effect into tumor lesions while limiting systemic toxicity. Systemic toxicity limits the efficacy of chemotherapy, a highly cytotoxic class of anti-tumor medicines. ADCs can significantly improve the therapeutic window of toxic payloads even more cytotoxic than traditional chemotherapies by targeting their delivery to tumorous cells and their local environment and sparing healthy tissue. ADCs achieve this level of precision by pairing payloads with monoclonal antibodies, proteins that can recognize their target antigens with great specificity. ADCs are an established and fast-growing class of biological products. To date, eleven ADCs have been approved by the FDA and are on the market.

Figure 3



Schematic representation of an ADC, highlighting the three key components; targeted antibody, linker, and payload or cytotoxic agent (dark blue: mAb heavy chain; pink: mAb light chain).

The clinical properties of ADCs are a function of three components (as show in Figure 3 above):

(1)A monoclonal antibody that selectively targets a distinct antigen preferentially expressed on tumor cells or other cells in the TME;

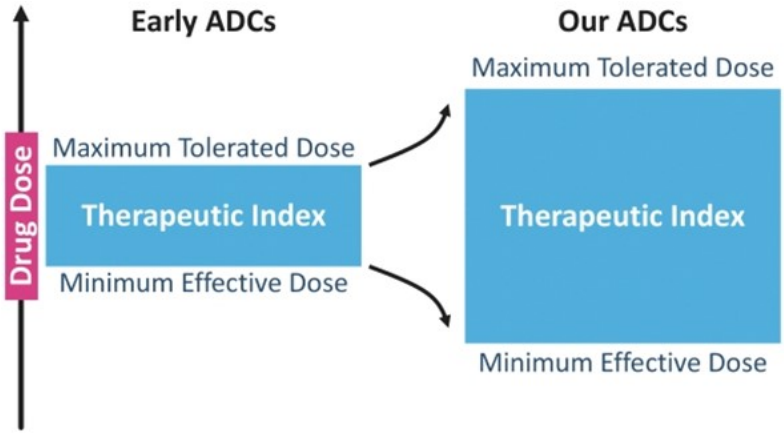
(2)A linker that joins together the antibody and the payload; and

(3)A payload that can effectively kill the targeted cells and/or the TME.

Ideal ADC targets typically have highly tumor restricted expression to spare healthy tissues, are accessible to circulating antibodies, and have well-defined internalization kinetics or can be effectively bound within the TME. Once administered, an ADC will travel in the bloodstream until it encounters its target antigen and will subsequently release the toxic payload.

A measure of drug tolerability for ADCs is the preclinical TI, which is calculated from data to estimate the safety profile (refer to Figure 4). This measure is the preclinical ratio of the highest non-severely toxic dose, or HNSTD, in monkeys versus the minimal effective dose, or MED, in mouse tumor models. The TI is defined formulaically as HNSTD (mg/m2) in monkeys / mouse minimal tumor regression dose (mg/m2). As further illustrated in Figure 4 below, a wider TI is a key attribute of an ADC's potential clinical success.

Figure 4



The TI is a measure to estimate the clinical tolerability profile of ADCs based upon the ratio of maximum tolerated dose, or MTD, in monkeys versus the MED in rodents from preclinical studies.

Key Areas of Innovation for Engineering the Next-Generation ADCs

Optimizing the Linker

The linker that joins the payload to the antibody should prevent the payload's premature release while in circulation and ensure efficient release of the payload into the target cell(s) and/or the TME. There are two general classes of linkers:

(1)Cleavable linkers are designed to conditionally unload cytotoxic agents within the tumor cell or TME in response to the presence of tumor-associated factors such as proteases or highly acidic conditions. Typically, cleavable linkers carry uncharged payloads, allowing the drug to diffuse out of the target cell to kill surrounding "bystander cells." Bystander killing can also occur when the uncharged payload is unleashed within the TME.

(2)Non-cleavable linkers remain intact upon internalization and rely on lysosomal degradation of the entire construct to achieve sufficient payload release. Non-cleavable ADCs typically release their payloads as charged catabolites, which traps the toxin within the cell where it was internalized. As a result, non-cleavable ADCs are naturally well suited to address cancers with a high and uniform expression of the target antigen since cells lacking the target antigen will not be directly affected.

We believe our toolbox of cleavable and non-cleavable linkers allows us to select the optimal linker tailored to each program. We select our linkers based on several factors, including but not limited to the level and distribution of the target antigen and rates of antigen turnover, internalization, lysosomal processing, and degradation. Our PYX-201 ADC product candidates use proteases-cleavable, valine citrulline linkers, which is optimized to improve stability in circulation and reduce free payload.

Site-Specific Conjugation

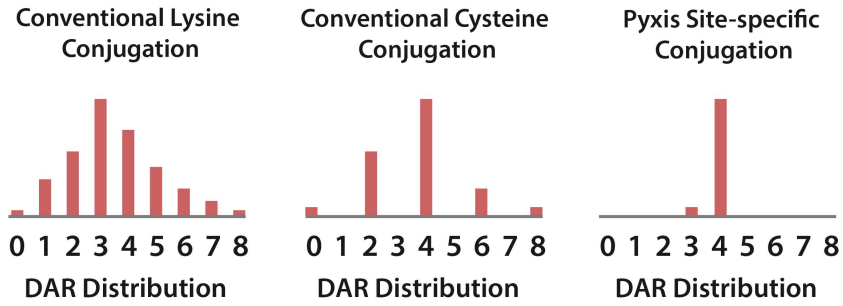
Site-specific conjugation chemistry enables the engineering of next-generation ADCs with predictable drug-to-antibody ratio, or DAR, with improved ADC PK observed preclinically. This improved PK results in minimizing premature payload release and less off-target toxicity and as a result improves the overall TI of the ADC.

DAR is defined as the number of payload moieties attached to each antibody, which typically range from zero to eight. Ideally, there is limited variability in DAR to allow for ADCs with predictable PK and more predictable efficacy. Variability in DAR and stability are primarily a consequence of the technology used to conjugate the linker to the antibody. The two conventional conjugation approaches employed in conventional ADC conjugation technology utilize either lysine residues or the interchain disulfides located on an antibody. These approaches result in a stochastic mixture of conjugates consisting of a heterogeneous pool of synthesized ADCs, as shown in Figure 5 below. Each bar in the graph consists of an ADC with the number of payloads indicated on the X-axis. Each one of these parts of the mixture of conjugates contributes to the efficacy and toxicity making it difficult to optimize for either property.

In addition to DAR, research has shown conjugate stability and the resulting rate of payload release can vary significantly between specific conjugation sites. Hence, conventional conjugation suffers from unpredictable and premature payload release outside of the tumor resulting in off target toxicities.

Together with our extensive toolbox of linkers, we believe our site-specific conjugation chemistry offers us the advantage of fine-tuning and optimizing the cleavage of the drug in the TME while limiting off-tumor release and allowing for predictable DAR distribution. Site-specific conjugation technologies have led to improved ADC predictability with narrow distribution of DAR to facilitate CMC manufacture and consistent potency (refer to Figure 5).

Figure 5



Depicted above is an illustrative example of DAR distribution for a DAR 4 ADC using different conjugation chemistries which highlights how our site-specific conjugation technology allows for linker/payload to be precisely conjugated, leading to more predictable DAR ADCs. This also improves CMC characteristics and enhances stability of ADCs to maximize tumor delivery of the payload.

The Selection of Cytotoxic Payload

The chemotherapeutic payload is a highly potent toxin that would otherwise carry devastating side effects as a systemically delivered monotherapy. There are several potential payloads, including antineoplastic auristatins, which act on microtubules to inhibit cell division, and alkylating or intercalating agents, which damage DNA.

While an ADC's primary mode of action is to induce direct cell death through the payload, ADCs can exploit multiple avenues of anti-tumor action beyond direct cytotoxicity. For example, a growing area of interest is applying ADCs to induce ICD allowing for synergy with immunotherapy modalities including checkpoint inhibitors. Rapid cancer cell death caused by ADCs results in the release of damage-associated molecular patterns and tumor antigens, stimulating a tumor-specific immune response and recruitment of T cells into the TME. An emerging area of interest is utilizing ADCs to disrupt various aspects of the TME, such as angiogenesis or tumor-associated fibroblasts. Furthermore, certain payloads, such as auristatins, have been shown to engender the maturation and activation of dendritic cells, a critical compartment of the immune system responsible for initiating and regulating the innate and adaptive immune response.

Our ADC Product Candidate

PYX-201: Investigational Site-Specific ADC Targeting Onco-Fetal EDB+FN

Overview

Our lead ADC product candidate, PYX-201, is an investigational, novel ADC consisting of human IgG1, site-specifically conjugated with a next-generation auristatin derivative via proteases-cleavable linker. PYX-201 is an ADC that uniquely targets EDB+FN within the tumor stroma. PYX-201 is in the clinical development and being evaluated in an ongoing Phase 1 clinical studies in patients with relapsed or refractory solid tumors, including NSCLC, locally advanced/metastatic breast cancer, HR+ HER- and HR- HER2+ breast cancers, TNBC, ovarian cancer, thyroid cancer, PDAC, STS, HCC, HNSCC, and kidney cancer. We licensed worldwide rights to PYX-201, built on the FACT Platform, from Pfizer.

Rationale for Targeting EDB+FN within Tumor Stroma

The extracellular matrix, or ECM, is a complex network of structural proteins and molecules that support tissues and organs within the body. The ECM is comprised of multiple fibrous proteins and molecules with unique composition and that play an important role in cell development. The ECM in solid tumors is an important component of the TME.

The TME is comprised of tumor cells, extracellular matrix, tumor vasculature, cancer-associated fibroblasts, mesenchymal stromal cells and the surrounding blood vessels which support tumor growth. The tumor stroma provides a lifeline necessary for tumor growth in solid tumors. The tumor stroma plays a major role in the initiation, growth, survival, invasion and drug-resistance of solid tumors, yet few therapeutics specifically target tumor-associated stroma. The stroma also forms an effective barrier to entry for therapeutic agents such as chemotherapy. Therapies that target the stroma may provide a new therapeutic area for patients.

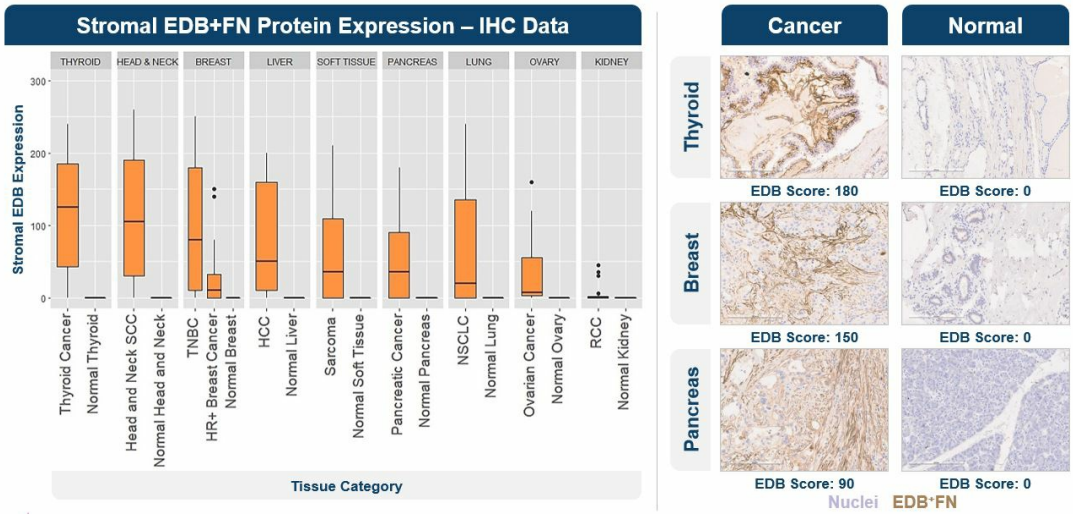
Fibronectin is a key component of the ECM and its downstream signaling pathways regulate cell adhesion, migration, differentiation, and wound healing. EDB+FN is an alternatively spliced form of fibronectin that occurs when ribonucleic acid, or RNA, is re-arranged to produce multiple variants of the same protein and accumulates around blood vessels within the tumor stroma. EDB+FN is typically only spliced during embryogenesis and is rarely found in healthy adult tissues. However, cancer cells take advantage of EDB+FN's ability to promote neo-vasculature structures, which are critical to feeding and supporting the uncontrolled growth of a tumor. As a result, EDB+FN is highly expressed in many solid tumors and has low expression in normal adult tissue.

EDB+FN within tumor stroma meets our criteria of a highly desirable ADC target due to its strict preferential expression in tumor tissue and its role as a driver of the poor prognosis in the treatment of many cancers. Because of this high differential expression, we believe EDB+FN may be an ideal target to address in many cancers with high unmet need given that tumors with stromal barriers may be underserved by currently available therapies.

EDB+FN is overexpressed in a variety of cancers, including, but not limited to, cancers of the lung, breast, ovary, pancreas, head and neck, thyroid, and brain. *In vitro* studies have shown that down regulation of EDB+FN resulted in a significant reduction in cancer motility. Furthermore, EDB+FN expression is maintained in distal metastasis in human cancer.

EDB+FN protein expression is also upregulated in the stroma of many tumor types, as compared to normal adult tissue (refer to Figure 6).

Figure 6

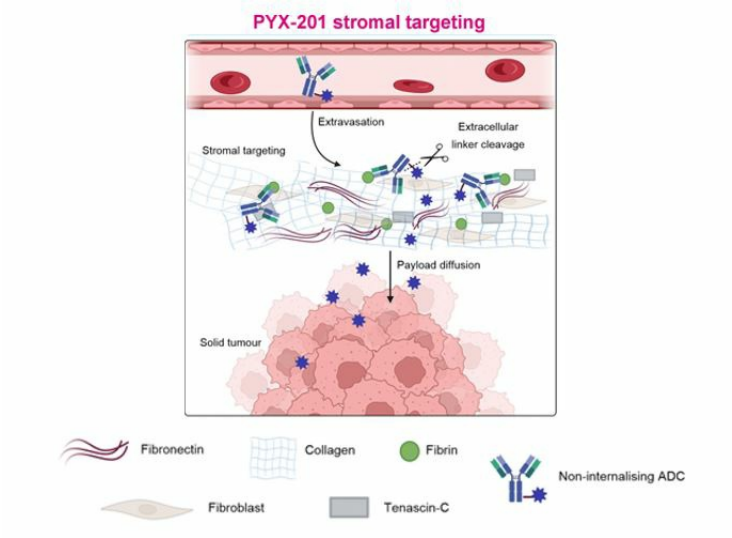


IHC analyses show that EDB+FN protein is upregulated in tumor stroma and is highly expressed in many solid tumors, with low expression in normal adult tissue.

Mechanism of Action for PYX-201

PYX-201 was developed using the FACT Platform to produce an ADC designed to be highly stable and target a predictable DAR of four. The complementarity-determining regions, or CDRs, of the EDB antibody used in PYX-201, which is the part of the antibody responsible for binding to EDB, is well characterized and has been tested clinically in the form of a radio-conjugated antibody for tumor imaging—demonstrating a high degree of tumor-directed specificity. Furthermore, PYX-201 is designed to optimize linker stability to enable delivery of the next generation auristatin payload that can be cleaved, released in the stroma and penetrate through the tumor cell membrane to kill tumor cells directly without the need of cell surface antigen-mediated internalization of the ADC. Unlike conventional ADCs which bind to the tumor cell surface antigens, PYX-201 is designed to deliver the auristatin payload to the TME and released the free payload to kill tumor cells as well as the tumor stroma cells such as activated fibroblasts and vascular endothelial cells. The mechanism of action for PYX-201 is illustrated in Figure 7 below.

Figure 7



PYX-201 is designed to exhibit anti-tumor activity through three distinct modes of action,

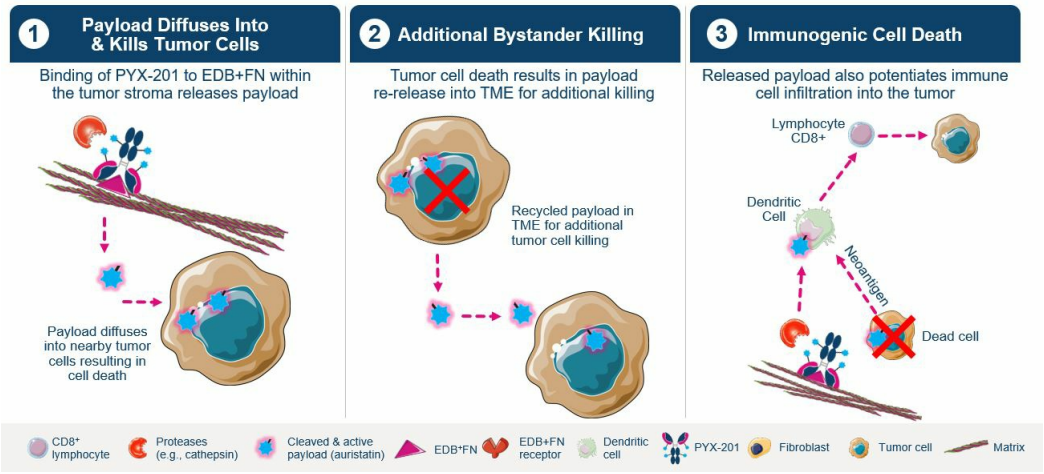
1.Tumor killing activity: After binding to EDB+FN within the tumor stroma, proteases which are aberrantly overexpressed in and secreted by invasive and metastatic cancers, cleave the linker enabling the cell-permeable auristatin toxin to kill the tumor cells. Releasing the payload from the killed tumor cells may also confer added cytotoxicity via bystander activity.

2.Effect on tumor stroma: Releasing the payload extracellularly within the TME may also kill the activated fibroblasts, vascular endothelial cells and other tumor stroma cells leading reduction of stroma density and inhibition of tumor angiogenesis.

3.Immunogenic cell death: Lastly, auristatin has been shown in preclinical models to attract immune cells such as T cells into TME possibly through immunogenic cell death, which initiate an anti-tumor immune response.

Taken together, we believe that PYX-201 may generate a multi-pronged attack on difficult-to-treat cancers by killing cancer cells, reducing stroma density, inhibiting tumor angiogenesis and mobilizing an anti-tumor immune response (as illustrated in Figure 8 below).

Figure 8



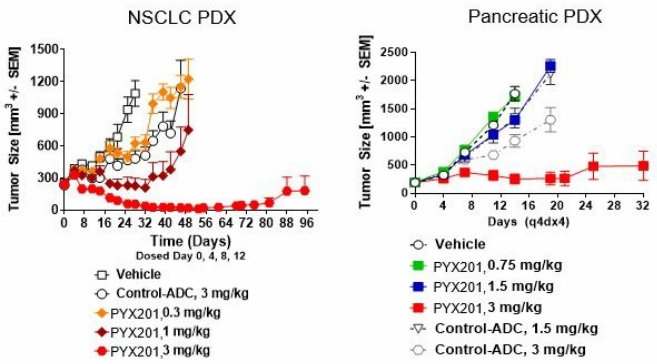
PYX-201 is designed to bind EDB+FN in the surrounding stroma to kill tumor cells and the supporting infrastructure through direct payload-induced killing of tumor cells and triggering immune cell infiltration into TME based on data from preclinical models.

Preclinical Development

PYX-201 has shown promising preclinical results. In preclinical studies, we have observed strong *in-vivo* activity in NSCLC PDX and pancreatic PDX models, as well as EMT-6 syngeneic mouse breast cancer models. PDX mouse models are generated by grafting patient derived cells into immune deficient mice, whereas syngeneic mouse models are grafted with tumors derived from mice which allows the immune system to remain intact. While PDX models provide the most clinically translatable signals of efficacy in a preclinical setting, syngeneic models allow us to assess the ability of PYX- 201 to generate an immune response. These syngeneic models show that PYX-201 effectively localizes to cancers and can generate not only significant reductions in tumor burden but can also mobilize an anti-tumor immune response.

For example, in PDX models of NSCLC and pancreatic cancer, PYX-201 was intravenously administered four days apart for twelve days and a dose-dependent regression in tumor burden and a durable response at 3 mg/kg was observed (Figure 9).

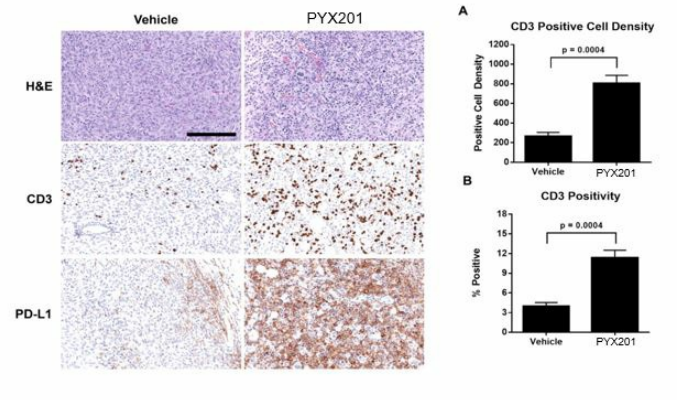
Figure 9



PYX-201 has been shown to be highly active in PDX models of NSCLC and pancreatic cancer.

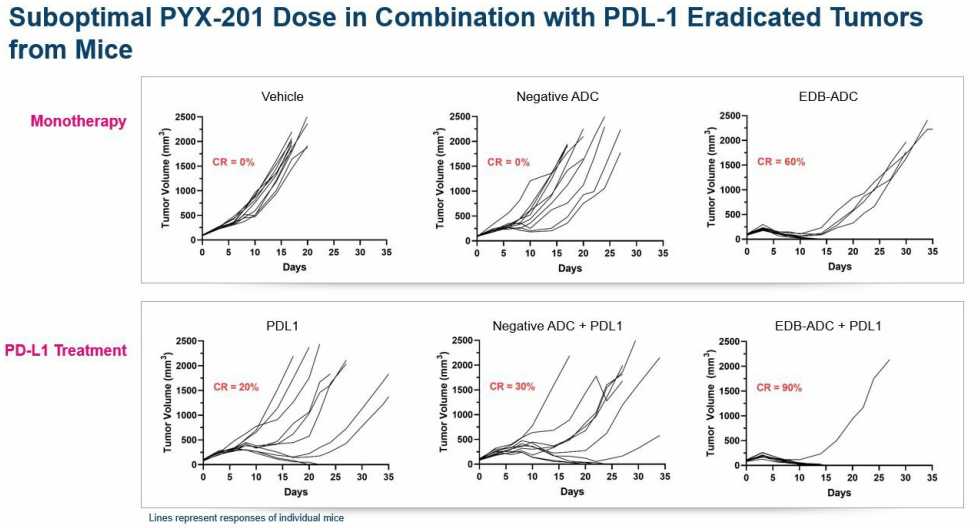
The anti-EDB human mAb used in PYX-201 is cross-reactive with mouse EDB+FN. As a result, in syngeneic tumor models conducted in immune competent mice, PYX-201 achieved a durable response with a single dose of 9 mg/kg (Figure 10). In preclinical studies, we observed increased infiltration in CD3 T cells and upregulation of PD-(L)1, which suggests that PYX-201 may be capable of inducing immunogenic cell death. Combining sub-optimal doses of PYX-201 with checkpoint therapy resulted in synergistic inhibition of tumor growth in the EMT-6 model. Consequently, we believe PYX-201 may synergize with checkpoint inhibitors, as shown in Figure 11. PYX-201 was also well-tolerated in our mouse models and toxicology studies conducted in rat and cynomolgus monkeys. In an exploratory toxicology study in cynomolgus monkeys the HNSTD was found to be greater than 12 mg/kg with three doses of PYX-201 administered every three weeks. There was no differential in body weight or food consumption detected and based on the types of toxicities observed (i.e., no fibrosis, neuropathology etc.), all toxicities are reversible, or are expected to be reversible. PYX-201 was observed to have a preclinical relevant TI of 16 (the HNSTD in monkeys was 144 mg/m2 and was 16 times greater than the dose required for a complete response in mice of 9 mg/m2), which we believe is promising based on our experience investigating the relative TI among different ADC constructs.

Figure 10



PYX-201 treatment in vivo of syngeneic cell-derived tumor models has been associated with enhanced T cell infiltration based on increased CD3 positivity. (CR: complete response; rcEDB: Reverse Chimeric EDB)

Figure 11

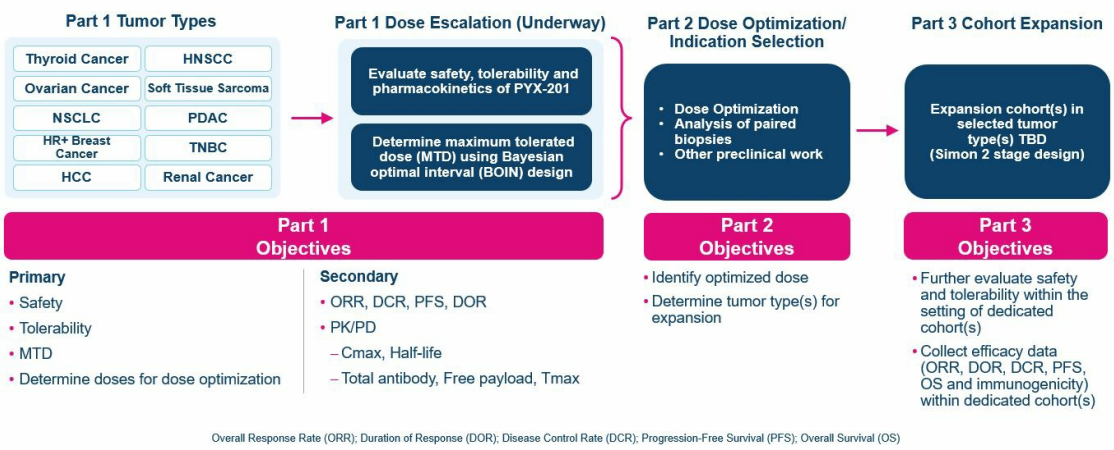


EDB vc0101 ADC combines with anti-PD-(L)1 to synergistically reduce tumor growth in EMT6 mouse syngeneic model.

Clinical Development

In December 2022, we announced clearance of our IND, by the FDA, to initiate a Phase 1 clinical trial. During the first quarter of 2023, we announced dosing of the first subject in a Phase 1 trial of PYX-201, referred to as PYX-201-101. PYX-201-101 is an open-label, multicenter, dose-escalation trial. As illustrated below in Figure 12, the Phase 1 monotherapy dose escalation trial is designed to evaluate the safety, tolerability, pharmacokinetics, pharmacodynamics, and preliminary efficacy of PYX-201, to identify a biologically active doses for cohort expansion and identify recommended doses for further study. Patients with relapsed or refractory solid tumors, including NSCLC, locally advanced/metastatic breast cancer, HR- HER2-, HR+ HER- and HR- HER2+ breast cancers, TNBC, ovarian cancer, thyroid cancer, PDAC, STS, HCC, HNSCC, and kidney cancer are eligible to enroll in this study. We may also pursue the development of PYX-201 as a combination therapy with the standard of care as appropriate in future studies. For example, in NSCLC and breast cancer, where immunotherapy is widely used in both first- and second-line settings, we believe PYX-201 may provide a synergistic treatment benefit since the auristatin payload has been observed in preclinical studies to trigger hallmarks of immunogenic cell death. Information on this clinical trial is available on ClinicalTrials.gov (NCT05720117).

Figure 12

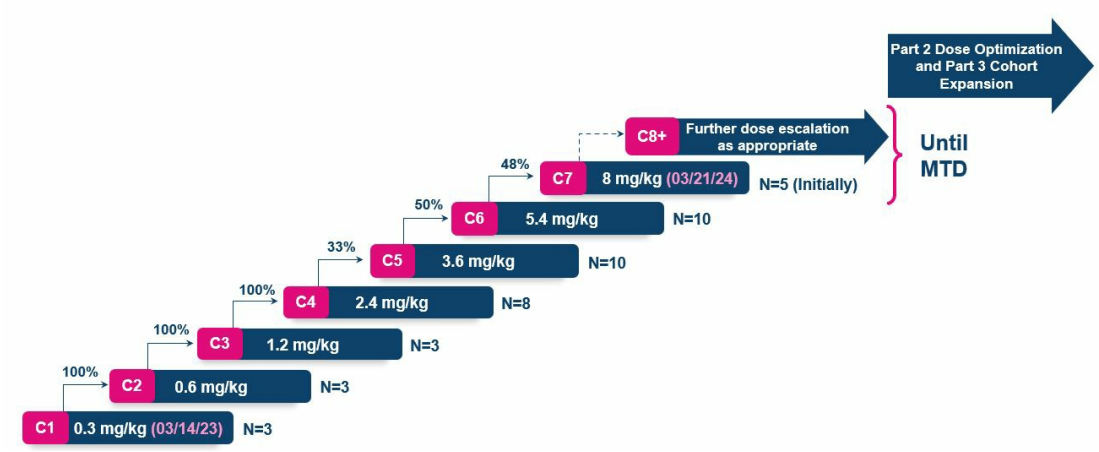


In the Phase 1 portion of the trial, the starting dose of PYX-201 was 0.3 mg/kg. The DESC approved escalating the dose after each cohort. PYX-201 is administered once every three weeks. Dose escalation follows the BOIN design until the RP2D is determined.

To date, 37 subjects in six cohorts have been dosed with PYX-201 in this Phase 1 trial. PYX-201 recently cleared the 21-day DLT observation period for ten subjects in Cohort 6 at a dose of 5.4 mg/kg. The DESC met on March 19, 2024, and voted to escalate dosing into Cohort 7 at a dose of 8 mg/kg and we are now enrolling subjects in Cohort 7 at this dose. PYX-201 has been well tolerated to date, with no significant evidence of target mediated toxicities experienced by the 37 subjects enrolled and dosed to date. Approximately 54% of subjects have experienced grade 2, and 6% of subjects have experienced grade 3 TEAEs. No subjects have reported TEAEs leading to dosing delay or study drug discontinuation. We anticipate enrolling and dosing another 10-15 subjects at Cohort 7 with a dose of 8 mg/kg or future higher dose level cohorts, should PYX-201's profile continue to support further dose escalation.

The dose escalation and number of subjects enrolled and dosed to date with PYX-201 in the PYX-201-101 trial, for each cohort since initiating the trial in March 2023, are provided in Figure 13 below.

Figure 13



As we continue to analyze the data generated, we anticipate that the data from the dose finding studies will guide the selection for the RP2D for subsequent multi-dosing and potential combination studies. We believe the encouraging PYX-201 safety profile observed to date likely reflects the specificity of target expression within tumor tissue and the potential for a wider TI given the novel mechanism of action within the TME. We anticipate reporting efficacy, safety, and PK/PD data from this Phase 1 clinical trial, in the fall of 2024. We also anticipate reporting pre-clinical insights along with the plan for the next phase of development at that time.

Immuno-Oncology Programs

Background on Current Immuno-Oncology Therapeutics

The advent of immuno-oncology therapeutics, particularly immune checkpoint inhibitors, has shifted the treatment paradigm for oncology. The immune system has the capability to recognize and eliminate cancer, but tumor cells take advantage of immune checkpoint pathways, which normally prevent autoimmunity, to suppress and evade immune effector cell activity. The first generation of drugs that interrupt these pathways, including PD-(L)1 and cytotoxic T-lymphocyte associated protein 4, or CTLA-4, inhibitors, has generated significant enthusiasm due to their ability to achieve durable responses in some patients. While these drugs provide significant therapeutic benefits for durable responders, response rates remain low for most patients, particularly for tumors with low levels of T-cells infiltrating the tumor. These non-inflamed (i.e., “cold”) tumors can suppress the adaptive immune response through a variety of mechanisms within the TME.

Immuno-Oncology Programs Overview

We have monoclonal antibody programs that address critical immunomodulatory pathways within the TME and are exploring additional potential targets.

PYX-106: Investigational IgG1 anti-Siglec-15 Targeting Antibody

Overview

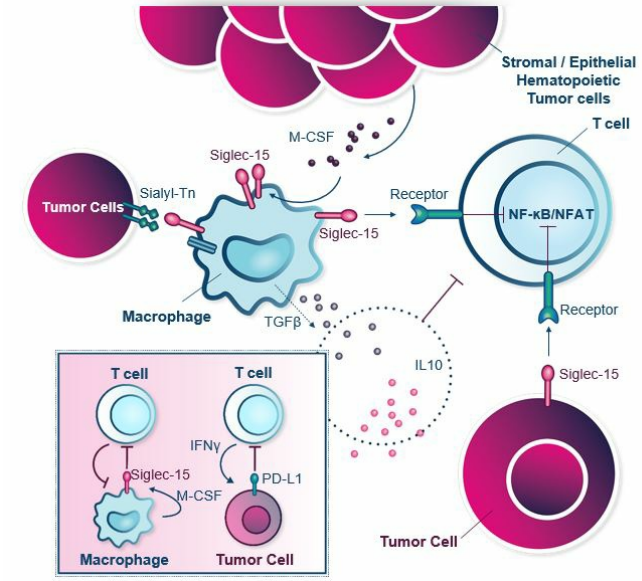
PYX-106 is an investigational fully human IgG1 antibody that is designed to block Siglec-15 mediated suppression of T-cell proliferation and function. PYX-106 aims to address critically important tumor infiltrating immune cell populations, such as macrophages, T cells, and natural killer, or NK cells, which may play crucial roles in limiting tumor growth and metastasis. In addition to singling out specific cell types, we believe PYX-106 may also address mechanisms responsible for T cell exhaustion and the immunosuppressive effects of the TME on T and NK cells. We believe that our in-licensed anti-Siglec-15 mAb, PYX-106, has the potential to provide additional benefit to cancer patients either alone or in combination with other therapies, including other immuno-therapies. PYX-106 is in the clinical development and being evaluated in an ongoing Phase 1 clinical studies in multiple types of solid tumors, including non-small cell lung cancer without driver mutations/translocations, breast cancer, endometrial cancer, thyroid cancer, kidney cancer, cholangiocarcinoma, bladder cancer, colorectal cancer, and head and neck squamous cell carcinoma. We licensed worldwide rights other than in Greater China (mainland China, Hong Kong, Macau and Taiwan) to PYX-106 from Biosion.

Rationale for Targeting Siglec-15 and Mechanism of Action for our Siglec-15 targeting antibody

Siglec-15 is a member of the Siglec family (Sialic acid-binding ImmunoGlobulin Lectins), a distinct subgroup of immunoglobulin, or Ig, superfamily proteins involved in immune regulation. Siglecs recognize and bind to sialic acid on the surface of cells and this binding can affect cell signaling on immune cells. Siglec-15 is a single-pass type I membrane protein that has been shown to associate with the activating adaptor proteins DNAX activation protein (DAP)12 and DAP10 via its lysine residue in the transmembrane domain, implying that it functions as an activating signaling molecule. While Siglec-15 is minimally expressed on normal tissues, it is highly expressed on both tumor cells and M2 macrophages in the TME across multiple tumor types, including thyroid cancer, HNSCC, lung cancer, breast cancer and cholangiocarcinoma. The increased presence of highly immunosuppressive M2 macrophages within tumors leads to impaired T cell proliferation and function, causing a decreased anti-tumor immune response. Additionally, Siglec-15 may exacerbate this immunosuppressive effect by interacting with tumor associated myeloid cells to promote their survival and differentiation to drive a tumor-promoting environment. Interestingly, Siglec-15 appears to function independently from the PD-L1 pathway with expression observed not to be mutually exclusive across tumor types. Instead, expression of Siglec-15 and PD-(L)1 genes vary broadly within tumor types. While Siglec-15 and PD-L1 expression have been observed to be positively correlated in certain tumor types like NSCLC, head and neck, kidney and thyroid cancer, they are rarely observed co-expressed on the same cell. Therefore, we believe targeting Siglec-15 in the TME may offer a promising therapeutic option for patients less likely to respond to a PD-1/PD-(L)1 targeted therapy.

An overview of the role of Siglec-15 in regulating the immune system and driving anti-tumor immune dysfunction is depicted in Figure 14 below.

Figure 14

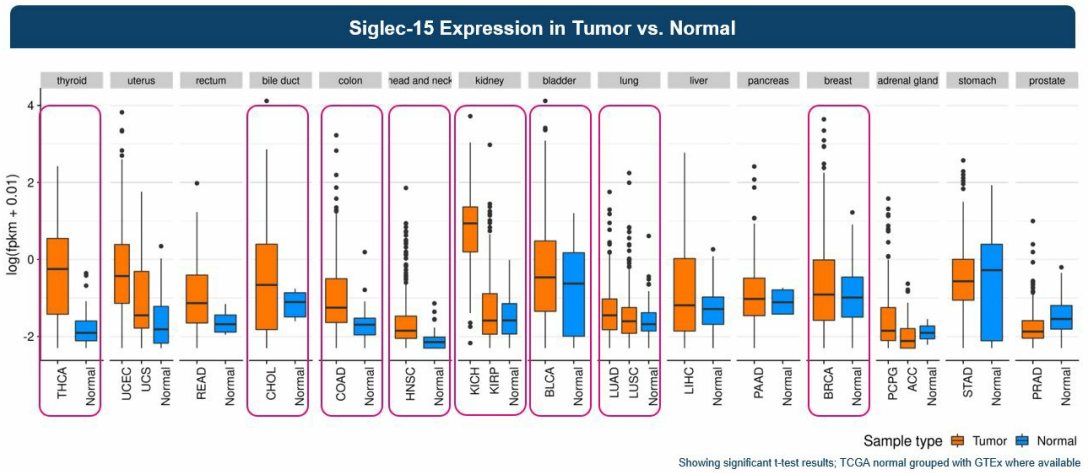


Source: Sun et al., Clin Cancer Res 2021; Wang et al., Nat Med 2019

Our Siglec-15 targeting antibody is a fully human monoclonal antibody and is engineered with high affinity to block Siglec-15 induced immune suppression and therefore restore T cell proliferation, function, and anti-tumor immunity in the TME. Overall, by binding and blocking Siglec-15 activity on myeloid cells and tumors, we believe our Siglec-15 targeting antibody is designed to enhance immune cell mediated tumor cell killing. PYX-106 has high binding affinity to a unique epitope and high potency. Given the broad tumor expression profile of Siglec-15, our Siglec-15 targeting antibody has the potential to treat multiple oncology indications including those where PD-1/PD-(L)1 directed cancer therapies are ineffective.

Expression data for Siglec-15 RNA in tissues where tumor expression was significantly higher than normal tissue expression are depicted in Figure 15. Of the indications tested, NSCLC, breast cancer, uterine cancer, thyroid cancer, kidney cancer, cholangiocarcinoma, bladder cancer, colorectal cancer, and sarcoma all show higher expression of Siglec-15 in tumor compared to normal samples. The low expression of Siglec-15 across the range of normal tissues tested suggests limited potential for effects in nontumor tissues of therapies targeting Siglec-15. Significantly higher expression in most tumor types indicates that patients with such tumors may respond to anti-Siglec-15 antibody treatment.

Figure 15



Siglec-15 RNA is broadly expressed across a range of solid tumors with overall lower expression observed in normal tissue.

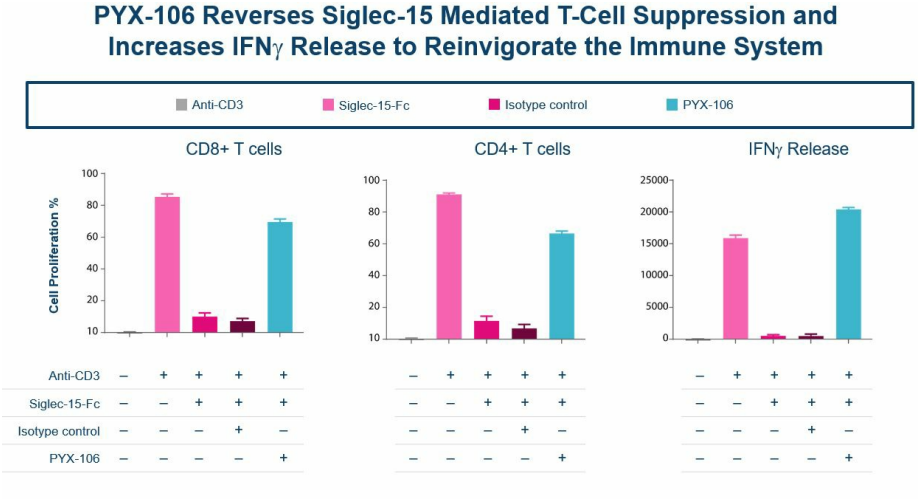
Preclinical Development

Blocking Siglec-15 with an antibody such as PYX-106 may overcome the immunosuppressive TME and enhance the anti-tumor activity of other immune checkpoint inhibitors. We have conducted a preclinical study in various animal models to evaluate the effect of blocking Siglec-15 and our observed results provide sufficient scientific rationale in both *ex vivo* and *in vivo* studies. PYX-106 was observed as well tolerated in preclinical studies with no evidence of anti-drug antibodies.

In an *in vivo* mouse syngeneic tumor model, PYX-106 demonstrated significant inhibition of tumor growth when administered at 15 mg/kg twice weekly for 6 weeks compared to the control group. PYX-106 resulted in an approximately 60% decrease in tumor volume at doses of 5 mg/kg and 15 mg/kg, with the decrease reaching statistical significance in the later dose group. Moreover, the inhibition of tumor growth was not accompanied by any changes in behavior, body weight, or spleen weight within the mice.

In an *ex vivo* study using normal human peripheral blood mononuclear cells, or PBMCs, which are blood cells that are considered critical components in the immune system, PYX-106 was able to reverse Siglec-15-mediated suppression of T cell proliferation and interferon-gamma, or IFN-γ, secretion. The numbers of CD4+ and CD8+ T cells and secretion of IFF-γ were increased substantially while the negative control antibody had no effect on the suppression of proliferation. The effects of a single concentration of anti-Siglec-15 antibodies on T-cell proliferation using PBMCs are shown in Figure 16. The addition of the anti-CD3 antibody led to proliferation of both CD4+ and CD8+ T cells, which was reduced by addition of Siglec-15. The addition of the negative control antibody had no effect on this suppression of proliferation. PYX-106 reversed this suppression. In our preclinical studies, PYX-106 was observed to have 7 days of half-life in monkeys. If the half-life of 7 days were observed in humans, then it would allow for less frequent dosing, maintain exposure and target engagement.

Figure 16



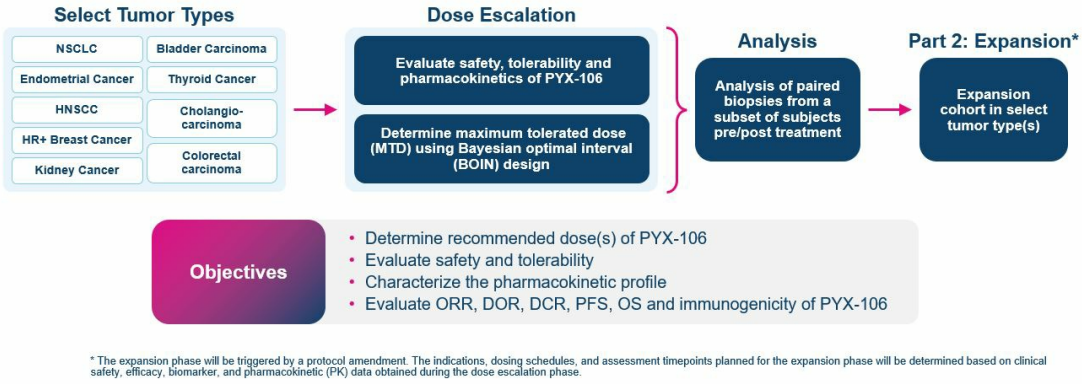
In an ex vivo assay using PBMCs, from normal healthy donors, PYX-106 reverses Siglec-15 mediated T cell suppression and upregulates IFN-γ release.

Clinical Development

In December 2022, we announced clearance of our IND by the FDA for PYX-106 to initiate a Phase 1 clinical trial. During the first quarter of 2023, we began activating clinical trial sites and are currently enrolling and dosing patients in the Phase 1 trial, referred to as PYX-106-101. PYX-106-101 is a first-in-human, Phase 1, multicenter, open-label dose escalation trial designed to evaluate the safety, tolerability, pharmacokinetics, pharmacodynamics, and preliminary efficacy of PYX-106 in patients with relapsed or refractory solid tumors. This Phase 1 monotherapy dose escalation trial includes patients who have developed solid tumors and disease progression through standard therapy and patients for whom standard of care therapy that prolongs survival is unavailable or unsuitable. Patients with solid tumors including non-small cell lung cancer without driver mutations/translocations, breast cancer, endometrial cancer, thyroid cancer, kidney cancer, cholangiocarcinoma, bladder cancer, colorectal cancer, and HNSCC are eligible to enroll in this study.

Information on this clinical trial is available on ClinicalTrials.gov (NCT05718557).

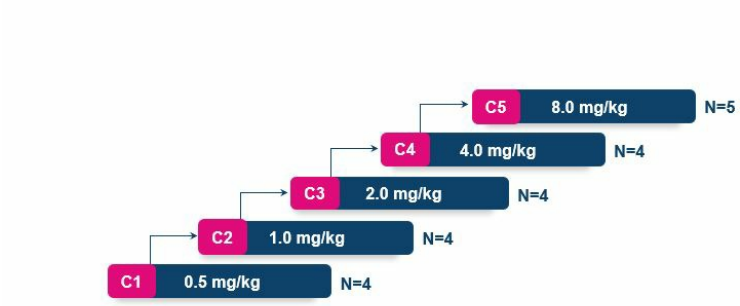
Figure 17



In the Phase 1 portion of the trial, the starting dose of PYX-106 was 0.5 mg/kg. The DESC approved escalating the dose after each cohort. We are currently dosing subjects in Cohort 5 at a dose of 8 mg/kg and Cohort 5 is fully enrolled. To date, 21 subjects have been dosed with PYX-106 in the Phase 1 trial. PYX-106 is administered once every two weeks. Dose escalation will follow the BOIN design until the RP2D is determined.

The dose escalation and number of subjects enrolled and dosed to date with PYX-106 in the PYX-106-101 trial, for each cohort since initiating the trial in May 2023, are provided in Figure 18 below.

Figure 18



We anticipate reporting preliminary data from this Phase 1 clinical trial, including PK/PD data and early signs of potential clinical activity, in the second half of 2024.

PYX-107: Humanized CD40 Agonist Antibody

On August 23, 2023, we completed the previously announced acquisition of Apexigen. The Merger expanded our existing pipeline with the addition of sotigalimab (now PYX-107), a CD40 agonist with demonstrated anti-cancer activity in patients who previously progressed on PD-(L)1 inhibitors.

Overview

Activation of CD40 initiates and amplifies a multi-cellular immune response, bringing different components of both the innate and adaptive arms of the immune system to work in concert and resulting in increased antigen presentation, maturation of DCs and activation of CD4+ and CD8+ T cells, NK cells and neutrophils to attack tumor cells.

PYX-107 is a CD40 agonist antibody designed to maximize its agonistic properties through:

•Unique epitope specificity to mimic the binding of CD40 ligand, or CD40L, to the CD40 receptor binding site for increased potency;

•An engineered Fc to increase binding to Fc gamma receptor 2B, or FcgRIIB, to increase antibody cross-linking and antitumor potency; and

•An engineered FC to reduce binding to Fc gamma receptor 3a, or FcgRIIIa, to eliminate antibody-dependent cell-mediated cytotoxicity, or ADCC, effects on CD40-expressing APCs.

We believe that PYX-107's ability to stimulate both innate and adaptive immunity enhances tumor infiltration of immune and proinflammatory cells such as M1 macrophages and T cells and immune stimulatory cytokines such as interferon-g. Tumors with an inflamed phenotype tend to be more responsive to anti-cancer therapies. We therefore believe PYX-107 has potential applicability across a variety of tumor types with high unmet need and may combine well with and enhance the efficacy of other immuno-oncology agents, targeted therapeutics, chemotherapies, vaccines and radiation therapy to improve outcomes for patients.

Clinical Development

PYX-107 is in Phase 2 clinical development for the treatment of solid tumors such as soft tissue sarcomas, esophageal and gastroesophageal junction, or GEJ, cancers and melanoma in combination with chemotherapy, radiation therapy and immunotherapy. The FDA has granted ODD for PYX-107 in the treatment of soft tissue carcinoma, esophageal and GEJ cancers, and PDAC.

To maximize the therapeutic potential of PYX-107, Apexigen initiated several Phase 2 trials across multiple important cancer indications, lines of therapy and combination settings, all of which we have the opportunity to advance. The clinical development of PYX-107 will be further assessed as part of portfolio evaluation.

The APX005M-009 Trial is a multi-center, investigator-sponsored Phase 2 clinical trial (NCT03719430) of PYXS-107 in combination with doxorubicin in patients with advanced soft tissue sarcoma. The trial completed enrollment of the originally planned 32 patients in January 2023. We observed a median progression-free survival, or mPFS, of 12.45 months (data as of September 27, 2022) in the evaluable patients (n=10) with advanced/unresectable or metastatic de-differentiated liposarcoma, or LPS. Based on the mPFS observed in these LPS patients, which is meaningfully higher than the historical mPFS of patients with LPS who are treated with standard-of-care doxorubicin alone, we and our collaborator, Columbia University, decided to expand the LPS cohort to enroll 10 additional patients with LPS to supplement the data we have observed and potentially inform a registration-enabling study in de-differentiated LPS. The primary endpoint for the study is objective response rate, with a secondary endpoint of progression free

The APX005M-002 Trial studies PYX-107 in combination with nivolumab, an anti-PD-1 antibody, in subjects with unresectable or metastatic melanoma that had progressive disease, or PD, during treatment with anti-PD-(L)1 therapy as one arm of a multi-indication trial. The study (NCT03123783) was a Phase 1-2 open-label dose escalation study. In the Phase 2 portion of the trial, which was completed in November 2020, 38 patients with anti-PD-(L)1 refractory metastatic melanoma were enrolled and evaluable for safety and 33 of these patients were evaluable for efficacy. Of the efficacy-evaluable patients, 14 (42%) had elevated levels of lactate dehydrogenase, or LDH, at baseline, a poor prognostic indicator of response to PD-(L)1 blockade therapy, seven (21%) had received two or more prior lines of therapy and eight (24%) had previously been treated with an anti-CTLA-4 antibody.

There were five partial responses, or PRs, in the trial for an overall response rate, or ORR, of 15.2% and ten patients with stable disease, or SD, (30.3%). The duration of response, or DoR, as determined in the trial ranged from 4.1+ to 24.7+ months, and was measured from the first documented PR to the earlier of the date of progression or the last imaging study prior to the end of the trial even if the patient was in an ongoing PR. Four of the responding patients remained in an ongoing PR at the completion of the trial, after which we ceased following and monitoring these patients for progression. The fifth responding patient developed an isolated brain lesion approximately nine months after stopping combination therapy (DoR of approximately 18.7 months), subsequently received radiation therapy for the brain lesion, and did not require any further local or systemic therapy through the end of the trial. The duration of SD was up to 14.0+ months and the majority of patients with SD had a duration of SD lasting longer than 3.5 months. These data suggest that treatment with PYX-107 in combination with nivolumab resulted in clinical benefits in PD-1 blockade refractory patients by achieving durable objective tumor responses and stable disease.

In the APX005M-002 Trial, we observed that the combination of PYX-107 and nivolumab could be administered to patients with anti-PD-(L)1 refractory melanoma repeatedly for greater than one year with an acceptable safety profile. The majority of adverse events, or AEs, considered related to PYX-107, nivolumab or the combination were transient and grade 1 or 2. The incidence of immune-related adverse events was low, and the AEs were similar in nature to those that have been reported with nivolumab alone. There were no reported cases of cytokine release syndrome.

The APX005M-006 Trial was a pilot Phase 2 clinical trial studying PYX-107 in combination with standard-of-care chemoradiation as a neoadjuvant treatment for patients with respectable esophageal or GEJ cancer (NCT03165994), which was completed in February 2024. Thirty-four patients were enrolled in the trial. The primary objective of the APX005M-006 Trial is to assess the efficacy of the combination, as measured by the pathologic complete response, or pCR, rate, and to further characterize the safety and feasibility of the combination in this setting.

APX005M-006 Trial showed that PYX-107 combined with neoadjuvant chemoradiation for esophageal and GEJ cancers was generally safe and well tolerated. The majority of patients treated in the trial had Grade 1-2 AEs. Six serious AEs considered at least possibly related to PYX-107 included cytokine release syndrome observed in three patients, nausea and vomiting in one patient, dysphagia in one patient and Guillain-Barre Syndrome in one patient. There were no patient withdrawals due to PYX-107 and no deaths related to the combination. As of July 2022, of the 29 evaluable patients, 11 (38%) patients had a pCR and 19 (66%) patients had a major pathological response, or mPR, with less than 10% of the residual tumor remaining after treatment. By histology, the pCR rate was 33% (8/24) in patients with adenocarcinoma and 60% (3/5) in patients with squamous cell carcinoma. The pCR rate was 41.2% for patients (n= 17) receiving four doses of PYX-107 versus 33.3% for patients (n= 12) receiving three doses. The R0 resection was achieved in 86% (25/29) of the patients and progressive disease was only 7%. Paired biomarker analysis collected before and one to two weeks following a single run-in dose of PYX-107 alone demonstrated significantly increased tumor infiltration of activated dendritic cells, monocytes and both CD8 and CD4 T cells compared to baseline. We believe that the observed immune/inflammatory response in the tumor demonstrates the ability of PYX-107 to change the tumor immune microenvironment from “cold” to “hot”, which we believe validates PYX-107’s mechanism of action.

Preclinical Programs Available for Partnership or Collaboration

We also have certain preclinical programs that we have chosen not to move into the clinic. The decision to pause these preclinical development efforts allowed us to refocus development efforts and resources towards clinical development of PYX-201 and PYX-106. We are seeking partnership opportunities for these program that maximizes potential value for patients and for our shareholders.

ADC Program

PYX-203 is an investigational ADC the targets and binds to the interleukin-3 receptor, also known as CD123, a rapidly internalizing target that is overexpressed in hematologic cancers by leukemic blasts and stem cells. After internalization, its highly potent cyclopropylpyrroloindoline, or CPI, payload is enzymatically released and trafficked to the nucleus, where it crosslinks DNA. CPI is engineered for enhanced tolerability and may allow PYX-203 to reach a broader patient population. CPI is resistant to drug efflux pumps and could confer superior cancer-killing activity. The antibody is also engineered to have a modified Fc region to mitigate off-tumor toxicity.

IO Programs

PYX-102 is an investigational immune-therapeutic that targets killer cell lectin-like receptor subfamily G member 1, or KLRG1, an inhibitory receptor expressed on T cells and NK cells. Its ligands, E- and N-cadherin are expressed in numerous solid cancers. By blocking KLRG1 signaling, PYX-102 may relieve immune inhibition in these tumors while rescuing KLRG1-mediated suppression of human CD8+ T cells. PYX-102 has significant potential as a monotherapy and in combination treatment strategies.

We also acquired certain preclinical programs, which were generated using the APXiMAB Platform, as part of the Merger. The development of these programs were previously paused by Apexigen.

- **APX601:** APX601 is a TNFR2 antagonist antibody designed to reverse immune suppression in the TME and unleash immune-mediated tumor killing activity through a unique mechanism of action. APX601 may deplete and inactivate TNFR2-expressing Tregs, reverse myeloid-mediated T cell suppression and directly kill TNFR2-expressing tumor cells. In preclinical models, APX601 has demonstrated anti-tumor activity and may have applicability for the treatment of multiple tumor indications of unmet medical need. The IND-enabling work for APX601 has been completed, prior to the Merger.

- **APX701:** APX701 is a novel anti-SIRPα antibody designed to enhance anti-tumor immunity by reactivating critical tumor clearance mechanisms within the TME currently at the pre-clinical stage.

- **APX801:** APX801 is an NK cell engager designed to specifically activate natural killer cells leading to effective killing of tumor cells currently at the pre-clinical stage.

Technology Platforms

FACT Platform

We are developing next-generation ADCs using customized linker-payload combinations that are novel and supported by the preclinical data and site-specific conjugation techniques derived from the FACT Platform. We believe that these payloads and linkers could be readily applied to any IgG1 antibodies using our site-specific conjugation techniques to efficiently develop novel product candidates. We believe that the site-specific conjugation techniques and ADC technology which underpin the FACT Platform enable us to develop next-generation ADCs with more favorable drug properties than traditional technologies based on preclinical studies.

We believe that the FACT Platform provides a toolkit of novel and validated payloads, cleavable and non-cleavable linkers, and a strong understanding of optimized conjugation sites. The FACT Platform provides the basis for our lead ADC product candidate, PYX-201 and will underpin our development of future ADCs that we believe are optimized for, and guided by the following design elements:

- **ADC cytotoxicity**. Target tumor cells require delivery of a certain threshold of payload molecules based on the payload's biochemical properties to induce cell killing at specific dose levels. Our ADC programs are designed to provide anti-tumor cytotoxicity and, as applicable, immunogenic cell death based on data from preclinical models.

- **Plasma stability and maintenance of the linker-payload**. ADCs must be optimized for systemic circulation to prevent premature linker cleavage or release of the linker-payload construct in the blood plasma that can result in off-target toxicity. We are designing our ADC candidates to optimize for stability when in circulation *in vivo* to avoid premature cleavage and support maximal payload delivery to the target site.

- **Efficient proteolytic cleavage of the linker for payload release**. The timing and rate of linker cleavage is important for achieving optimal delivery and release of a specific payload at the target site. We believe that we have the capability to utilize both cleavable and non-cleavable linkers to achieve potential therapeutic effects that are optimized for individual payloads and targets.

- **High target specificity**. Our ADC programs are founded on the identification of promising tumor targets and developing highly specific antibodies against these tumor targets. We draw upon our empirical understanding of site-specific conjugation sites and linker-payload toolkit to select combinations that we believe are well-suited for individual targets.

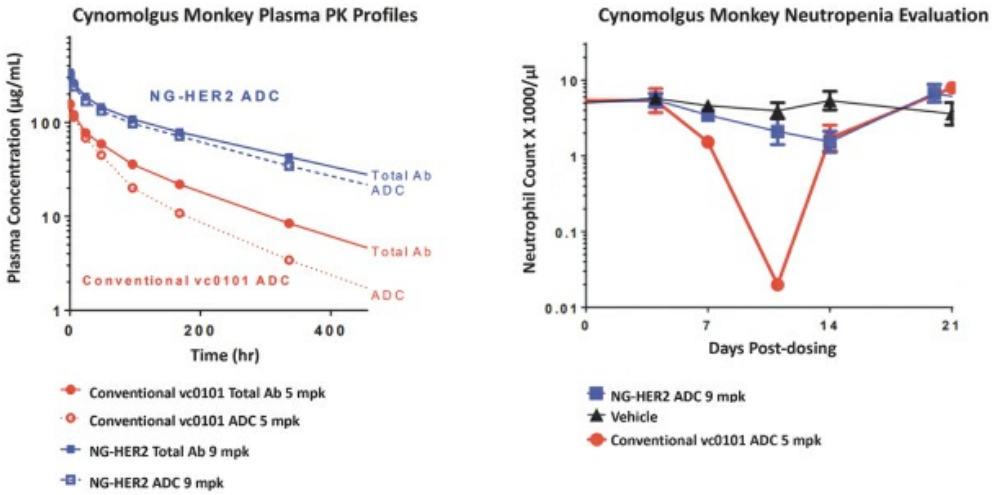
- **Defined and target specific DAR.** Intrinsic to the FACT Platform and conjugation techniques is the development of products with a consistent DAR, which we believe may enable us to develop a product with optimized stability, tolerability, and cytotoxicity.

We believe that the FACT Platform conveys several distinct advantages and flexibility in the development of our ADC candidates, including the following:

•**Improved anti-tumor activity in preclinical models with optimized conjugation sites for linker-payload combinations**. The FACT Platform is designed to select for optimal conjugation sites that are specific to each linker-payload combination. We employ site-specific conjugation techniques to conserved regions found within the antibody backbones that do not affect antigen binding or other normal antibody functional properties, such as Fc binding when appropriate, which we believe makes our conjugation technology broadly applicable to a wide variety of IgG monoclonal antibodies. Leveraging our diverse toolkit of improved and novel payloads, cleavable and non-cleavable linkers, and deep understanding of optimized site-specific conjugation sites, we have developed payload and linker combinations that can readily be applied to other antibodies in the same class. For example, our auristatin analogues, a potent microtubule inhibitor, and CPI, a highly potent DNA-cross-linking agent, have site-specific conjugation engineering with several linkers alongside IgG1 antibodies. These payloads and linkers could be readily applied to other IgG1 antibodies to efficiently develop novel product candidates.

•**Potential for improved TI and ADC stability**. We believe that our site-specific conjugation technology has potential to mitigate off-target liabilities of ADCs contributing to an enhanced plasma stability and enhanced TI. As shown in Figure 19, applying the FACT Platform to a well-established antibody, NG-HER2-ADC, to generate a model ADC was observed to mitigate toxicity and increase the TI and PK exposure and half-life of the ADC *in vivo*. The rate of linker cleavage and release of the linker/payload construct has been observed to be heavily dependent on the conjugation location and we optimize our linkers for both specific targets and payloads. As a result, we believe the FACT Platform and our empirical understanding of optimal site-specific conjugation may allow us to generate candidates against a broad set of targets that result in superior cell killing.

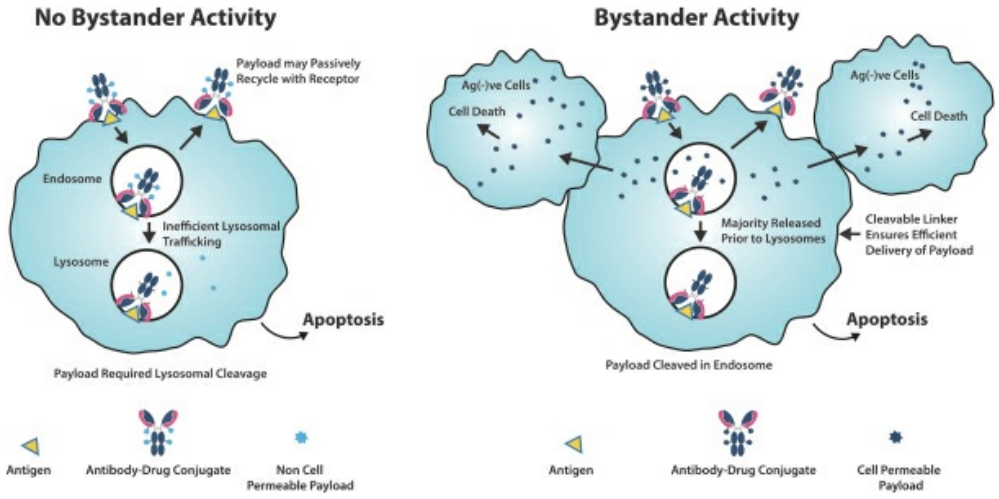
Figure 19



Comparison of stability and exposure in cynomolgus monkeys of Pfizer's NG-HER2-ADC using the same linker-payload and conjugation site chemistry as our PYX-201 ADC was observed to improve the stability and tolerability over conventional ADCs conjugated with the same linker-payload in preclinical studies (NG: next generation).

•**Enhanced anti-tumor activity through bystander activity.** As depicted in Figure 20 below, bystander activity occurs when payloads that are delivered to target cells diffuse into and kill neighboring cells in the TME and is of particular importance if the target is not uniformly expressed on all tumor cells. Bystander activity also has the potential to overcome resistance that may occur over time to treatment with ADCs, carrying non-bystander active payloads, as anti-tumor activity is not directly tied to antigen expression at the target site and destruction of a single target cell. We believe our toolkit of novel and validated payloads, linkers and site-specific conjugation techniques will allow us to further develop ADC candidates with bystander activity that may result in greater clinical activity, especially in cases with heterogeneous target expression.

Figure 20



The following table summarizes the potential advantages of our next-generation ADC platform that utilizes preclinically optimized payloads and site-specific conjugation compared to the currently approved ADCs using conventional conjugation:

	Pyxis Oncology's Next-Generation ADCs	Conventional ADCs
Potential Therapeutic Index	•8 – 16	•1 – 5
Conjugation Chemistry	•Site-specific conjugation leads to a more consistent drug product, more homogeneous DAR and high TI.	•Random attachment of payloads to an antibody leads to a more inconsistent drug product and variable DAR.
Linker	•Highly stable linkers designed to prevent premature release of payload.	•Many linkers are labile, resulting in premature release of payload and systemic toxicity.
Payload	•Auristatin payload AUR0101 engineered for better potency and permeability across cell membrane enables improved bystander effect. •Payloads include microtubule inhibitors and DNA damaging agents whose potential mechanism of action has been shown to induce immunogenic cell death in preclinical models for combination with immunotherapy.	•Due to the labile nature of linkers, some conventional ADCs are built with less potent payloads and lower bystander activity.
Antibody	•Generates novel, humanized antibodies to a target library, with high affinity and unique binding epitopes.	•Often lower affinity, less specific antibodies.

APXiMAB Platform

Overview

The APXiMAB Platform was used to discover certain wholly owned product candidates and several programs for the development of product candidates that we have out-licensed. Our proprietary APXiMAB Platform is comprised of two primary components:

•Generation of hybridomas from rabbit B cells using fusion cell lines which enable us to reproducibly generate large numbers of rabbit monoclonal antibodies; and

•Humanization of these antibodies using our multi lineage guided, or MLG, humanization technology.

Rabbit antibodies offer:

•diverse epitope recognition to enable fit-for-purpose therapeutic antibody generation;

•the ability to recognize epitopes that are not immunogenic in other species, including small-size epitopes; and

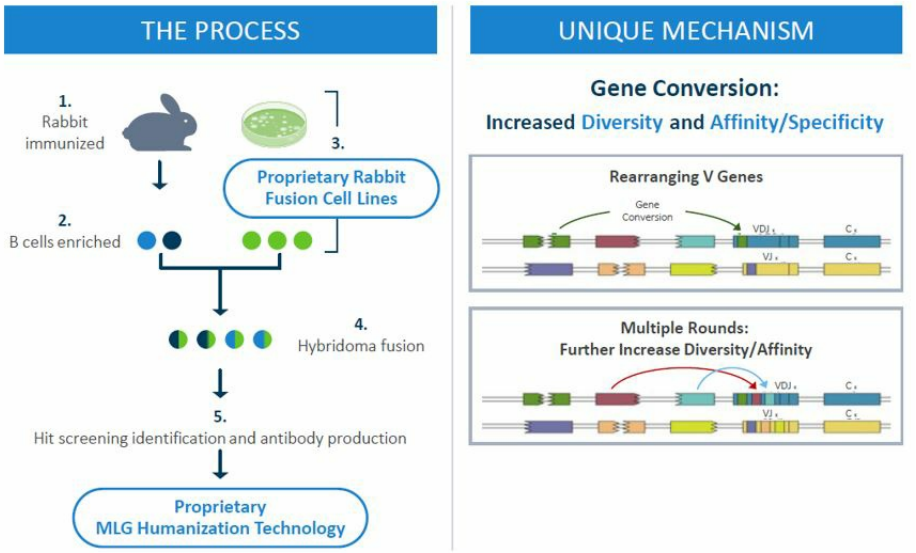
•high affinity and specificity.

Hybridoma Technology

We have developed a fusion cell line capable of generating stable hybridoma clones, which enables generation of high quality rabbit-derived antibodies from hybridoma cell lines.

As depicted in Figure 21 below, our antibody generation process begins with immunization of rabbits from which B cells are isolated and fused to a rabbit myeloma cell line, generating hybridoma cells capable of stably producing rabbit antibodies. These antibodies are screened for desired properties such as affinity and specificity and evaluated in panels of biochemical and cellular assays.

Figure 21



The APXiMAB Platform Process

Proprietary MLG Humanization Technology

To facilitate drug development, we humanize these rabbit monoclonal antibodies using our proprietary MLG humanization technology. Antibodies generated in non-human species and given to people as drugs can induce the formation of antibodies that neutralize the antibody-drug or induce an undesirable immune response. These are often referred to as anti-drug antibodies or ADAs. Most therapeutic antibodies are therefore modified to have their sequences resemble human antibody sequences as much as possible in an attempt to avoid the development of ADAs.

In conventional humanization, sequences of antibodies derived from non-human species are altered to be closer to human antibody sequences by replacing the sequences of the antibody scaffold with that of human scaffolds. This creates a novel antibody in which the majority of the sequence comes from human antibody genes and the antigen-binding portions from the originating non-human species.

In our MLG humanization technology, we examine the antibody sequences generated in rabbits to better understand the importance of various residues both in the antigen-binding portions and the antibody scaffold. Residues that are highly conserved are preserved while other residues that are highly variable in the sequences of the rabbit antibodies are replaced with conservative amino acid substitutions found in human antibodies. Because our MLG technology enables humanization of antigen-binding regions, we believe that this process results in humanized antibodies that maintain the desired characteristics of the original rabbit antibody, including high affinity, while reducing immunogenicity.

Target Catalog and Discovery Efforts

We have a large proprietary target catalog that we have assembled through both our own discovery activities and through an exclusive license from the University of Chicago for the work on immunotherapy targets out of Dr. Thomas Gajewski's laboratory. We are also building a large "cold" tumor target discovery database leveraging several human tumor databases.

The target catalog is based upon findings from an in vivo mouse model system which examined tumor tissue for functional and dysfunctional T cells based on the ability of the T cells to produce the cytokine IL-2. Furthermore, since 4-1BB and LAG3 positive T cells do not secrete IL-2, the CD8+ T cells were sorted based on cell surface marker expression i.e., 4-1BB and LAG3, which further defined functional or dysfunctional T cells. Gene expression analysis identified upregulated cell surface molecules in dysfunctional cells which included well established markers such as PD1, CTLA4, and TIM3 and many other novel targets were identified based on bioinformatics and deep biological rationale.

Our cold tumor target discovery database used RNA-seq transcriptome analysis of human tumor databases to identify potential novel targets involved in regulation of T cell function and/or infiltration leading to cold tumors. We have supplemented this database with additional resources which we continue to mine to identify additional novel targets for immunomodulation. These cold tumor targets are potentially dominant immune suppressors that are expressed across a variety of tumor associated cells, including immune cells, tumors cells, and stroma, offering the potential to uncover novel IO mechanisms and additional novel targets for our ADC platform.

While we have large opportunity to advance product candidates based on the target catalog, however, we have chosen not to conduct additional discovery efforts to refocus our development efforts and resources toward clinical development of PYX-201 and PYX-106.

Competition

The biotechnology and pharmaceutical industries, including the oncology subsector, are characterized by rapidly evolving technologies, intense competition, and strong defense of intellectual property and proprietary technologies. Any product candidates that we successfully commercialize may be competitive with currently marketed therapies and any new therapies commercialized in the future. While we believe our technology, drug development expertise, leadership team and strong scientific understanding of cancer targets and biology provides us with certain competitive advantages, we face potential competition from many sources, including major pharmaceutical companies, biotechnology companies, academic institutions, and other public and private research institutions.

Many companies are active across various stages of development in the oncology subsector and are marketing and developing products that employ similar ADC and immunotherapy approaches. As of October 2023, there were approximately 304 ADCs in clinical or preclinical development worldwide, of which the vast majority are being developed for the treatment of various cancer indications. Additionally, there are several large and small companies working on various immunotherapy approaches for treatment of cancer. Multiple companies are also involved in the development of ADC therapeutics and immunotherapies, including, but not limited to, AbbVie Inc., Abcure, Inc., ADC Therapeutics SA, Alligator Bioscience AB, Astellas Pharma, Inc., AstraZeneca plc, Celldex Therapeutics, Inc., Daiichi Sankyo Company, Ltd., Eucure Biopharma, a subsidiary of Biocytogen, Genentech, Inc., Gilead Sciences, Inc, GlaxoSmithKline, plc, Lyvgen Biopharma, Nextcure, Inc., Pfizer, Philogen S.p.A., and Rakuten Medical, Inc.

Our ADC and immunotherapy candidates may also face substantial competition from alternative therapeutic modalities, such as CAR-T therapies, bispecific antibodies, and small molecules that are being developed for the same cancer types that we are targeting with our pipeline candidates. These approaches could achieve regulatory approval before our product candidates or prove to be more effective, safer, or convey other advantages over any products resulting from our technology. In addition, we also face competition with respect to specific targets, including the target of our PYX-201 candidate, EDB, by Philogen S.p.A., and the target of our PYX-106 product candidate, BSI-060T, by Nextcure, Inc. In addition, each of Alligator Bioscience AB, Celldex Therapeutics, Inc., Lyvgen Biopharma, Eucure Biopharma, a subsidiary of Biocytogen, Hoffmann-La Roche AG, and AbbVie Inc. is developing CD40-based antibody product candidates for solid tumor oncology indications that are in clinical trials, typically in combination therapies. Other companies and institutions also have CD40-based product candidates in development, which may compete with PYX-107. Additionally, there is a wide array of activity in the development of immunotherapies for oncology which may be competitive with our preclinical discovery programs. Furthermore, if any of our product candidates are approved in oncology indications such as lung, hematological and other cancers, they may compete with existing approaches to treating cancer including surgery, radiation, and drug therapy, including conventional chemotherapy, biological products, and targeted drug small molecule therapies.

Our competitors may possess greater scientific, research and development capabilities, as well as greater financial, technical, manufacturing, marketing, sales and supply resources or experience than we do. These competitors may compete with us on the basis of establishing clinical trial sites and patient registration, recruiting and retaining qualified scientific and management personnel, and acquiring new technologies that may be complementary to, or necessary for, our programs. If we achieve regulatory approval, commercial opportunity for our product candidates may be dependent on the ability of our competitors to develop new products that may be more effective, safer, or less expensive than any products that we may develop. Our competitors may succeed in developing competing products before we do, obtaining marketing approval for products and gaining acceptance for such products in the same markets that we are targeting. Smaller or earlier-stage companies that seek collaborative arrangements with large and established companies, may prove to be significant competitors. In addition, our ability to compete may be affected by the availability of reimbursement from government and other third-party payors. Competitive factors affecting the success of our programs, if approved, will likely be based on their safety and effectiveness, the timing and scope of marketing approvals, the availability and cost of supply, the depth of marketing and sales capabilities, and reimbursement coverage, among other considerations.

Chemistry, Manufacturing and Controls

We believe the manufacturing of our ADCs and monoclonal antibodies requires considerable expertise, know-how, and resources. We do not own or operate and currently have no plans to establish any Current Good Manufacturing Practices, or cGMP, compliant manufacturing facilities. We currently rely, and expect to continue to rely, on external contract development manufacturing organization, or CDMOs, for the manufacture of product to support non-clinical and clinical testing, as well as for commercial manufacture if our product candidates receive marketing approval. Furthermore, the raw materials and intermediates for our product candidates may be sourced, in some cases, from a single-source supplier. As part of the manufacture and design process for our product candidates, we rely on internal scientific and manufacturing know-how and trade secrets and the know-how and trade secrets of third party manufacturers. We believe that this strategy allows us to maintain a more efficient infrastructure by eliminating the need for us to invest in our own manufacturing facilities, equipment and personnel while also enabling us to focus our expertise and resources on the development of our current product candidates. We maintain agreements with our CDMOs that include confidentiality and intellectual property provisions to protect our proprietary rights related to our product candidates. We have personnel with significant technical, manufacturing, analytical, quality, including cGMP and project management experience to oversee our CDMOs and to manage manufacturing and quality data and information for regulatory compliance purposes.

Commercialization Plans

If any of our product candidates achieves FDA approval, we intend to retain full commercialization rights for all our product candidates, including those obtained through exclusive collaboration agreements. We currently have no sales, marketing, or commercial product distribution capabilities. We intend to build our own specialized sales and marketing organization over time to support the commercialization of any approved product candidates. We may also pursue collaboration, co-promotion, distribution and/or other marketing arrangements with one or more third parties to commercialize our product candidates in markets the United States, potentially other regions. We may also pursue these arrangements for situations in which a larger sales and marketing organization is necessary to realize the full commercial value of any approved wholly owned or collaboration product candidates.

Licensing and Collaboration Agreements

License Agreement with Pfizer Inc.

In December 2020, we entered into a license agreement, as amended, or the Pfizer License Agreement, with Pfizer for worldwide development and commercialization rights to two of Pfizer's proprietary ADC product candidates (now referred to as PYX-201 and PYX-203), as well as other ADC product candidates directed to the licensed targets. The initial exclusively licensed targets are extra domain B (EDB+FN) and CD123 and we have the option to expand the scope of our license to add other licensed targets. Pfizer also granted us a non-exclusive license to use Pfizer's FACT Platform technology to develop and commercialize the licensed ADCs. In March 2021, we entered into an amendment to the Pfizer License Agreement to include additional know-how within the scope of our license. The Pfizer License Agreement, as amended, became effective for the Company in March 2021. Pursuant to the Pfizer License Agreement, we paid a combined $25.0 million for the license fee, consisting of an upfront fee of $5.0 million and issued 12,152,145 shares of Series B convertible preferred stock, which was converted into 1,911,015 shares of our common stock upon our initial public offering, or IPO, in October 2021, with a value of $20.0 million to Pfizer.

On October 6, 2022, we entered into an amended and restated license agreement, or the A&R License Agreement, with Pfizer, which amends and restates the Pfizer License Agreement. Pursuant to the A&R License Agreement, Pfizer granted us exclusive worldwide rights under Pfizer's FACT Platform technology to develop and commercialize ADC product candidates directed to certain licensed targets, including PYX-201 and PYX-203, and products containing the ADC product candidates. Additional ADC targets may be licensed for a nominal upfront payment and milestones. In accordance with the terms of the A&R License Agreement, the Company issued 2,229,654 shares of its common stock to Pfizer in October 2022, paid $8.0 million to Pfizer in January 2023 and issued 1,811,594 shares of its common stock to Pfizer in March 2023.

We are also obligated to pay future contingent payments and royalties, including up to an aggregate of $665 million in milestones for the first four licensed ADCs. In addition, we are required to pay future contingent payments including development, regulatory and commercial milestones for ADCs for each additional licensed target beyond the first four licensed ADC targets developed and commercialized via the FACT Platform. Additionally, if ADC licensed products are launched, we will pay Pfizer tiered royalties on net sales of licensed products in varying royalty rates ranging from low single digits to mid-teens. Our royalty obligations apply on a licensed product-by-licensed product and country-by-country basis from first commercial sale until the latest to occur of: (1) 12 years from first commercial sale; (2) the expiration of all regulatory or data exclusivity; and (3) the expiration of the last valid claim of a licensed patent covering the licensed product in a country. We are also obligated to pay Pfizer a percentage of certain sublicensing revenue ranging from twenty percent to low-double digits based on the stage of development of the licensed product at the time of entering into the applicable sublicense.

Under the Pfizer License Agreement, we are obligated to use commercially reasonable efforts to nominate a clinical candidate within four years of a target becoming a licensed target. We are also required to use commercially reasonable efforts to develop and seek regulatory approval for at least one licensed product directed to each licensed target in the United States and at least one other major market country (France, Germany, Italy, Japan, Spain and the United Kingdom), and to commercialize any licensed product in each such country after receiving regulatory approval. We control prosecution and enforcement with respect to any exclusively licensed patents, and Pfizer has prosecution and enforcement rights if we elect not to exercise such rights.

The Pfizer License Agreement will remain in effect until the expiration of the last to expire royalty term, unless terminated in accordance with the following: (1) by either party for the other party's material breach if such party fails to cure such breach within the specified cure period; (2) by either party upon certain insolvency events of the other party; or (3) prior to receipt of the first regulatory approval for a licensed product, by us for any reason upon 90 days' prior written notice, or after receipt of the first regulatory approval for a licensed product, by us for any reason upon one year's prior written notice.

License Agreement with the University of Chicago

In April 2020, we entered into a license agreement, or the University License Agreement, with the University of Chicago, or the University, to obtain an exclusive license under certain patents resulting from research performed, in-part, by our scientific founder, Dr. Thomas Gajewski, as well as a non-exclusive license to certain know-how and materials. Under the terms of the license, we have the exclusive global right to develop and commercialize products that are covered by a valid claim of a licensed patent, incorporate or use the licensed know-how and materials or are known to assess, modulate or utilize the activity of certain specified biological targets.

In partial consideration for the license from the University, we issued to the University 48,919 shares of our common stock in 2020. Pursuant to the University License Agreement, we are obligated to pay to the University an annual maintenance fee of $10,000 commencing on the third anniversary of the effective date, potential development and commercial milestones of up to an aggregate of $7.7 million as well as running royalties on net sales of licensed products at varying rates ranging from less than one percent to the low single digits, subject to a minimum annual royalty ranging from $1.0 million to $3.0 million during certain years following the first commercial sale of a licensed product. Our royalty obligations apply on a licensed product-by-licensed product and country-by-country basis until: (1) for licensed products covered by a valid claim of a licensed patent in a given country, the expiration of such valid claims; and (2) for all other licensed products, 10 years from the first commercial sale of a licensed product in a given country. We are also obligated to pay the University a percentage of certain sublicensing revenue ranging from low- to mid-teens based on the date of entering into the applicable sublicense.

Under the University License Agreement, we are obligated to use commercially reasonable efforts to develop and bring licensed products to market, meet certain preclinical and clinical development milestones by specific dates, and promote and sell licensed products after receipt of regulatory approval, subject to certain free and payment-based extensions. The University controls prosecution of the licensed patents at our cost and we have the first right to enforce the licensed patents subject to the University's backup enforcement rights.

The University License Agreement will remain in effect on a licensed product-by-licensed product basis until the expiration of all royalty obligations with respect to a licensed product, unless terminated in accordance with the following: (1) by the University upon 30 days' prior written notice for any uncured payment breaches or 90 days' prior written notice for all other uncured breaches; (2) by the University upon certain insolvency events or dissolution by us or any affiliate; or (3) by us in full or with respect to a particular licensed product at the end of the calendar quarter following the calendar quarter when we provide written notice of termination.

The Voxall Joint Venture with Alloy Therapeutics, Inc.

In March 2021, we entered into definitive transaction agreements with Alloy Therapeutics, Inc., or Alloy, to finance and operate Voxall, a joint venture company formed in collaboration with Alloy to leverage Pyxis Oncology's site-specific target catalog and Alloy's ATX-Gx™ platform and antibody discovery services. Voxall granted to both Pyxis Oncology and Alloy 50% of the voting membership units of Voxall in exchange for certain initial contributions, including $50,000 from both Pyxis Oncology and Alloy, and certain intellectual property and services agreements to enable the collaboration.

In February 2024, the board of directors of Voxall, comprised of equal participation from Pyxis Oncology directors and Alloy, approved dissolution of the joint venture. The decision to dissolve was mutual and was not due to any disagreement between Pyxis Oncology and Alloy; instead, the decision came as a result of our corporate reorganization announced in November 2023, as we continue to align our resources and refocus our efforts on our progressing the clinical trials. Upon dissolution, Alloy retained rights to certain intellectual property and may develop and commercialize at its sole discretion. Any amounts owed by Voxall to either Pyxis Oncology or Alloy were discharged in their entirety without further liability upon the dissolution.

Agreements with LegoChem Biosciences, Inc.

In December 2020, we entered into a license agreement, or the LegoChem License Agreement, and an opt-in, investment and additional consideration agreement, or the Opt-In Agreement, with LegoChem Biosciences, Inc., or LegoChem. Pursuant to the LegoChem License Agreement, we obtained worldwide (other than Korea) development and commercialization rights for LCB67, an ADC product candidate targeting DLK-1, and products containing the licensed compound. We paid $9.0 million in March 2021 to LegoChem, which was recorded as research and development expenses. Additionally, we may purchase certain initial quantities of licensed products from LegoChem for an estimated cost of $7.0 million and are also obligated to make future contingent payments including development, regulatory and commercial milestones as well as running royalties on net sales of licensed products at varying rates. In the third quarter of the calendar year 2022, we stopped the continued development of LCB67, based on review and analysis of data from the toxicity studies, and anticipated clinical use and commercial prospects of anti-DLK1 ADC.

In addition, as part of the Opt-in Agreement, LegoChem exercised an option to pay $8.0 million to us, in exchange for the right to receive a milestone payment, or the Extra Milestone Payment, of $9.6 million upon the earliest to occur of certain events, including the date of pricing or offer of the first public offering of our common stock or if we are the subject of a change in control transaction. Upon our IPO in October 2021, the extra milestone payment event triggered, and we paid $9.6 million in January 2022 to LegoChem.

License Agreement with Biosion USA, Inc.

On March 28, 2022, we entered into a license agreement, or the Biosion License Agreement, with Biosion pursuant to which we obtained an exclusive, worldwide (other than Greater China (mainland China, Hong Kong, Macau and Taiwan)) license for development, manufacture and commercialization rights for BSI-060T, a Siglec-15 targeting antibody, an IO product candidate (now referred to as PYX-106), and products containing the licensed compound. Under the terms of the Biosion License Agreement, each party granted to the other party a right of first offer to obtain an exclusive license in the other party's territory (Greater China for Biosion, and the rest of the world for Pyxis) to develop, manufacture and commercialize any bi-specific or multi-specific antibody any antibody-drug conjugate controlled by a party or its affiliate that inhibits, modulates or binds to Siglec-15 as an intended mechanism of action.

Pursuant to the Biosion License Agreement, we paid an upfront fee of $10 million and are obligated to pay future contingent payments including development, regulatory and commercial milestones up to an aggregate of $217.5 million in case of normal approval and $222.5 million in case of accelerated approval. Additionally, if products are launched, we will pay Biosion tiered royalties on net sales of licensed products in varying royalty rates ranging from low single digits to low teens. Our royalty obligations apply on a licensed product-by-licensed product and country-by-country basis from first commercial sale until the latest to occur of: (1) 12 years from first commercial sale; (2) the expiration of all regulatory or data exclusivity; and (3) the expiration of the last valid claim of a licensed patent covering the licensed product in a country. We are also obligated to pay Biosion a percentage of certain sublicensing revenue ranging from mid-double to low-double digits based on the stage of development of the licensed product at the time of entering into the applicable sublicense.

Under the Biosion License Agreement, we are obligated to use commercially reasonable efforts to clinically develop and seek regulatory approval for at least one licensed product in the licensed territory, and to commercialize such licensed product following receipt of regulatory approval. We control prosecution and enforcement with respect to the licensed patents in the licensed territory.

The Biosion License Agreement will remain in effect on a licensed product-by-licensed product and country-by-country basis until the expiration of the applicable royalty term, unless terminated in accordance with the following: (1) by either party for the other party's material breach if such party fails to cure such breach within the specified cure period; (2) by either party upon certain insolvency events of the other party; (3) by us for scientific or safety reasons; (4) any time following completion of our first clinical trial for a licensed product, by us for convenience; or (5) by Biosion if we cease development and commercialization activities for licensed products for a specified period of time, subject to certain exceptions.

Out-License Relationships

In August 2023, we completed the acquisition of Apexigen contemplated by the Merger Agreement, with Apexigen surviving as a wholly owned subsidiary of the Company. Upon the Merger Agreement, we assumed all out-licensing agreements of Apexigen. The assumed agreements consist of licenses with several biopharmaceutical companies that are developing product candidates that were discovered using our APXiMAB platform, which has been important to prosecuting the full value of our platform. We believe the licenses for the programs for the development of product candidates we have helped generate demonstrate the productivity and utility of our platform and position us to receive meaningful royalty payments if those product candidates are approved and successfully commercialized.

Described below are the out-license relationships and the related agreements under which we may receive milestone or royalty payments.

Beovu and Novartis Antibody Candidate Discovery and Development Agreement

In March 2007, Epitomics (Apexigen's predecessor), entered into an antibody candidate discovery and development agreement with ESBATech AG, or ESBA Tech, in March 2007, or the ESBATech Agreement. ESBATech was acquired by Alcon Research, Ltd. in 2009 and later merged with Novartis AG, or Novartis, in 2011.

Under the ESBATech Agreement, Apexigen provided antibodies discovered using the APXiMAB platform that target certain molecules to ESBATech. ESBATech used those antibodies to develop drug product candidates to two different drug targets. Under the ESBATech Agreement, Apexigen granted ESBATech a non-exclusive, irrevocable, worldwide, sublicensable, royalty-bearing and perpetual license to our rights in certain intellectual property to develop and commercialize those drug product candidates. Other than financial interests, Apexigen did not have any ownership or right in those drug product candidates or any intellectual property covering or enabling the manufacture, use or sale of those drug product candidates.

Novartis, the successor in interest to ESBATech, has successfully developed and commercialized one of those drug product candidates, brolucizumab-dbll, a single-chain antibody fragment, or scFv, targeting all of the isoforms of VEGF-A, which Novartis markets under the brand name Beovu®. Beovu was approved for commercial sale in October 2019, is approved for use in over 70 countries, and is indicated for the treatment of neovascular (wet) age-related macular degeneration and has received European Commission approval for use in the treatment of visual impairment due to diabetic macular edema. Novartis is also developing Beovu for additional uses in several Phase 3 clinical trials.

In or around January 2019, Novartis licensed another of the drug product candidates covered by the ESBATech Agreement, which was named LME636, to Oculis SA. Oculis renamed the drug candidate OCS-02. OCS-02 is a topical single-chain anti-TNF alpha antibody fragment. Oculis is in Phase 2 development of OCS-02 for the treatment of dry eye and uveitis.

Novartis and its predecessors have paid all upfront fees and milestone payments due under the ESBATech Agreement. The term of the ESBATech Agreement expired in March 2010; however, Novartis' royalty payment obligations under the ESBATech Agreement survive indefinitely. Novartis was obligated to pay Apexigen, and is now obligated to pay us, a very low single-digit royalty on worldwide net sales of Beovu and OCS-02 for therapeutic uses by Novartis, its affiliates or licensees in perpetuity. However, despite the approval of Beovu for commercial sale in October 2019, Novartis disputed its obligation to pay royalties to Apexigen under the ESBATech Agreement and continues to pay such royalties under protest. Until December 31, 2023, we received $7.7 million of royalties on net sales of Beovu, which is disputed by Novartis.

Simcere License and Collaboration Agreement

In December 2008, Epitomics (Apexigen's predecessor) and Jiangsu Simcere Pharmaceutical R&D Co., Ltd., or Simcere, entered into a license and collaboration agreement, or the Simcere Agreement, for the development and commercialization of suvemcitug (BD0801) for oncology in China. Suvemcitug is a humanized anti-VEGF rabbit monoclonal antibody molecule. Simcere is responsible for conducting the development and commercialization of suvemcitug in China at its cost. Under the terms of the Simcere Agreement, Apexigen had, and now we have, reserved the right to develop and commercialize suvemcitug outside of China at our discretion. If we develop and commercialize suvemcitug outside of China, we will share with Simcere costs incurred and revenue earned outside of China. Under the Simcere Agreement, Simcere has an exclusive, royalty-bearing license (without the right to sublicense) to Apexigen's rights in certain intellectual property to develop and commercialize suvemcitug in the field of oncology therapeutics in China.

Simcere granted Apexigen a non-exclusive, royalty-free, worldwide license (without the right to sublicense) to improvements derived from suvemcitug using the intellectual property licensed to Simcere for any purpose outside of China and for purposes outside of oncology therapeutics in China. Intellectual property created in the collaboration program with Simcere is jointly owned by Apexigen and Simcere. Simcere is obligated to pay milestone payments for achievement of certain clinical development milestones and low to high single-digit percentage royalties on net sales of suvemcitug in China until 15 years after the first commercial sale of suvemcitug. If we choose to commercialize suvemcitug outside of China, we will share with Simcere a mid-double-digit percentage of costs and revenue arising from the development and commercialization of suvemcitug outside of China. Unless earlier terminated, the Simcere Agreement continues until 15 years after the first commercial sale of suvemcitug. Either party may terminate the Simcere Agreement for the other party's uncured material breach. Simcere may terminate the Simcere Agreement upon a decision by an appellate court in China that suvemcitug infringes a third party patent and such dispute cannot be resolved by settlement, licensing or other alternatives.

In January 2024, Simcere announced that the Phase 3 clinical trial of Suvemcitug for injection combined with chemotherapy in patients with recurrent, platinum-resistant epithelial ovarian, fallopian tube or primary peritoneal cancer met its primary endpoints of the progression-free survival. Simcere intends to submit a New Drug Application, or NDA, for Suvemcitug for injection in the treatment of platinum-resistant ovarian cancer to the National Medical Products Administration, or NMPA, of China in the near future.

T-Mab/Mabwell Agreement

In May 2008, Epitomics (Apexigen's predecessor) and Jiangsu T-Mab Biotechnology Ltd., Co., or T-Mab, entered into a license, co-development and contract manufacture agreement, or the T-Mab Agreement, for the development and commercialization of therapeutic candidates in two therapeutic programs, each directed to a specified target for specified fields, including VEGF for the treatment of ocular diseases, in China. Mabwell (Shanghai) Bioscience Co., Ltd., or Mabwell, acquired T-Mab in 2015. Mabwell is responsible for conducting the development and commercialization of the therapeutic candidates in China. We may, at our discretion, develop and commercialize such therapeutic candidates outside of China, however, we must pay Mabwell a royalty on sales of such therapeutic candidates made outside of China if we do so.

Under the T-Mab Agreement, Apexigen granted Mabwell an exclusive, royalty-bearing, perpetual license (without the right to sublicense) to its rights in certain intellectual property that it licensed from Epitomics to develop and commercialize such therapeutic candidates. Mabwell is obligated to pay us a mid-single-digit percentage royalty on net sales of such therapeutic candidates in China. If we choose to commercialize such therapeutic candidates outside of China, we would be obligated to pay Mabwell a mid-single-digit percentage royalty on net sales of such therapeutic candidates outside of China that we sell directly to end users and a mid-single-digit percentage of revenue we receive as sublicense fees, milestone payments and royalties related to the sale of such therapeutic candidate. Each party's obligations to pay royalties to the other party continue until 15 years after the first commercial sale of licensed product in each party's respective territory. The term of the T-Mab Agreement expired in May 2013; however, Mabwell's royalty payment obligations under the agreement survive expiration. The royalty term for 9MW0211, an anti-VEGF antibody licensed under the T-Mab Agreement, will begin with the first commercial sale in China and end a low two-digit number of years after such first commercial sale.

Mabwell is currently in Phase 3 development of 9MW0211.

Toray Sublicense Agreement

Under an agreement between Epitomics (Apexigen's predecessor) and Toray Industries, Inc., or Toray, Epitomics provided Toray with antibodies created using the APXiMAB platform that target certain molecules to use in the development of its drug product candidates. In May 2012, Apexigen entered into a non-exclusive sublicense agreement with Toray, or the Toray Agreement, under which Apexigen granted Toray a non-exclusive, worldwide sublicense, with the right to grant further sublicenses, to develop and commercialize drug product candidates that Toray develops using those antibodies in the field of pharmaceutical products for human or veterinary use. Under the Toray Agreement, Toray paid an upfront fee, and agreed to pay certain development- and regulatory-related milestone payments and a low single-digit percentage royalty on net sales of licensed products by Toray or its affiliates. Toray is also obligated to pay us a mid-teens percentage of certain payments Toray receives from sublicensees under the Toray Agreement, which payments may limit Toray's obligations to pay the milestone payments described above. Subject to certain termination rights, including Toray's right to terminate the agreement for convenience upon 60 days' prior written notice, the Toray Agreement continues on a product-by-product and country-by-country basis until 10 years after the first commercial sale of such product in such country. Upon expiration or early termination of the agreement, Toray's sublicense and any further sublicenses granted by Toray will automatically terminate.

Toray is currently in Phase 2 development of TRK-950, an antibody licensed under the Toray Agreement.

Intellectual Property

Our intellectual property is critical to our business, and we strive to protect it, including by obtaining and maintaining patent protection in the United States and internationally for our product candidates, new therapeutic approaches and potential indications, and other inventions that are important to our business. We also rely on trade secrets and proprietary know-how to protect aspects of our business that are not amenable to, or that we do not consider appropriate for, patent protection.

Our patent portfolio includes patents and patent applications that are exclusively licensed from the University of Chicago, Pfizer, and Biosion, and patent and patient applications that are wholly owned by us. Our patent portfolio includes patents and patent applications that cover our product candidates PYX-201, PYX-203, PYX-106, PYX-107 and PYX-102 and the use of these candidates for therapeutic purposes in certain territories. Our proprietary technology has been developed primarily through internal development efforts and relationships with academic institutions, Pfizer, Biosion and contract research organizations.

For our product candidates, we will, in general, initially pursue patent protection covering compositions of matter and methods of use. Throughout the development of our product candidates, we seek to identify additional means of obtaining patent protection that would potentially enhance commercial success, including through additional methods of use, process of making, formulation and dosing regimen-related claims.

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

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

Regardless of the coverage we seek under our existing patent applications, there is always a risk that an alteration to the product or process may provide sufficient basis for a competitor to avoid infringement claims. In addition, the coverage claimed in a patent application can be significantly reduced before a patent is issued, and courts can reinterpret patent scope after issuance. Moreover, many jurisdictions, including the United States, permit third parties to challenge allowed or issued patents in administrative proceedings, which may result in further narrowing or even cancellation of patent claims. Moreover, we cannot provide any assurance that any patents will be issued from our pending or any future applications or that any current or future issued patents will adequately protect our products.

In total, our patent portfolio, including patents licensed from the University of Chicago, Pfizer and Biosion, and patents owned by us, comprises 31 different patent families, filed in various jurisdictions worldwide, including families directed to composition of matter for antibodies and antibody-drug conjugates, families directed towards the manufacture, use, and compositions of antibodies and antibody-drug conjugates generally, families directed towards methods of identifying patients for treatment with compositions of antibodies and antibody-drug conjugates and subsequently treating said patients, and families directed to methods of treating cancer and identifying potential targets. Our patent portfolio as of December 31, 2023, is outlined below.

Composition of Matter Patents

PYX-201 Anti-EDB Antibody-Drug Conjugate. We have exclusively licensed from Pfizer a patent family for antibodies and antibody-drug conjugates that bind to the extra domain B splice variant of fibronectin, that includes granted patents in Australia, China, Hong Kong, Japan, Russia, South Korea, and the United States, and pending applications in Australia, Brazil, Canada, China, Europe, Hong Kong, India, Israel, Japan, Mexico, Singapore, South Africa, and the United States that claim the composition of matter and certain methods of use with respect to PYX-201. The 20-year term of the patents in this family runs through 2037, absent any available patent term adjustments or extensions.

PYX-203 Anti-CD123 Antibody-Drug Conjugate. We have exclusively licensed from Pfizer a patent family for antibodies and antibody-drug conjugates that specifically bind to CD123, that includes granted patents in Canada, Colombia, India, Indonesia, Japan, Russia, Saudi Arabia, South Korea, Taiwan, and the United States, and pending applications in Australia, Brazil, Canada, China, Europe, Hong Kong, Israel, Malaysia, Mexico, New Zealand, Peru, Philippines, Singapore, South Africa, and the United States that claim the composition of matter and certain methods of use with respect to PYX-203. The 20-year term of the patents in this family runs through 2038, absent any available patent term adjustments or extensions.

PYX-106 Anti-Siglec-15 Antibody. We have exclusively licensed from Biosion USA, Inc. a patent family for monoclonal antibodies that specifically bind human Siglec15, that includes granted patents in Australia, China, Japan, and the United States, and pending applications in Australia, Brazil, Canada, Egypt, Europe, Hong Kong, India, Indonesia, Israel, Japan, Malaysia, Mexico, New Zealand, Philippines, Russia, Saudi Arabia, Singapore, South Africa, South Korea, United Arab Emirates, and the United States. The 20-year term of the patent in this family runs through 2041, absent any available patent term adjustments or extensions.

PYX-107A/B "Sotigalimab" CD40 Agonist Antibodies. Through our acquisition of Apexigen, Inc. we have acquired sole ownership of two patent families for high affinity CD40 agonist monoclonal antibodies and related compositions, which may be used in any of a variety of therapeutic methods for the treatment of cancer and other diseases. The first patent family includes granted patents in Australia, Belgium, Brazil, Canada, China, France, Germany, Great Britain, Hong Kong, India, Israel, Italy, Japan, Mexico, New Zealand, Russia, Singapore, South Africa, South Korea, Spain, Switzerland, and the United States, with pending applications in Europe and the United States. The 20-year term of this first patent family runs through 2032, absent any available patent term adjustments or extensions. The second patent family includes granted patents in Australia, Belgium, Canada, China, Denmark, France, Germany, Great Britain, Hong Kong, India, Ireland, Italy, Japan, Luxembourg, Macau, Mexico, Monaco, Netherlands, New Zealand, Norway, South Africa, South Korea, Spain, Sweden, Switzerland, and the United States, with pending applications in Canada, China, Europe, Japan and the United States. The 20-year term of this second patent family runs through 2033, absent any available patent term adjustments or extension.

APX-601 Anti-tnfr2 Antibodies and Methods of Use. Through our acquisition of Apexigen, Inc. we have acquired sole ownership of a patent family for anti-tumor necrosis factor receptor 2 (TNFR2) antibodies and related compositions, which may be used in any of a variety of therapeutic or diagnostic methods, including the treatment or diagnosis of oncological diseases, inflammatory and/or autoimmune diseases, that includes pending applications in Australia, Brazil, Canada, China, Eurasia, Europe, India, Israel, Japan, Mexico, New Zealand, Singapore, South Africa, South Korea, Taiwan, and the United States. The 20-year term of the patents in this family runs through 2040, absent any available patent term adjustments or extension.

Methods Patents Related to Compositions of Matter

PYX-107D Methods of Treating Cancer with CD-40 Agonists. Through our acquisition of Apexigen we have acquired sole ownership of a patent family for methods of identifying a sub-population of cancer patients amenable for a combination therapy with a CD40 agonist and one or more chemotherapy drugs and subsequently treating the sub-population of cancer patients with said combination therapy, that includes recently filed pending patent applications in Canada, China, Europe, Japan, and the United States. The 20-year term of the patents in this family runs through 2042, absent any available patent term adjustments or extension.

PYX-107F Biomarkers for CD40 Agonist Therapy. Through our acquisition of Apexigen we have acquired sole ownership of a patent family for biomarkers and other characteristics for predicting tumor responsiveness to CD40 agonist therapy in melanomas, and related kits, compositions, and methods of treating said melanomas, including PD-1 refractory melanomas, that includes a PCT application with a national phase entry deadline in the first half of 2024.

*PYX-002 Site Specific Ligand-Payload Conjugate*s. We have sole ownership of a patent family for ligand-payload conjugates, and compositions and use thereof for treating diseases, disorders, or conditions, such as cancers, autoimmune diseases, or infectious diseases, that includes a PCT application with a national phase entry deadline in the second half of 2024.

ADC Patent Rights

Spliceostatin analogs. We have exclusively licensed from Pfizer, subject to certain reservations, a patent family for compositions, methods of use, and/or methods of manufacture useful in antibody-drug conjugates generally, directed toward novel cytotoxic spliceostatin analogs and derivatives, that includes granted patents in Australia, Belgium, Brazil, Canada, China, Denmark, Finland, France, Germany, Great Britain, Hong Kong, India, Ireland, Italy, Japan, Mexico, Netherlands, Russia, South Korea, Spain, Sweden, Turkey, and the United States, and no pending applications. The 20-year term of the patents in this family runs through 2033, absent any available patent term adjustments or extensions.

Tubulysin analogs and methods for their preparation. We have exclusively licensed from Pfizer, subject to certain reservations, a patent family for compositions, methods of use, and/or methods of manufacture useful in antibody-drug conjugates generally, directed toward cytotoxic tubulysin analogs and derivatives, that includes a granted patent in the United States, and no pending applications. The 20-year term of the patent in this family runs through 2037, absent any available patent term adjustments or extensions.

Heteroaryl Sulfone-based Conjugation Handles, Methods for Their Preparation, and Their Use in Synthesizing Antibody-Drug Conjugates. We have exclusively licensed from Pfizer, subject to certain reservations, a patent family for compositions, methods of use, and/or methods of manufacture useful in antibody-drug conjugates generally, directed toward heteroaryl sulfone-based conjugation handles for use in synthesizing antibody-drug conjugates, that includes a granted patents in Canada and the United States, and pending applications in Europe and Japan. The 20-year term of the patents in this family runs through 2037, absent any available patent term adjustments or extensions.

Purification of Antibody-Drug Conjugates Using a Sodium Phosphate Gradient. We have exclusively licensed from Pfizer, subject to certain reservations, a patent family for compositions, methods of use, and/or methods of manufacture useful in antibody-drug conjugates generally, directed toward methods of removing high molecular weight species, in particular aggregates, from antibody-drug conjugate preparations, by contacting preparations of the antibody-drug conjugate reaction mixture with a hydroxyapatite resin and selectively eluting the ADC from the resin using a gradient comprising sodium phosphate, that includes granted patents in France, Germany, Great Britain, Ireland, Italy, Spain, and the United States, and a pending application in the United States. The 20-year term of the patents in this family runs through 2036, absent any available patent term adjustments or extensions.

Bifunctional Cytotoxic Agents Containing the CTI Pharmacophore. We have exclusively licensed from Pfizer, subject to certain reservations, a patent family for compositions, methods of use, and/or methods of manufacture useful in antibody-drug conjugates generally, directed toward bifunctional CTI-CTI and CBI-CTI dimers that can function as stand-alone drugs, payloads in ADCs, and linker-payload compounds useful in connection with the production or administration of such ADCs, that includes granted patents in Australia, Belgium, Canada, China, Denmark, Finland, France, Germany, Great Britian, Hong Kong, India, Ireland, Israel, Italy, Japan, Mexico, Netherlands, Norway, Russia, Singapore, South Africa, South Korea, Spain, Sweden, Taiwan, Turkey, and the United States, and a pending application in Brazil. The 20-year term of the patents in this family runs through 2036, absent any available patent term adjustments or extensions.

Calicheamicin Derivatives and Antibody-Drug Conjugates Thereof. We have exclusively licensed from Pfizer, subject to certain reservations, a patent family for compositions, methods of use, and/or methods of manufacture useful in antibody-drug conjugates generally, directed toward calicheamicin derivatives useful as payloads in antibody drug-conjugates, that includes granted patents in Canada and Japan, and pending applications in the United States and Europe. The 20-year term of the patents in this family runs through 2038, absent any available patent term adjustments or extensions.

Cysteine Engineered Antibody-Drug Conjugate. We have exclusively licensed from Pfizer, subject to certain reservations, a patent family for compositions, methods of use, and/or methods of manufacture useful in antibody-drug conjugates generally, directed toward anti-CD33 antibody-drug conjugates with an engineered cysteine residue, that includes a granted patent in the United States, and no pending applications. The 20-year term of the patent in this family runs through 2038, absent any available patent term adjustments or extensions.

Platform Patent Rights (Pyxis Oncology Managed)

Antibodies Specific for Trop-2 and Their Uses. We have exclusively licensed from Pfizer, subject to certain reservations, a patent family for compositions, methods of use, and/or methods of manufacture related to Pfizer's FACT Platform, directed toward antibodies and antibodies conjugates specific for Trop-2 in treating cancer, that includes a granted patent in the United States, and no pending applications. The 20-year term of the patents in this family runs through 2032, absent any available patent term adjustments or extensions.

Engineered Polypeptide Conjugates Using Transglutaminase. We have exclusively licensed from Pfizer, subject to certain reservations, a patent family for compositions, methods of use, and/or methods of manufacture related to Pfizer's FACT Platform, directed toward engineered polypeptide conjugates comprising specific acyl donor glutamine-containing tags and amine donor agents, that includes granted patents in Canada, France, Germany, Great Britain, Ireland, Italy, Japan, Spain, and the United States, and a pending application in the United States. The 20-year term of the patents in this family runs through 2034, absent any available patent term adjustments or extensions.

Stability-Modulating Linkers For Use With Antibody-Drug Conjugates. We have exclusively licensed from Pfizer, subject to certain reservations, a patent family for compositions, methods of use, and/or methods of manufacture related to Pfizer's FACT Platform, directed toward stability-modulating linker components used to make these stability-modulated antibody-drug conjugates, that includes granted patents in Australia, Austria, Belgium, Brazil, Canada, China, Denmark, France, Germany, Great Britain, Hong Kong, Hungary, India, Ireland, Israel, Italy, Japan, Mexico, Netherlands, Poland, Russia, South Korea, Spain, Sweden, Switzerland, Turkey, and the United States, and pending applications in Mexico and the United States. The 20-year term of the patents in this family runs through 2035, absent any available patent term adjustments or extensions.

Synergistic Auristatin Combinations. We have exclusively licensed from Pfizer, subject to certain reservations, a patent family for compositions, methods of use, and/or methods of manufacture related to Pfizer's FACT Platform, directed toward combinations of an auristatin or an auristatin-based ADC with second active agents including PI3K/mTOR inhibitors, MEK inhibitors, taxanes, or other anti-cancer agents, that includes granted patents in the United States and Japan, and pending applications in Canada and Europe. The 20-year term of the patents in this family runs through 2035, absent any available patent term adjustments or extensions.

Capped and Uncapped Antibody Cysteines, and Their Use in Antibody-Drug Conjugation. We have exclusively licensed from Pfizer, subject to certain reservations, a patent family for compositions, methods of use, and/or methods of manufacture related to Pfizer's FACT Platform, directed toward antibody production process in which engineered unpaired cysteine residues are post-translationally modified and capped with particular chemical entities, which capped antibodies are well suited to further site-specific conjugation steps to form antibody-drug conjugates, that includes granted patents in Australia, Austria, Belgium, China, Denmark, France, Germany, Great Britain, Hong Kong, Hungary, India, Ireland, Israel, Italy, Japan, Mexico, Netherlands, Poland, Russia, South Korea, Spain, Sweden, Switzerland, Turkey, and the United States, and pending applications in Brazil, Canada, Europe, Russia, and the United States. The 20-year term of the patents in this family runs through 2036, absent any available patent term adjustments or extensions.

Large Scale Production Process for Capped and Un-capped Antibody Cysteines and Their Use in Therapeutic Protein Conjugation. We have exclusively licensed from Pfizer, subject to certain reservations, a patent family for compositions, methods of use, and/or methods of manufacture related to Pfizer's FACT Platform, directed toward optimizing production of selectively capped, and uncapped, cysteines on antibodies by manipulation of cell growth conditions, that includes granted patents in Canada, Japan, Russia, and South Korea, and pending applications in Australia, Brazil, Europe, Hong Kong, and the United States. The 20-year term of the patents in this family runs through 2038, absent any available patent term adjustments or extensions.

Platform Patent Rights (Pfizer Managed)

Cytotoxic Peptides and Antibody-Drug Conjugates Thereof. We have exclusively licensed from Pfizer, subject to certain reservations, a patent family currently managed by Pfizer for compositions, methods of use, and/or methods of manufacture related to Pfizer's FACT Platform, directed toward cytotoxic pentapeptides, to antibody-drug conjugates thereof, that includes granted patents in Argentina, Australia, Austria, Belgium, Bulgaria, Canada, China, Colombia, Czech Republic, Denmark, Finland, France, Germany, Great Britain, Greece, Hong Kong, Hungary, Iceland, Indonesia, Ireland, Israel, Italy, Japan, Luxembourg, Malaysia, Mexico, Netherlands, New Zealand, Norway, Peru, Philippines, Poland, Portugal, Romania, Russia, Saudi Arabia, Singapore, Slovak Republic, Slovenia, South Africa, South Korea, Spain, Sweden, Switzerland, Taiwan, Turkey, and the United States, and pending applications in Brazil, India, Peru, and Venezuela. The 20-year term of the patents in this family runs through 2032, absent any available patent term adjustments or extensions.

Bifunctional Cytotoxic Agents. We have exclusively licensed from Pfizer, subject to certain reservations, a patent family currently managed by Pfizer for compositions, methods of use, and/or methods of manufacture related to Pfizer's FACT Platform, directed toward cytotoxic dimers comprising CBI-based and/or CPI-based sub-units, antibody-drug conjugates comprising such dimers, that includes granted patents in Australia, Austria, Belgium, Brazil, Bulgaria, Canada, China, Colombia, Czech Republic, Denmark, Finland, France, Germany, Great Britain, Greece, Hong Kong, Hungary, Iceland, India, Indonesia, Ireland, Israel, Italy, Japan, Luxembourg, Malaysia, Mexico, Netherlands, New Zealand, Norway, Peru, Philippines, Poland, Portugal, Romania, Russia, Saudi Arabia, Singapore, Slovak Republic, Slovenia, South Africa, South Korea, Spain, Sweden, Switzerland, Taiwan, Turkey, and the United States, and pending applications in Argentina and Venezuela. The 20-year term of the patents in this family runs through 2035, absent any available patent term adjustments or extensions.

Antibodies and Antibody Fragments for Site-Specific Conjugation. We have exclusively licensed from Pfizer, subject to certain reservations, a patent family currently managed by Pfizer for compositions, methods of use, and/or methods of manufacture related to Pfizer's FACT Platform, directed toward polypeptides, antibodies, and antigen-binding fragments thereof, that comprise a substituted cysteine for site-specific conjugation, that includes granted patents in Australia, China, Colombia, Hong Kong, India, Japan, Malaysia, Russia, South Africa, South Korea, and Taiwan, and pending applications in Argentina, Brazil, Canada, Europe, Indonesia, Israel, Mexico, New Zealand, Peru, Philippines, Saudi Arabia, Singapore, the United States, and Venezuela. The 20-year term of the patents in this family runs through 2036, absent any available patent term adjustments or extensions.

Engineered Antibody Constant Regions for Site-Specific Conjugation and Methods and Uses Therefor. We have exclusively licensed from Pfizer, subject to certain reservations, a patent family currently managed by Pfizer for compositions, methods of use, and/or methods of manufacture related to Pfizer's FACT Platform, directed toward antibodies, and antigen-binding portions thereof, engineered to introduce amino acids for site-specific conjugation, that includes granted patents in Canada, France, Germany, Great Britain, Ireland, Italy, Japan, Spain, and the United States, and pending applications in Canada, Europe and Japan. The 20-year term of the patents in this family runs through 2032, absent any available patent term adjustments or extensions.

Engineered Polypeptide Conjugates and Methods for Making Thereof Using Transglutaminase. We have exclusively licensed from Pfizer, subject to certain reservations, a patent family currently managed by Pfizer for compositions, methods of use, and/or methods of manufacture related to Pfizer's FACT Platform, directed toward engineered polypeptide conjugates comprising acyl donor glutamine-containing tags and amine donor agents, that includes granted patents in Canada, Japan, and the United States, and a pending application in Europe. The 20-year term of the patents in this family runs through 2031, absent any available patent term adjustments or extensions.

Antibody-Drug Conjugates with High Drug Loading. We have exclusively licensed from Pfizer, subject to certain reservations, a patent family currently managed by Pfizer for compositions, methods of use, and/or methods of manufacture related to Pfizer's FACT Platform, directed toward transglutaminase-mediated antibody-drug conjugates with high anti-body-drug ratio, that includes granted patents in Australia, Austria, Belgium, Bulgaria, Canada, China, Czech Republic, Denmark, Finland, France, Germany, Great Britain, Greece, Hong Kong, Hungary, India, Ireland, Israel, Italy, Japan, Luxembourg, Mexico, Netherlands, Poland, Portugal, Romania, Russia, Slovak Republic, Slovenia, South Korea, Spain, Sweden, Switzerland, Turkey, and the United States, and pending applications in Brazil and South Korea. The 20-year term of the patents in this family runs through 2035, absent any available patent term adjustments or extensions.

Methods in Immuno-Oncology

Methods and Compositions Related to T-Cell Activity. We have exclusively licensed from the University of Chicago a patent family for methods for treating patients with immunotherapy based on the identification of the patient as having non-anergic T cells after measuring expression levels of various genes that includes granted patents in France, Germany, Great Britian, Italy, Spain, and the United States, and a pending application in the United States. The 20-year term for patents in this family runs through March 2034, absent any available patent term adjustments or extensions.

Beta-catenin Inhibitors in Cancer Immunotherapy. We have exclusively licensed from the University of Chicago a patent family for methods for treating solid tumor cancers that includes a granted patent and one pending application in the United States. The 20-year term for patents in this family runs through March 2036, absent any available patent term adjustments or extensions.

Dysfunctional Antigen-specific CD8+ T Cells in the Tumor Microenvironment. We have exclusively licensed from the University of Chicago a patent family for methods of treating cancer comprising administering an agent that specifically targets dysfunctional tumor antigen-specific CD8+T cells that includes pending applications in Canada, China, Europe, Japan, Hong Kong, and the United States. The 20-year term for patents in this family runs through January 2038, absent any available patent term adjustments or extensions.

Patent Term and Term Extensions

Individual patents have terms for varying periods depending on the date of filing of the patent application or the date of patent issuance and the legal term of patents in the countries in which they are obtained. Generally, utility patents issued for applications filed in the United States are granted a term of 20 years from the earliest effective filing date of a non-provisional patent application. In addition, in certain instances, the term of a U.S. patent can be extended to recapture a portion of the United States Patent and Trademark Office, or the USPTO, delay in issuing the patent as well as a portion of the term effectively lost as a result of the FDA regulatory review period. However, as to the FDA component, the restoration period cannot be longer than five years and the restoration period cannot extend the patent term beyond 14 years from FDA approval. In addition, only one patent applicable to an approved drug is eligible for the extension, and only those claims covering the approved drug, a method for using it, or a method of manufacturing may be extended. Similar provisions are available in Europe and other foreign jurisdictions to extend the term of a patent that covers an approved drug. We will, in general, pursue available patent term extensions in the U.S. and in foreign jurisdictions that provide for patent term extensions, however, there is no guarantee that the applicable authorities, including the FDA in the United States, will agree with our assessment of whether such extensions should be granted, and if granted, the length of such extensions. All taxes, annuities or maintenance fees for a patent, as required by the USPTO and various foreign jurisdictions, must be timely paid in order for the patent to remain in force during this period of time.

The actual protection afforded by a patent may vary on a product-by-product basis, from country to country, and can depend upon many factors, including the type of patent, the scope of its coverage, the availability of regulatory-related extensions and the availability of legal remedies in a particular country and the validity and enforceability of the patent.

Our patents and patent applications may be subject to procedural or legal challenges by others. We may be unable to obtain, maintain and protect the intellectual property rights necessary to conduct our business, and we may be subject to claims that we infringe or otherwise violate the intellectual property rights of others, which could materially harm our business. For more information, see the section titled “Risk Factors—Risks Related to Our Intellectual Property.”

Trademarks and Know-How

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

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

For more information regarding the risks related to our intellectual property, please see “Risk Factors—Risks Related to Our Intellectual Property.”

Government Regulation

The research, development, testing, manufacture, quality control, approval, labeling, packaging, storage, recordkeeping, serialization and tracking, promotion, advertising, distribution and marketing, post-approval or licensure monitoring and reporting, and export and import, among other things, of our product candidates are extensively regulated by governmental authorities in the United States and other countries. In the United States, the FDA regulates biological products under the Federal Food, Drug, and Cosmetic Act, or the FDCA, and its implementing regulations, and the Public Health Service Act, or the PHSA, and its implementing regulations. Failure to comply with the applicable U.S. requirements may subject us to administrative or judicial sanctions, such as the FDA’s refusal to approve a Biologics License Application, or BLA, warning letters, product recalls, product seizures, total or partial suspension of production or distribution, injunctions and/or criminal prosecution.

Preclinical Studies

Before testing any biologic product candidate in humans, the product candidate undergoes preclinical testing. Preclinical tests, also referred to as nonclinical studies, include laboratory evaluations of the product chemistry, pharmacology, toxicity and formulation, as well as animal studies to assess the pharmacokinetics, metabolism, bio-distribution, elimination and toxicity of the product candidate. The conduct of the pre-clinical tests and formulation of the compounds for testing must comply with federal regulations and requirements and certain preclinical trials must conform to the FDA’s Good Laboratory Practice requirements, or GLP.

The results of preclinical testing, manufacturing information, analytical data, any available clinical data or literature and a proposed clinical protocol, among other things, must be submitted to the FDA as part of an IND that must be reviewed and cleared by the FDA before clinical testing can begin. The IND will become effective 30 days after the FDA receives the application, unless the FDA raises concerns or questions related to the investigations in the application and places the trial on clinical hold. In this situation, the IND sponsor must resolve any outstanding FDA concerns before clinical trials can proceed. As a result, submission of an IND may or may not result in the FDA authorizing clinical trials to commence.

Clinical Trials

Clinical trials involve the administration of the biologic product candidate to healthy volunteers or patients under the supervision of qualified investigators in accordance with Good Clinical Practice, or GCP, requirements, which include the requirement that all research subjects provide their informed consent for their participation in any clinical trial. Clinical trials are conducted under protocols detailing the objectives of the study, dosing procedures, inclusion and exclusion criteria, study procedures, parameters to be used in monitoring safety and the effectiveness criteria to be evaluated.

Further, the study protocol and informed consent information for patients in clinical trials must also be submitted to an Institutional Review Board, or IRB, for approval covering each institution at which the clinical trial will be conducted. The IRB will consider, among other things, rationale for conducting the trial, clinical trial design, participant informed consent, ethical factors, the safety and rights of human subjects and the possible liability of the institution. The FDA can temporarily or permanently halt a clinical trial at any time, or impose other sanctions, if it believes that the clinical trial is not being conducted in accordance with FDA requirements or presents an unacceptable risk to the clinical trial subjects. The IRB may also require the clinical trial at a particular site be halted, either temporarily or permanently, for failure to comply with GCP or the IRB's requirements, or may impose other conditions.

Clinical trials typically involve a three-phase process; however, the phases may overlap or be combined:

•Phase 1 clinical trials typically are conducted in a small number of volunteers or patients to assess the early tolerability and safety profile, the pattern of drug absorption, distribution and metabolism, the mechanism of action in humans, and may include studies where investigational drugs are used as research to explore biological phenomena or disease processes;

•Phase 2 clinical trials typically are conducted in a limited patient population with a specific disease in order to assess appropriate dosages and dose regimens, expand evidence of the safety profile and evaluate preliminary efficacy; and

•Phase 3 clinical trials typically are larger scale, multicenter, well-controlled trials conducted on patients with a specific disease to generate enough data to statistically evaluate the efficacy and safety of the product, to establish the overall benefit-risk relationship of the drug and to provide adequate information for the labeling of the drug.

Post-approval clinical trials, sometimes referred to as Phase 4 clinical trials, may be conducted after initial marketing approval. These clinical trials may be conducted to fulfill mandatory conditions of product approval or used to gain additional experience from the treatment of patients in the intended therapeutic indication, particularly for long-term safety follow-up. The mandatory studies are used to confirm clinical benefit in the case of drugs approved under the accelerated approval regulations or to provide additional clinical safety or efficacy data for "full" approvals. Failure to promptly conduct and complete mandatory Phase 4 clinical trials could result in withdrawal of approval for products approved under accelerated approval regulations.

A therapeutic product candidate being studied in clinical trials may be made available for treatment of individual patients, intermediate-size patient populations, or for widespread treatment use under an expanded access protocol, under certain circumstances. Pursuant to the 21st Century Cures Act, or Cures Act, which was signed into law in December 2016, the manufacturer of one or more investigational products for the diagnosis, monitoring, or treatment of one or more serious diseases or conditions is required to make available, such as by posting on its website, its policy on evaluating and responding to requests for individual patient access to such investigational product.

Additionally, on May 30, 2018, the Trickett Wendler, Frank Mongiello, Jordan McLinn, and Matthew Bellina Right to Try Act of 2017 was signed into law. The law, among other things, provides a federal framework for certain patients to access certain investigational new drug products that have completed a Phase 1 clinical trial and that are undergoing investigation for FDA approval. Under certain circumstances, eligible patients can seek treatment without enrolling in clinical trials and without obtaining FDA authorization under an FDA expanded access program; however, manufacturers are not obligated to provide investigational new drug products under the current federal right to try law.

Disclosure of Clinical Trial Information

Sponsors of certain clinical trials of FDA-regulated products are required to register and disclose certain clinical trial information. Information related to the product, patient population, phase of investigation, trial sites and investigators, and other aspects of the clinical trial are then made public as part of the registration. Sponsors are also obligated to disclose the results of their clinical trials after completion. Competitors may use this publicly available information to gain knowledge regarding the progress of development programs. Information for certain clinical trials also must be publicly disclosed within certain time limits on the clinical trial registry and results databank maintained by the National Institutes of Health, or NIH.

Expedited Development and Review Programs

The FDA has a number of programs intended to expedite the development and review of product candidates. These programs include Fast Track designation, Breakthrough Therapy designation, priority review designation, and accelerated approval. Fast Track designation is intended to expedite or facilitate the process for reviewing new biological products that meet certain criteria. Specifically, new biological products are eligible for Fast Track designation if they are intended to treat a serious or life-threatening condition and demonstrate the potential to address unmet medical needs for the condition. Fast Track designation applies to the combination of the product and the specific indication for which it is being studied. The sponsor of a new biological product may request the FDA to designate the biological product as a Fast Track product at any time during the clinical development of the product. Unique to a Fast Track product, the FDA may consider for review sections of the marketing application on a rolling basis before the complete application is submitted, if the sponsor provides a schedule for the submission of the sections of the application, the FDA agrees to accept sections of the application and determines that the schedule is acceptable, and the sponsor pays any required user fees upon submission of the first section of the application. FDA may revoke the Fast Track designation if it believes that the designation is no longer supported by data emerging in the clinical trial process.

Under the Breakthrough Therapy program, products intended to treat a serious or life-threatening disease or condition may be eligible for Breakthrough Therapy designation, which includes eligibility for the benefits of the Fast Track program, when preliminary clinical evidence demonstrates that such product may have substantial improvement on one or more clinically significant endpoints over existing therapies. Additionally, FDA will seek to ensure the sponsor of a Breakthrough Therapy product receives timely advice and interactive communications to help the sponsor design and conduct a development program as efficiently as possible.

A product is eligible for Priority Review if it is intended to treat a serious condition and, if approved or licensed, it would provide a significant improvement in safety or effectiveness. FDA intends to take action on a priority review marketing application within six months of receipt, compared to 10 months of receipt for regular review submissions.

Additionally, a product may be eligible for accelerated approval if it is intended to treat a serious or life-threatening disease or condition and would provide meaningful therapeutic benefit over existing treatments. Accelerated approval may be granted on the basis of adequate and well-controlled clinical studies establishing that the product has an effect on a surrogate endpoint that is reasonably likely to predict a clinical benefit, or on a clinical endpoint that can be measured earlier than irreversible morbidity or mortality and is reasonably likely to predict an effect on irreversible morbidity, mortality, or other clinical benefit. As a condition of approval, the FDA may require that a sponsor of a biological product receiving accelerated approval diligently perform adequate and well-controlled clinical studies demonstrating clinical benefit, and may require that these studies be underway prior to approval under the Food and Drug Omnibus Reform Act of 2022, or FDORA. In addition, the FDA requires as a condition for accelerated approval the submission of promotional materials in advance, which could adversely impact the timing of the commercial launch of the product. Fast Track designation, Breakthrough Therapy designation, priority review and accelerated approval do not change the standards for licensure but may expedite the review process.

Orphan Drugs

Under the Orphan Drug Act, the FDA may grant orphan drug designation to therapeutic candidates (drugs or biological products) intended to treat a rare disease or condition, which is a disease or condition that affects fewer than 200,000 individuals in the U.S. or more than 200,000 individuals in the U.S. and for which there is no reasonable expectation that the cost of developing and making available in the U.S. a therapeutic candidate for this type of disease or condition will be recovered from sales in the U.S. for that therapeutic candidate. Orphan drug designation must be requested before submitting a marketing application for the therapeutic candidate for that particular disease or condition. 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 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 an exemption from the BLA application fee. The FDA may revoke orphan drug designation, and if it does, it will publicly disclose that the product is no longer designated as an orphan drug.

If a product that has orphan drug designation subsequently receives the first FDA approval for the disease for which it has such designation, the product is entitled to orphan drug exclusivity, which means that the FDA may not approve any other applications, including a full BLA, to market the same biological product for the same indication for seven years, except in limited circumstances, such as a showing of clinical superiority to the product with orphan drug exclusivity or if the FDA finds that the holder of the orphan drug exclusivity has not shown that it can assure the availability of sufficient quantities of the orphan drug to meet the needs of patients with the disease or condition for which the biological product was designated. Orphan drug exclusivity does not prevent the FDA from approving a different biological product for the same disease or condition, or the same biological product for a different disease or condition.

A designated orphan drug may not receive orphan drug exclusivity if it is licensed 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.

Additional controls for biologics

To help reduce the increased risk of the introduction of adventitious agents, the PHSA emphasizes the importance of manufacturing controls for products whose attributes cannot be precisely defined. The PHSA also provides authority to the FDA to immediately suspend biologics licenses in situations where there exists a danger to public health, to prepare or procure products in the event of shortages and critical public health needs, and to authorize the creation and enforcement of regulations to prevent the introduction or spread of communicable diseases within the United States.

After a BLA is approved, the product may also be subject to official lot release as a condition of approval. As part of the manufacturing process, the manufacturer is required to perform certain tests on each lot of the product before it is released for distribution. If the product is subject to official release by the FDA, the manufacturer submits samples of each lot of product to the FDA together with a release protocol showing a summary of the lot manufacturing history and the results of all of the manufacturer's tests performed on the lot.

The FDA may also perform certain confirmatory tests on lots of some products, such as viral vaccines, before allowing the manufacturer to release the lots for distribution. In addition, the FDA conducts laboratory research related to the regulatory standards on the safety, purity, potency, and effectiveness of biological products. As with drugs, after approval of a BLA, biologics manufacturers must address any safety issues that arise, are subject to recalls or a halt in manufacturing, and are subject to periodic inspection after approval.

FDA Review of BLAs

After completion of the required clinical testing, a BLA is prepared and submitted to the FDA. FDA approval of the BLA is required before marketing of the product may begin in the United States. The BLA must include the results of all preclinical, clinical and other testing and a compilation of data relating to the product's pharmacology, chemistry, manufacture and controls. The cost of preparing and submitting a BLA is substantial. The submission of most BLAs is additionally subject to a substantial application user fee, currently $4,048,695 for BLAs requiring clinical data for fiscal year 2024, and the manufacturer and sponsor under an approved BLA are also subject to annual program fees, currently $416,734 for each prescription product. These fees are typically increased annually. Sponsors of applications for drugs granted Orphan Drug Designation are exempt from these user fees.

The FDA has 60 days from its receipt of a BLA to determine whether the application will be accepted for filing based on the Agency's threshold determination that it is sufficiently complete to permit substantive review. The FDA may request additional information rather than accept a BLA for filing. In this event, the application must be resubmitted with the additional information. The resubmitted application is also subject to review before the FDA accepts it for filing. If the application is accepted for review, the FDA reviews the application to determine, among other things, whether a product is safe and effective for its intended use and whether the manufacturing controls are adequate to assure and preserve the product's identity, strength, quality, and purity.

The FDA has agreed to certain performance goals in the review of BLAs to encourage timeliness. Applications for standard review biological products are meant to be reviewed within ten months; applications for priority review drugs are meant to be reviewed in six months. Priority review can be applied to biological products that the FDA determines offer major advances in treatment or provide a treatment where no adequate therapy exists. The review process for both standard and priority review may be extended by the FDA for three additional months ("major amendment") to consider certain late-submitted information, or information intended to clarify information already provided in the submission.

The FDA is required to refer an application for a novel biological product to an advisory committee or explain why such referral was not made. An advisory committee is typically a panel that includes clinicians and other experts—for review, evaluation and a recommendation as to whether the application should be approved. The FDA is not bound by the recommendation of an advisory committee, but it generally follows such recommendations.

Before approving a BLA, the FDA will typically inspect one or more clinical sites to assure compliance with GCP. Additionally, the FDA will inspect the facility or the facilities at which the drug is manufactured. The FDA will not license the product unless compliance with cGMPs is satisfactory, and the application meets the appropriate standard. A BLA must include data that demonstrate that the biological product is safe, pure, and potent.

After the FDA evaluates the BLA and accompanying information and the manufacturing facilities, it issues either an approval letter or a complete response letter. An approval letter authorizes commercial marketing of the product with specific prescribing information for specific indications. A complete response letter generally outlines the deficiencies in the submission and may require substantial additional testing, or information, in order for the FDA to reconsider the application. If, or when, those deficiencies have been addressed to the FDA's satisfaction in a resubmission of the BLA, the FDA will issue an approval letter. The FDA has committed to reviewing such resubmissions in two or six months depending on the type of information included. Even with submission of this additional information, the FDA ultimately may decide that the application does not satisfy the regulatory criteria for approval.

If the FDA approves a product, it may limit the approved indications for use for the product; require that contraindications, warnings or precautions be included in the product labeling; require that post-marketing studies, including Phase 4 clinical trials, be conducted to further assess the drug's safety after licensure; require testing and surveillance programs to monitor the product after commercialization; or impose other conditions, including distribution restrictions or other risk management mechanisms, which can materially affect the potential market and profitability of the product. As a condition of BLA licensure, the FDA may require a risk evaluation and mitigation strategy, or REMS, to help ensure that the benefits of the biological product outweigh the potential risks. REMS can include medication guides, communication plans for healthcare professionals and elements to assure safe use, or ETASU. ETASU can include, but are not limited to, special training or certification for prescribing or dispensing, dispensing only under certain circumstances, special monitoring and the use of patient registries. The requirement for a REMS can materially affect the potential market and profitability of the drug. Moreover, product licensure may require substantial post-approval testing and surveillance to monitor the drug's safety or efficacy. Once granted, product licenses may be withdrawn if compliance with regulatory standards is not maintained, or problems are identified following initial marketing.

The FDA may prevent or limit further marketing of a product based on the results of post-market studies or surveillance programs. Changes to some of the conditions established in an approved application, including changes in indications, labeling, or manufacturing processes or facilities, require submission and FDA approval, as applicable, of a new BLA or supplement before the change can be implemented. A BLA supplement for a new indication typically requires similar non-clinical and CMC data to that in the original application, and the FDA uses the same procedures and actions in reviewing supplements as it does in reviewing BLAs.

Pediatric studies and exclusivity

Under the Pediatric Research Equity Act of 2003, a BLA or supplement thereto must contain data that are adequate 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 product is safe and effective. With enactment of the Food and Drug Administration Safety and Innovation Act of 2012, or FDASIA, sponsors must also submit pediatric study plans prior to the assessment data.

Those pediatric study plans must contain an outline of the proposed pediatric study or studies the applicant plans to conduct, including study objectives and design, any deferral or waiver requests, and other information required by regulation. The applicant, the FDA and the FDA's internal review committee must then review the information submitted, consult with each other and agree upon a final plan. The FDA or the applicant may request an amendment to the plan at any time.

The FDA may, on its own initiative or at the request of the applicant, grant deferrals for submission of some or all pediatric data until after licensure of the product for use in adults, or full or partial waivers from the pediatric data requirements. Additional requirements and procedures relating to deferral requests and requests for extension of deferrals are contained in FDASIA. Unless otherwise required by law or regulation, the pediatric data requirements do not apply to products with orphan designation.

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

Post-Licensure FDA Requirements

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

Often times, even after a biological product has been licensed by the FDA for sale, the FDA may require that certain post-licensure requirements be satisfied, including the conduct of additional clinical studies. If such post-approval requirements are not satisfied, the FDA may withdraw its licensure of the biological product. In addition, holders of a biological product license are required to report certain adverse reactions to the FDA, comply with certain requirements concerning advertising and promotional labeling for their products, and continue to have quality control and manufacturing procedures conform to cGMP after approval. In addition, biological product manufacturers and their subcontractors are required to register their establishments with the FDA and state agencies, and are subject to periodic unannounced inspections by the FDA and these state agencies for compliance with cGMP requirements and other aspects of regulatory compliance. Changes to the manufacturing process are strictly regulated and often require prior FDA approval before being implemented. FDA regulations also require investigation and correction of any deviations from cGMP and impose reporting and documentation requirements upon the sponsor and any third-party manufacturers that the sponsor may decide to use. Accordingly, manufacturers must continue to expend time, money and effort in the area of production and quality control to maintain cGMP compliance.

Among the conditions for BLA licensure is the requirement that the manufacturing operations conform on an ongoing basis with cGMP. In complying with cGMP, we must expend time, money and effort in the areas of training, production and quality control within our own organization and at our contract manufacturing facilities. A successful inspection of the manufacturing facility by the FDA is usually a prerequisite for final licensure of a biological product. Following licensure of the BLA, we and our manufacturers will remain subject to periodic inspections by the FDA to assess continued compliance with cGMP requirements and the conditions of licensure. We will also face similar inspections coordinated by foreign regulatory authorities. The FDA periodically inspects the sponsor's records related to safety reporting and/or manufacturing facilities; this latter effort includes assessment of compliance with cGMP. Accordingly, manufacturers must continue to expend time, money, and effort in the area of production and quality control to maintain cGMP compliance.

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

- Restrictions on the marketing or manufacturing of the product, including total or partial suspension of production, complete withdrawal of the product from the market or product recalls;
- Fines, warning letters or holds on post-licensure clinical trials;
- Refusal of the FDA to license pending BLAs or supplements, or suspension or revocation of product licensure;
- Product seizure or detention, or refusal to permit the import or export of products;
- Consent decrees, corporate integrity agreements, debarment or exclusion from federal healthcare programs;
- Mandated modification of promotional materials and labeling and the issuance of corrective information;
- The issuance of safety alerts, Dear Healthcare Provider letters, press releases and other communications containing warnings or other safety information about the product; or
- Injunctions or the imposition of civil or criminal penalties.

The FDA closely regulates marketing, labeling, advertising and promotion of products that are placed on the market. Biological products may be promoted only for the licensed indications and in accordance with the provisions of the approved labeling. The FDA and other agencies actively enforce the laws and regulations prohibiting the promotion of off-label uses, and a company that is found to have improperly promoted off-label uses may be subject to significant liability. Failure to comply with these requirements can result in, among other things, adverse publicity, warning letters, corrective advertising and potential civil and criminal penalties. Physicians may prescribe legally available products for uses that are not described in the product's labeling and that differ from those tested by us and approved by the FDA. Such off-label uses are common across medical specialties. Physicians may believe that such off-label uses are the best treatment for many patients in varied circumstances. The FDA does not regulate the behavior of physicians in their choice of treatments. The FDA does, however, restrict manufacturer's communications on the subject of off-label use of their products.

In addition, the distribution of prescription drug products, including most biological products that require a prescription, are subject to the Prescription Drug Marketing Act, or the PDMA, which regulates the distribution of drug samples at the federal level, and sets minimum standards for the registration and regulation of drug distributors by the states. Both the PDMA and state laws limit the distribution of prescription drug product samples and impose requirements to ensure accountability in distribution

Biosimilars and Reference Product Exclusivity

The Biologics Price Competition and Innovation Act of 2009, or BPCIA, created an abbreviated approval pathway for biological product candidates shown to be highly similar, or "biosimilar," to or interchangeable with an FDA licensed reference biological product. Biosimilarity, which requires that a product is 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 generally be shown through analytical studies, animal studies, and a clinical study or studies. Interchangeability requires that a product is biosimilar to the reference product and the product must demonstrate that it can be expected to produce the same clinical results as the reference product in any given patient and, for products that are administered multiple times to an individual, the interchangeable biosimilar and the reference biological 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. A product shown to be biosimilar or interchangeable with an FDA-approved reference biological product may rely in part on the FDA's previous determination of safety and effectiveness for the reference product for approval, which can potentially reduce the cost and time required to obtain approval to market the product. Complexities associated with the larger, and often more complex, structures of biological products, as well as the processes by which such products are manufactured, pose significant hurdles and have slowed implementation of the BPCIA by the FDA.

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 reference product exclusivity, another company may obtain FDA licensure and market a competing version of the reference product if the FDA approves a full BLA for the competing product containing that applicant's own preclinical data and data from adequate and well-controlled clinical trials to demonstrate the safety, purity and potency of its product. The BPCIA also created certain exclusivity periods for biosimilars approved as interchangeable products. At this juncture, it is unclear whether products deemed "interchangeable" by the FDA will, in fact, be readily substituted by pharmacies, which are governed by state pharmacy law.

A biological product can also obtain pediatric market exclusivity in the United States. As stated above, pediatric exclusivity, if granted, adds six months to existing exclusivity periods and patent terms. This six-month exclusivity, which runs from the end of other exclusivity protection or patent term, may be granted based on the voluntary completion of a pediatric study in accordance with an FDA-issued "Written Request" for such a study.

The BPCIA is complex and continues to be interpreted and implemented by the FDA. In addition, there has been discussion of whether Congress should reduce the 12-year reference product exclusivity period. Other aspects of the BPCIA, some of which may impact the BPCIA exclusivity provisions, have also been the subject of recent litigation. As a result, the ultimate implementation of the BPCIA is subject to significant uncertainty.

Patent term extension

In the United States, after BLA licensure, owners of relevant drug patents may apply for up to a five-year patent extension, which permits patent term restoration as compensation for the patent term lost during the FDA regulatory process. The allowable patent term extension is typically calculated as one-half the time between, the latter of the effective date of an IND and issue date of the patent for which extension is sought, and the submission date of a BLA, plus the time between BLA submission date and the BLA approval date up to a maximum of five years. The time can be shortened if the FDA determines that the applicant did not pursue licensure with due diligence. The total patent term after the extension may not exceed 14 years from the date of product licensure. Only one patent applicable to a licensed biological product is eligible for extension and only those claims covering the product, a method for using it, or a method for manufacturing it may be extended and the application for the extension must be submitted prior to the expiration of the patent in question. However, we may not be granted an extension because of, for example, failing to exercise due diligence during the testing phase or regulatory review process, failing to apply within applicable deadlines, failing to apply prior to expiration of relevant patents or otherwise failing to satisfy applicable requirements. Some, but not all, foreign jurisdictions possess patent term extension or other additional patent exclusivity mechanisms that may be more or less stringent and comprehensive than those of the United States.

Other Federal and State Regulatory Requirements

Various federal, state and local laws, regulations, and recommendations relating to safe working conditions, laboratory practices, the experimental use of animals, the environment and the purchase, storage, movement, import, export, use, and disposal of hazardous or potentially hazardous substances, including radioactive compounds and infectious disease agents, used in connection with our research are applicable to our activities. They include, among others, the U.S. Atomic Energy Act, the Clean Air Act, the Clean Water Act, the Occupational Safety and Health Act, the National Environmental Policy Act, the Toxic Substances Control Act, and Resources Conservation and Recovery Act, national restrictions on technology transfer, import, export, and customs regulations, and other present and possible future local, state, or federal regulation.

Foreign Regulation

In addition to regulations in the United States, we will be subject to a variety of foreign regulations governing clinical trials and commercial sales and distribution of our product candidates to the extent we choose to sell any products outside of the United States. Whether or not we obtain FDA approval for a product, we must obtain the requisite approvals from regulatory authorities and, if required, from independent ethics committees in foreign countries before we can commence clinical trials as well as regulatory approvals prior to marketing the product candidates in those countries. The approval processes vary from country to country and the time may be longer or shorter than that required for FDA approval. The requirements governing the conduct of clinical trials, product licensing, pricing and reimbursement vary greatly from country to country. As in the United States, post-approval regulatory requirements, such as those regarding product manufacture, marketing, or distribution would apply to any product that is approved outside the United States.

Other Healthcare Laws

Among others, the FDA, U.S. Department of Health and Human Services, or HHS, Office of Inspector General, the Centers for Medicare and Medicaid Services, or CMS, and comparable regulatory authorities in state and local jurisdictions and in other countries impose substantial and burdensome requirements upon companies involved in the preclinical and clinical development, manufacture, marketing, and distribution of drugs such as those we are developing. These agencies and other federal, state, and local entities regulate, among other activities, the research and development, testing, manufacture, quality control, safety, effectiveness, labeling, storage, record keeping, approval, sales, commercialization, marketing, advertising and promotion, distribution, post-approval monitoring and reporting, sampling, and export and import of our product candidates. Any drug candidates that we develop must be approved by the FDA before they may be legally marketed in the United States and by the appropriate foreign regulatory agency before they may be legally marketed in those foreign countries. Generally, our activities in other countries will be subject to regulation that is similar in nature and scope as that imposed in the United States, although there can be important differences. Additionally, some significant aspects of regulation in the European Union, or EU, are addressed in a centralized way, but country-specific regulation remains essential in many respects.

Although we do not currently have any products on the market, in addition to FDA restrictions on marketing of pharmaceutical products, we are also subject to healthcare statutory and regulatory requirements and enforcement by the U.S. federal and state governments. Pharmaceutical companies like us are subject to additional healthcare regulation and enforcement by the federal government and by authorities in the states and foreign jurisdictions in which they conduct their business. Such regulation may constrain the financial arrangements and relationships through which we research, develop, and, ultimately, sell, market, and distribute any products for which we obtain marketing approval. Such laws include, without limitation:

- The federal Anti-Kickback Statute, an intent-based criminal statute that prohibits, among other activities, persons and entities from knowingly and willfully soliciting, offering, paying, receiving, or providing any remuneration (including any kickback, bribe, or rebate), directly or indirectly, overtly or covertly, in cash or in kind, to induce or reward, or in return for, either the referral of an individual for, or the purchase, lease, order, or recommendation of, any item or service for which payment may be made, in whole or in part, under a federal healthcare program, such as Medicare or 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. A conviction for violation of the federal Anti-Kickback Statute can result in criminal fines and/or imprisonment and requires mandatory exclusion from participation in federal health care programs. Exclusion may also be imposed if the government determines that an entity has committed acts that are prohibited by the federal Anti-Kickback Statute.

- The federal civil and criminal false claims laws, including the civil False Claims Act, or FCA, which prohibit individuals or entities from, among other activities, knowingly presenting, or causing to be presented, to the federal government claims for payment or approval that are false, fictitious, or fraudulent; knowingly making, using, or causing to be made or used, a false statement or record material to a false or fraudulent claim or obligation to pay or transmit money or property to the federal government; or knowingly concealing or knowingly and improperly avoiding or decreasing an obligation to pay money to the federal government. In addition, the government may assert that a claim that includes items or services resulting from a violation of the federal Anti-Kickback Statute constitutes a false or fraudulent claim for purposes of the FCA. Moreover, pharmaceutical 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. The FCA also permits a private individual acting as a “whistleblower” to bring *qui tam* actions on behalf of the federal government alleging violations of the FCA and to share in any monetary recovery or settlement. FCA liability is potentially significant in the healthcare industry because the statute provides for treble damages and significant mandatory penalties per false or fraudulent claim or statement for violations. Criminal penalties, including imprisonment and criminal fines, are also possible for making or presenting a false, fictitious or fraudulent claim to the federal government.

- The federal civil monetary penalties laws, which prohibit, among other activities (1) arranging for or contracting with an individual or entity that is excluded from participation in federal healthcare programs to provide items or services reimbursable by a federal healthcare program, (2) failing to report and return a known overpayment, or (3) offering or transferring any remuneration to a Medicare or Medicaid beneficiary if the person knows or should know it is likely to influence the beneficiary's selection of a particular provider, practitioner, or supplier of items or services reimbursable by Medicare or Medicaid, unless an exception applies.

- The federal criminal statutes enacted under the Health Insurance Portability and Accountability Act of 1996, or HIPAA, which impose criminal liability for knowingly and willfully executing, or attempting to execute, a scheme to defraud any healthcare benefit program, including private third-party payors, or obtain, by means of false or fraudulent pretenses, representations, or promises, any of the money or property owned by, or under the custody or control of, any healthcare benefit program; knowingly and willfully embezzling or stealing from a healthcare benefit program; willfully preventing, obstructing, misleading, or delaying a criminal investigation of a healthcare offense; and knowingly and willfully falsifying, concealing, or covering up a material fact or making any materially false statements 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.

•The federal Physician Payments Sunshine Act, enacted as part of the Patient Protection and Affordable Care Act, which requires certain manufacturers of drugs, devices, biological products, and medical supplies for which payment is available under Medicare, Medicaid, or the Children's Health Insurance Program, among others, to track and report annually to CMS certain payments and other "transfers of value" provided to "covered recipients," which include U.S.-licensed physicians (defined to include doctors, dentists, optometrists, podiatrists and licensed chiropractors), physician assistants, nurse practitioners, clinical nurse specialists, certified registered nurse anesthetists, anesthesiologist assistants, certified nurse midwives, and U.S. teaching hospitals, as well as tracking and reporting of certain ownership and investment interests held by U.S.-licensed physicians and their immediate family members.

•The FDCA and PHSA, which regulate licensure of biological products and prohibit the misbranding and adulteration of biological products.

•Analogous state and foreign laws and regulations, such as state anti-kickback and false claims laws, which may apply with respect to healthcare items or services reimbursed by non-governmental third-party payors and may be broader than their federal equivalents; state and foreign laws requiring pharmaceutical companies to comply with the pharmaceutical industry's voluntary compliance guidelines and/or the relevant compliance guidance promulgated by the federal government or otherwise restricting payments that may be made to healthcare providers; state laws and regulations requiring drug manufacturer disclosures to state agencies and/or commercial purchasers with respect to certain price increases or imposing payment caps on certain pharmaceutical products deemed by the state to be "high cost"; state and foreign laws requiring drug manufacturers to report information related to payments and other transfers of value to physicians and other healthcare providers and restricting marketing practices or requiring disclosure of marketing expenditures and pricing information; and state and local laws that requiring registration of pharmaceutical sales representatives.

Violations of any of these laws or any other applicable laws or regulations may result in significant penalties, including, without limitation, administrative, civil, and criminal penalties, damages, fines, disgorgement, the curtailment or restructuring of operations, integrity oversight and reporting obligations to resolve allegations of noncompliance; exclusion from participation in federal and state healthcare programs, such as Medicare and Medicaid; and imprisonment. Ensuring business arrangements comply with applicable healthcare laws, as well as responding to possible investigations by government authorities, can be time- and resource-consuming and can divert a company's attention from its business.

Coverage and Reimbursement

Sales of any pharmaceutical product depend, in part, on the extent to which such product will be covered by third-party payors, such as federal, state, and foreign government healthcare programs, commercial insurance and managed healthcare organizations, and the level of reimbursement for such product by third-party payors. Decisions regarding the extent of coverage and amount of reimbursement to be provided are made on a payor-by-payor basis. These third-party payors are increasingly reducing coverage and reimbursement for healthcare items (including drugs) and services. Moreover, for products administered under the supervision of a physician, obtaining coverage and adequate reimbursement may be particularly difficult because of the higher prices often associated with such drugs. Additionally, separate reimbursement for the product itself may or may not be available. Instead, the hospital or administering physician may be reimbursed only for providing the treatment or procedure in which our product is used.

In addition, the U.S. government, states, and foreign governments have continued implementing cost-containment programs, including price controls, restrictions on coverage and reimbursement, and requirements for substitution of lower-cost or generic products. Adoption of price controls and cost-containment measures and adoption of more restrictive policies in jurisdictions with existing controls and measures could further limit sales of any drug product. Decreases in third-party reimbursement for any drug product or a decision by a third-party payor not to cover a product could reduce physician usage and patient demand for the product and also have a material adverse effect on sales.

Moreover, as a condition of participating in, and having products covered under, certain federal healthcare programs, such as Medicare and Medicaid, we may become subject to federal laws and regulations that require pharmaceutical manufacturers to calculate and report certain pricing metrics to the government, including the Average Manufacturer Price, or AMP, and Best Price under the Medicaid Drug Rebate Program, the Medicare Average Sales Price, the 340B Ceiling Price, and Non-Federal AMP reported to the Department of Veteran Affairs, with respect to Medicaid, pay statutory rebates on utilization of manufacturers' products by Medicaid beneficiaries, and with respect to Medicare, to pay rebates based on price increases greater than the rate of inflation. Judicial decisions may also affect the implementation of these programs. Compliance with these laws and regulations will require significant resources and may have a material adverse effect on our revenues.

Healthcare Reform

In March 2010, the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act, collectively the ACA, was enacted in the United States, which made a number of substantial changes in the way healthcare is financed by both governmental and private insurers. Among other ways in which it may affect our business, the ACA established a new Patient-Centered Outcomes Research Institute to oversee and identify priorities in comparative clinical effectiveness research in an effort to coordinate and develop such research; implemented payment system reforms including a national pilot program on payment bundling to encourage hospitals, physicians and other healthcare providers to improve the coordination, quality and efficiency of certain healthcare services through bundled payment models; implemented the federal Physician Payments Sunshine Act; and expanded the eligibility criteria and rebates for Medicaid programs.

Since its enactment, there have been executive, judicial and legislative branch challenges to certain aspects of the ACA. For example, while Congress has not passed comprehensive repeal legislation, two bills affecting the implementation of certain taxes under the ACA have been signed into law, including the repeal, effective January 1, 2019, of the tax-based shared responsibility payment imposed by the ACA on certain individuals who fail to maintain qualifying health coverage for all or part of a year that is commonly referred to as the "individual mandate." Additionally, on June 17, 2021, the U.S. Supreme Court dismissed a judicial challenge to the ACA brought by several states without specifically ruling on the constitutionality of the ACA. Prior to the Supreme Court's decision, President Biden had issued an executive order that instructed certain governmental agencies to review and reconsider their existing policies and rules that limit access to healthcare, including among others, policies that create barriers to obtaining access to health insurance coverage through the ACA marketplaces. It is unclear how healthcare reform measures enacted by Congress or implemented by the Biden or a future administration or other efforts to challenge, repeal or replace the ACA, if any, will impact the ACA.

Other legislative changes have been proposed and adopted in the U.S. since the ACA was enacted. These changes include the Budget Control Act of 2011, which, among other changes, led to aggregate reductions in Medicare payments to providers of up to 2% per fiscal year that started in April 2013 and, due to subsequent legislation, will continue into through the first seven months of federal fiscal year 2032 (with the exception of a temporary suspension instituted during the COVID-19 pandemic that halted the sequestration from May 1, 2020 to March 31, 2022, and later reduced the reductions to 1% from April 1, 2022 until July 1, 2022). In addition, effective January 1, 2024, manufacturers' Medicaid Drug Rebate Program rebate liability is no longer capped, potentially resulting in a manufacturer paying more in Medicaid Drug Rebate Program rebates than it receives on the sale of certain covered outpatient drugs.

Moreover, in August 2022, President Biden signed into law the Inflation Reduction Act of 2022, or the IRA, which implements substantial changes to the Medicare program, including drug pricing reforms and the creation of new Medicare inflation rebates. Namely, the IRA (1) imposes inflation rebates on drug manufacturers for products reimbursed under Medicare Parts B and D if the prices of those products increase faster than inflation; (2) implements changes to the Medicare Part D benefit that, beginning in 2025, will cap beneficiary annual out-of-pocket spending at $2,000, while imposing new discount obligations for pharmaceutical manufacturers; and, (3) beginning in 2026, establishes a "maximum fair price" for a fixed number of high expenditure pharmaceutical and biological products covered under Medicare Parts B and D following a price negotiation process with CMS. CMS has also taken steps to implement the IRA, including: on June 30, 2023, issuing guidance detailing the requirements and parameters of the first round of price negotiations, to take place during 2023 and 2024, for products subject to the "maximum fair price" provision that would become effective in 2026; on August 29, 2023, releasing the initial list of ten drugs subject to price negotiations; on November 17, 2023, releasing guidance outlining the methodology for identifying certain manufacturers eligible to participate in a phase-in period where discounts on applicable products will be lower than those required by the Medicare Part D Manufacturer Discount Program; and on December 14, 2023, releasing a list of 48 Medicare Part B products that had an adjusted coinsurance rate based on the inflationary rebate provisions of the IRA for the time period of January 1, 2024 to March 31, 2024. Judicial challenges to different portions of the IRA and its implementation continue. Although we cannot predict whether the IRA or any of its component parts will be overturned, repealed, replaced or amended, nor can we predict the likelihood, nature, or extent of other health reform initiatives that may arise from future legislation, administrative or other action, we expect these initiatives to increase pressure on drug pricing.

On February 2, 2022, the Biden Administration signaled its continued commitment to the Cancer Moonshot initiative, which was initially launched in 2016. In its announcement, the administration noted that its new goals under the initiative include addressing inequities in order to ensure broader access to cutting-edge cancer therapeutics and investing in a robust pipeline for new treatments. In alignment with President Biden's Cancer Moonshot initiative, on June 27, 2023, the Center for Medical Innovation at CMS announced a new model, the Enhancing Oncology Model, that is designed to make higher-quality cancer care more affordable to both patients and Medicare. Additionally, on October 14, 2022, President Biden also issued an Executive Order on Lowering Prescription Drug Costs for Americans, which instructed the Secretary of the HHS to consider whether to select for testing by the CMS Innovation Center new health care payment and delivery models that would lower drug costs and promote access to innovative drug therapies for beneficiaries enrolled in the Medicare and Medicaid programs. Most recently, on February 14, 2023, the HHS issued a report in response to the October 14, 2022 Executive Order, which, among other things, selects three potential drug affordability and accessibility models to be tested by the CMS Innovation Center. Specifically, the report addresses: (1) a model that would allow Part D Sponsors to establish a "high-value drug list" setting the maximum co-payment amount for certain common generic drugs at $2; (2) a Medicaid-focused model that would establish a partnership between CMS, manufacturers, and state Medicaid agencies that would result in multi-state outcomes-based agreements or certain cell and gene therapy drugs; and (3) a model that would adjust Medicare Part B payment amounts for Accelerated Approval Program drugs to advance the developments of novel treatments.

Meanwhile, individual states in the U.S. have increasingly passed legislation and implemented regulations designed to control pharmaceutical and biological product pricing, including price or patient reimbursement constraints, discounts, restrictions on certain product access and marketing cost disclosure and transparency measures. In some cases, states have also encouraged importation of pharmaceutical and biological products from other countries and employed bulk purchasing. Legally mandated price controls on payment amounts by third-party payors or other restrictions could adversely affect our business prospects, financial condition, and results of operations. 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. This could reduce the ultimate demand for our product candidates or put pressure on our product pricing.

We expect that additional state and federal healthcare reform and/or drug pricing measures will be adopted in the future, any of which could affect the pricing and/or availability of drug products, the amounts that federal and state governments and other third-party payors will pay for healthcare products and services, and/or our ability to generate revenue, attain or maintain profitability, or commercialize products for which we may receive regulatory approval in the future.

Data Privacy & Security

Numerous state, federal and foreign laws and regulations govern the collection, dissemination, use, access to, privacy and security of personal information (including health-related information). Such laws and regulations that could apply to our operations or the operations of our partners include health information privacy and security laws (e.g., HIPAA), federal and state consumer protection laws and regulations (e.g., Section 5 of the Federal Trade Commission Act), state privacy laws (e.g., the California Consumer Privacy Act, or CCPA, as modified by the California Consumer Privacy Rights Act, or CPRA; and other state comprehensive privacy laws), data breach notification laws, and the EU General Data Protection Regulation, or GDPR.

Privacy and security laws, regulations, and other obligations are constantly evolving, may conflict with each other to complicate compliance efforts, and can result in investigations, proceedings, or actions that lead to significant civil and/or criminal penalties and restrictions on data processing.

Employees and Human Capital Management

Our values of “Be Clever,” “Be of Service,” “Be Gutsy,” “Be Tenacious,” and “Be You,” are the foundation of our organization and drives our mission to improve the quality of life for patients and their families.

We believe that our continued success is directly due to the commitment, engagement and performance of our employees. We strive to attract and retain experienced operators, oncology experts, clinicians, and biopharma veterans with deep market knowledge and insights with an uncompromising vision of delivering solutions for patients. In order to achieve this, we provide an inclusive and empowering work environment, foster a culture built on diversity, equity and inclusion, reward performance and leadership skills, and by offering competitive compensation and benefits programs.

Employees

As of March 20, 2024, we had 50 full-time permanent employees. Of these employees, approximately 73% were engaged in research and development activities and 49% had advanced degrees including Ph.D., M.D., M.B.A., J.D. More than half of our workforce is comprised of women. None of our employees is represented by a labor union or covered by a collective bargaining agreement. We consider our relationship with our employees to be good. In November 2023, we undertook a corporate reorganization, which included a headcount reduction of approximately 40%, to refocus our efforts to our progressing clinical trials. The corporate reorganization was completed in the fourth quarter of 2023.

Culture and Employee Engagement

We place a high value on the diversity of our team, including gender, background and expertise, to foster our culture of innovation. Our employees are guided by our Code of Conduct, which sets basic requirements for business conduct and serves as a foundation for our policies, procedures and guidelines, all of which provide additional guidance on expected employee behaviors.

Compensation, Benefits and Ongoing Professional Development

Drug development is a complex endeavor which requires deep expertise and experience across a broad array of disciplines. Biotechnology and pharmaceutical companies both large and small compete for a limited number of qualified applicants to fill specialized positions. As part of our total rewards philosophy, we offer competitive compensation and benefits to attract and retain top talent.

We are committed to fair and equitable treatment in our compensation and benefits for employees at all levels. We provide our employees with compensation packages that include competitive base salaries, incentive bonuses, and new hire and long-term incentive equity awards. We believe that providing employees with the opportunity to earn ownership interest in the company encourages employees to act in our long-term best interests, aligns the interests of our stockholders with our employees, and further strengthens the level of employee engagement. Employees can also participate in our Employee Share Purchase Plan, or ESPP, which provides our employees with an opportunity to purchase shares of our common stock at a discount.

Our total rewards offerings also include an array of programs to support our employees' financial well-being, including retirement savings programs with matching contributions for eligible employees, health and welfare benefits, and paid time off. We have also created a flexible work policy to allow our employees to work remotely. For our facility-dependent employees, including those needed to maintain our research and development activities, we implemented comprehensive safety protocols designed to ensure a healthy environment.

We also provide reimbursement and time for employees to attend professional development courses ranging from technical training, competency-based workshops, and leadership development programs. Direct managers also take an active role in identifying individualized development plans to assist their employees in realizing their full potential and creating opportunities for promotions and added responsibilities that enhance the engagement and retention of our workforce. We are committed to maintaining and increasing our investment in our workforce as we grow, including improvements in the way we hire, develop, motivate and retain employees.

Board of Directors Oversight

Our Board of Directors, or the Board, recognizes the critical importance of our team and the necessity to ensure a diverse, inclusive, and innovative work environment that is centered around a values-based culture. Our Board meets regularly with management to discuss issues impacting our employees, and to focus on ways to support our workforce. Our focus on culture comes from our Board and flows throughout our company. In evaluating our Chief Executive Officer and management team, significant emphasis is placed on their contributions to our overall culture.

Our Board's Compensation Committee is responsible for reviewing with management our human resources activities, which include, among other things, matters relating to employee development, management and engagement, pay equity, and our demographics, diversity and inclusion.

Our Board's Nominating and Corporate Governance Committee is responsible for developing and recommending to the Board any company program relating to corporate responsibility and sustainability, including environmental, social and governance matters.

Corporate Information

We were incorporated in the state of Delaware on June 11, 2018 and launched with our first employee and Series A funding in July 2019. Our principal executive offices are located at 321 Harrison Avenue, Boston, MA 02118, and our telephone number is (617) 221-9059. Our website address is www.pyxisoncology.com.

The information in, or that can be accessed through, our website is not a part of this Annual Report on Form 10-K. Our Annual Report on Form 10-K, Quarterly Reports on Form 10-Q, Current Reports on Form 8-K, and amendments to those reports filed or furnished pursuant to Section 12(a) or 15(d) of the Exchange Act are available, free of charge, on or through our website as soon as reasonably practicable after such reports and amendments are electronically filed with or furnished to the SEC. The SEC maintains an Internet site that contains, reports, proxy and information statements and other information regarding our filings at sec.gov. The contents of these websites are not incorporated into this filing. Further, references to the URLs for these websites are intended to be inactive textual references only.

Item 1A. Risk Factors.

Our business involves a high degree of risk. You should consider and read carefully all of the risks and uncertainties described below, as well as other information included in this Annual Report on Form 10-K, including our financial statements and related notes appearing at the end of this Annual Report on Form 10-K. The risks described below are not the only ones facing us. The occurrence of any of the following risks or additional risks and uncertainties not presently known to us or that we currently believe to be immaterial could materially and adversely affect our business, financial condition or results of operations. In such case, the trading price of our common stock could decline, and you may lose all or part of your investment. This Annual Report on Form 10-K also contains forward-looking statements and estimates that involve risks and uncertainties. Our actual results could differ materially from those anticipated in the forward-looking statements as a result of specific factors, including the risks and uncertainties described below.

Risks Related to Our Financial Position and Need for Additional Capital

We are a clinical stage biopharmaceutical company with a limited operating history and have incurred significant losses since our inception. We expect to incur losses over at least the next several years and may never achieve or maintain profitability.

We are a clinical stage biopharmaceutical company with a limited operating history. Since our inception, we have incurred significant operating losses. We reported net losses of $73.8 million and $120.7 million for the years ended December 31, 2023 and 2022, respectively. As of December 31, 2023 we had an accumulated deficit of $286.2 million. To date, we have not generated any revenue from product sales and have financed our operations primarily through sales of our equity interests. As such, we expect that it will be several years, if ever, before we have a product candidate ready for regulatory licensure and commercialization. We may never succeed in these activities and, even if we do, may never generate revenues that are significant enough to achieve profitability. To become and remain profitable, we must succeed in developing, obtaining marketing licensure for and commercializing products that generate significant revenue. This will require us to be successful in a range of challenging activities, including, without limitation, procuring clinical- and commercial-scale manufacturing, successfully completing preclinical studies and clinical trials of our product candidates, establishing arrangements with third parties for the conduct of our clinical trials, obtaining marketing licensure for our product candidates, manufacturing, marketing and selling any products for which we may obtain marketing licensure, discovering or obtaining rights to additional product candidates, identifying collaborators to develop product candidates we identify or additional uses of existing product candidates and successfully completing development of product candidates for our collaboration partners. In addition, for certain of our licensees from whom we are entitled to receive royalty payments if they successfully develop and commercialize any products covered by the licenses we acquired in the Merger, there is no guarantee that their product development and commercialization will lead to any such payments even if any such product candidates receive regulatory approval for commercial sale. For Beovu (brolucizumab-dbll), which is currently commercialized by Novartis, and we are now receiving, sales-based royalties that are currently fully constrained and recorded as deferred revenue on our consolidated balance sheet, as discussed below, there is still no guarantee of ongoing payment of royalties, as Novartis has disputed its obligation to pay royalties to Apexigen under the ESBATech Agreement and continues to pay such royalties under protest.

We expect to continue to incur significant expenses and increasing operating losses for at least the next several years. We anticipate that our expenses will increase substantially if and as we:

- manufacture product candidates and continue to develop and conduct clinical trials for our ADC product candidate, PYX-201, and our IO product candidates, PYX-106 and PYX-107;
- select antibody programs to take into development, manufacture product candidates, conduct IND enabling studies and submit INDs and initiate, conduct and successfully complete clinical trials;
- scale up external manufacturing capabilities for later stage trials and to commercialize our products;
- seek marketing licenses for any product candidates that successfully complete clinical trials;
- ultimately establish a sales, marketing and distribution infrastructure for which we may obtain marketing licensure;
- leverage the APXiMAB Platform and FACT Platform to identify and then advance additional product candidates into preclinical and clinical development;
- expand, maintain and protect our intellectual property portfolio;
- hire additional clinical, regulatory, scientific, operational, financial and management information personnel; and
- continue to operate as a public company.

Our expenses could increase beyond our expectations if we are required by the U.S. Food and Drug Administration, or FDA, the European Medicines Agency, or EMA, or other comparable regulatory authorities to perform trials in addition to those that we currently expect to perform, or if we experience any delays in establishing appropriate manufacturing arrangements for completing our clinical trials or the clinical development of any of our product candidates.

Because of the numerous risks and uncertainties associated with pharmaceutical product development, we are unable to accurately predict the timing or amount of increased expenses we will incur or when, if ever, we will be able to achieve profitability. Even if we do achieve profitability, we may not be able to sustain or increase profitability on a quarterly or annual basis. Our failure to become and remain profitable would depress the value of our company and could impair our ability to raise capital, expand our business, maintain our research and development efforts or continue operations. A decline in the value of our company, or in the value of our common stock, could also cause investors to lose all or part of their investment.

If one or more of the product candidates that we develop is approved for commercial sale, we anticipate incurring significant costs associated with commercializing those approved product candidates. Even if we are able to generate revenues from the sale or out-licensing of any approved products, we may not become profitable and may need to obtain additional funding to continue operations.

We will require substantial additional capital to finance our operations. If we are unable to raise such capital when needed, or on acceptable terms, we may be forced to delay, reduce or eliminate one or more of our research and product development programs or future commercialization efforts.

The development of biopharmaceutical products, including conducting preclinical studies and clinical trials, is a very time-consuming, expensive and uncertain process that takes years to complete. Our operations have consumed substantial amounts of cash since inception, and we expect our expenses to increase in connection with our ongoing activities, particularly as we continue our clinical trials of our product candidates PYX-201, PYX-106 and PYX-107 and advance our other preclinical research and development programs. For example, to refocus development efforts and spending towards our most advanced programs, we have elected to pause preclinical development of PYX-203 and PYX-102. Even if one or more of the product candidates that we develop is approved for commercial sale, we anticipate incurring significant costs associated with sales, marketing, manufacturing and distribution activities. Our expenses could increase beyond expectations if we are required by the FDA, the EMA or other comparable regulatory authorities to perform clinical trials or preclinical studies in addition to those that we currently anticipate. Other unanticipated costs may also arise. Because the design and outcome of our planned and anticipated clinical trials are highly uncertain, we cannot reasonably estimate the actual amount of resources and funding that will be necessary to successfully complete the development and commercialization of any product candidate we develop. Accordingly, we will need to obtain substantial additional funding in order to continue our operations.

As of December 31, 2023, we had approximately $119.3 million in cash, cash equivalents, and short-term investments. Following the end of fiscal year 2023, on January 30, 2024, we issued additional shares under our ATM offering program that resulted in net proceeds of $10.6 million, after deducting placement agent commissions. Additionally, on February 29, 2024, we completed the Private Placement, as described below, which resulted in gross proceeds of $50 million, before deducting placement agent commissions and other offering expenses. We believe that our cash, cash equivalents and short-term investments as of December 31, 2023, along with proceeds from the ATM and the proceeds from the Private Placement will be sufficient to fund our operations into the second half of 2026.

Our estimate as to how long we expect to be able to continue to fund our operations is based on assumptions that may prove to be wrong, and we could use our available capital resources sooner than we currently expect. Changing circumstances, some of which may be beyond our control, could cause us to consume capital significantly faster than we currently anticipate, and we may need to seek additional funds sooner than planned.

We intend to use our cash and cash equivalents for development and regulatory activities relating to our product candidates, discovery programs, business development activities and other general corporate purposes. Advancing the development of our product candidates will require a significant amount of capital. Our cash and cash equivalents will not be sufficient to fund any of our product candidates through regulatory licensure. Because the length of time and activities associated with successful research and development of any individual product candidate are highly uncertain, we are unable to estimate the actual funds we will require for development, marketing licensure and commercialization activities. The timing and amount of our operating expenditures will depend largely on:

- the manufacture of product candidates and conduct of Phase 1 clinical trials for PYX-201 and PYX-106 and clinical trials for PYX-107;
- the timing and progress of our other preclinical and clinical development activities;
- the number and scope of other preclinical and clinical programs we decide to pursue;
- the progress of the development efforts of parties with whom we have entered or may in the future enter into in-licensing, collaborations and research and development agreements;
- the costs and timing of future commercialization activities, including product manufacturing, marketing, sales and distribution, for any of our product candidates for which we receive marketing licensure;
- our ability to maintain our current licenses and research and development programs and to establish new collaboration arrangements;
- the costs involved in prosecuting, maintaining and enforcing patent and other intellectual property rights;

•any delays or interruptions that we experience in our preclinical studies, clinical trials and/or supply chain;

•the cost and timing of regulatory licenses; and

•our efforts to hire additional clinical, regulatory, scientific, operational, financial and management personnel.

If we are unable to obtain funding on a timely basis or on acceptable terms, we may have to delay, reduce or terminate our research and development programs and preclinical studies or clinical trials, if any, limit strategic opportunities or undergo reductions in our workforce or other corporate restructuring activities. We also could be required to seek funds through arrangements with collaborators or others that may require us to relinquish rights to some of our technologies or product candidates that we would otherwise pursue on our own. We do not expect to realize any revenue from sales of products or any significant revenue from royalties from licensed products in the foreseeable future, if at all, and not until our product candidates are clinically tested, licensed for commercialization and successfully marketed. To date, we have primarily financed our operations through the sale of equity securities. We will be required to seek additional funding in the future and our ability to raise additional funds will depend on financial, economic and other factors, many of which are beyond our control. Additional funds may not be available to us on acceptable terms or at all. For example, market volatility resulting from global economic developments, political unrest, high inflation and other factors could adversely impact our ability to access capital as and when needed. If we raise additional funds by issuing equity securities, our stockholders will suffer dilution and the terms of any financing may adversely affect the rights of our stockholders. In addition, as a condition to providing additional funds to us, future investors may demand, and may be granted, rights superior to those of existing stockholders.

Our limited operating history may make it difficult for you to evaluate the success of our business to date and to assess our future viability.

We incorporated in 2018 and staffing and meaningful operations commenced in mid-2019 and our operations to date have been focused on developing and conducting preclinical and, since the first quarter of 2023, initiating Phase 1 clinical trials of our product candidates. To date, we have not yet demonstrated our ability to successfully complete a clinical trial, obtain marketing licenses, manufacture a commercial scale product directly or through a third party, or conduct sales, marketing, and distribution activities necessary for successful product commercialization. Consequently, any predictions you make about our future success or viability may not be as accurate as they could be if we had a longer operating history or if we had already successfully completed some or all of these types of activities

In addition, as a clinical stage biopharmaceutical company, we may encounter unforeseen expenses, difficulties, complications, delays and other known and unknown challenges. We will need to transition at some point from a company with a research and development focus to a company capable of supporting commercial activities and we may not be successful in making that transition.

We expect our financial condition and operating results to continue to fluctuate significantly from quarter to quarter and year to year due to a variety of factors, many of which are beyond our control. Accordingly, you should not rely upon the results of any quarterly or annual periods as indications of future operating performance.

Adverse developments affecting the financial services industry, including events or concerns involving liquidity, defaults or non-performance by financial institutions or transactional counterparties, could adversely affect our business, financial condition or results of operations.

Events involving limited liquidity, defaults, non-performance or other adverse developments that affect financial institutions, transactional counterparties or other companies in the financial services industry or the financial services industry generally, or concerns or rumors about any events of these kinds or other similar risks, have in the past and may in the future lead to market-wide liquidity problems. Although we assess our banking and customer relationships as we believe necessary or appropriate, our access to funding sources and other credit arrangements in amounts adequate to finance or capitalize our current and projected future business operations could be significantly impaired by factors that affect us, the financial services industry or economy in general. These factors could include, among others, events such as liquidity constraints or failures, the ability to perform obligations under various types of financial, credit or liquidity agreements or arrangements, disruptions or instability in the financial services industry or financial markets, or concerns or negative expectations about the prospects for companies in the financial services industry.

In addition, investor concerns regarding the U.S. or international financial systems could result in less favorable commercial financing terms, including higher interest rates or costs and tighter financial and operating covenants, or systemic limitations on access to credit and liquidity sources, thereby making it more difficult for us to acquire financing on acceptable terms or at all. Any decline in available funding or access to our cash and liquidity resources could, among other risks, adversely impact our ability to meet our operating expenses, financial obligations or fulfill our other obligations, result in breaches of our contractual obligations or result in violations of federal or state wage and hour laws. Any of these impacts, or any other impacts resulting from the factors described above or other related or similar factors not described above, could have material adverse impacts on our liquidity and our business, financial condition or results of operations.

We may be unable to complete future strategic acquisitions or successfully integrate strategic acquisitions which could adversely affect our business and financial condition.

Our inability to complete any future strategic acquisitions or to successfully integrate any new or previous strategic acquisitions could have a material adverse effect on our business. We may continue to seek attractive opportunities to acquire businesses, enter into joint ventures and make other investments that are complementary to our existing strengths. There are no assurances, however, that any strategic acquisition opportunities will arise or, if they do, that they will be consummated. Certain acquisitions may be difficult to complete for a number of reasons, including the need to satisfy customary closing conditions, the need for antitrust and/or other regulatory approvals, as well as disputes or litigation. Any strategic acquisition we may complete may be made at a substantial premium over the fair value of the net identifiable assets of the acquired company and thus our realization of this value relies on successful integration and continued operations. We may not be able to integrate acquired businesses successfully into our existing businesses, make such businesses profitable, retain key employees or realize anticipated cost savings or synergies, if any, from these acquisitions, which could adversely affect our business and financial condition. Further, our ongoing business may be disrupted, and our management's attention may be diverted by acquisitions, investments, transition and/or integration activities.

Risks Related to the Merger

We may fail to realize the benefits and synergies expected from the Merger, which could adversely affect our stock price.

The anticipated benefits and synergies we expect from the Merger are, necessarily, based on projections and assumptions about the combined businesses of Pyxis Oncology and Apexigen, which may not materialize as expected or which may prove to be inaccurate. The value of our common stock could be adversely affected if we are unable to realize the anticipated benefits and synergies from the Merger on a timely basis or at all.

We cannot predict with certainty if or when any benefits and synergies from the Merger will be realized, or the extent to which they will actually be achieved. Whether we realize any benefits or synergies could be affected by the factors described in other risk factors contained in this report and a number of factors beyond our control, including, without limitation, general economic conditions, increased operating costs and regulatory developments.

We may be unable to appropriately integrate the business, operations and assets of Apexigen into our existing business.

Achieving the benefits of the Merger will depend, in part, on our ability to integrate the business, operations and assets of Apexigen successfully and efficiently with our business. The challenges involved in this integration, which will be complex and time-consuming, include, without limitation, the following:

•difficulties integrating new and existing technologies, systems and processes into our platform and operations;

•successfully managing relationships with the combined supplier base of Pyxis Oncology and Apexigen;

•coordinating and integrating independent research and development teams across platforms while reducing costs;

•consolidating and integrating procurement, research and development activities and processes and management and administrative functions;

•limitations or encumbrances on certain Apexigen intellectual property or other difficulties integrating Apexigen intellectual property into our portfolio;

•the increased scale and complexity of our operations resulting from the Merger; and

•minimizing the diversion of our management's attention from other important business objectives.

If we do not successfully manage these and other challenges inherent in integrating an acquired business of the size and complexity of Apexigen into our business, then we may not achieve the anticipated benefits of the Merger and our expenses, operating results and financial condition could be materially and adversely affected.

The acquisition of Apexigen may result in significant charges or other liabilities that could adversely affect the financial results of the combined company.

The financial results of the combined company may be adversely affected by cash expenses and non-cash accounting charges incurred in connection with Pyxis Oncology's integration of the business and operations of Apexigen. The amount and timing of these possible charges are not yet known. Further, our failure to identify or accurately assess the magnitude of certain liabilities we are assuming in the Merger could result in unexpected litigation or regulatory exposure, unfavorable accounting charges, unexpected increases in taxes due, a loss of anticipated tax benefits or other adverse effects on our business, operating results or financial condition. The price of our common stock could decline to the extent the combined company's financial results are materially affected by any of these events.

Pyxis Oncology's future results will suffer if it does not effectively manage its expanded operations following the Merger.

The size and scope of operations of the business of the combined company has increased beyond the size and scope of operations of either Pyxis Oncology's or Apexigen's businesses prior to the completion of the Merger. Our future success depends, in part, upon our ability to manage our expanded business, which may pose substantial challenges for our management, including challenges related to the management and monitoring of new operations, products and locations and associated increased costs and complexity. There can be no assurances that we will be successful in managing such expanded business or that we will realize the expected economies of scale, synergies and other benefits currently anticipated from the Merger.

Risks Related to the Discovery and Development of our Product Candidates

We are heavily dependent on the success of PYX-201 and PYX-106, which are in the early stages of development, and PYX-107, which is in a Phase II clinical trial. If PYX-201, PYX-206 and/or PYX-107 are not successful in clinical trials or do not receive regulatory approval or licensure or are not successfully commercialized, our business will be materially and adversely affected.

To date, we have invested a significant portion of our efforts and financial resources in the development of PYX-201 and PYX-106, and Apexigen had invested a significant portion of its efforts and financial resources in the development of PYX-107. Our future success is substantially dependent on our ability to successfully initiate and complete clinical development for, obtain regulatory licensure for, and successfully commercialize PYX-201, PYX-106 and PYX-107, which may never occur. We currently have no products that are approved or licensed for commercial sale and may never be able to develop a marketable product. We expect that a substantial portion of our efforts and expenditures over the next few years will be devoted to the development of, and related clinical and other activities associated with, advancing PYX-201, PYX-106 and PYX-107, which will require clinical development, management of clinical and manufacturing activities, regulatory licensure, establishing commercial scale manufacturing, and significant sales, marketing, and distribution efforts before we can generate any revenues from any commercial sales. We cannot be certain that we will be able to successfully complete any of these activities or that, even if PYX-201, PYX-106 and PYX-107, receive regulatory licensure, such products will be able to successfully compete against therapies and technologies offered by other companies.

The research, testing, manufacturing, labeling, licensure, sale, packaging, marketing, and distribution of biological products are subject to extensive regulation by the FDA and comparable regulatory authorities in other countries. We are not permitted to market PYX-201, PYX-106 or PYX-107, in the United States until we receive licensure of a Biologics License Application, or BLA, or New Drug Application, or NDA, from the FDA for such product candidates, as appropriate. Further, we are not permitted to market PYX-201, PYX-106 or PYX-107, in any foreign countries until we receive the requisite licensure or approvals from such countries. We have not submitted a BLA or NDA to the FDA or comparable applications to any other comparable regulatory authorities for PYX-201, PYX-106 or PYX-107. We will not be in a position to do so for several years, if ever. If we are unable to obtain the necessary regulatory licensure or approvals for PYX-201, PYX-106 or PYX-107, in a country, we will not be able to commercialize such product candidate in that country. As a result, our financial position will be materially adversely affected, and we may not be able to generate sufficient revenue to continue our business.

The outcome of preclinical testing for PYX-201 and PYX-106 and early clinical trials for PYX-107 may not predict the success of later clinical trials, and the results of clinical trials for PYX-107 may not satisfy the requirements of the FDA, EMA, or comparable foreign regulatory authorities.

PYX-201, PYX-106 and PYX-107 is in the early stages of development and is not currently approved for sale and there is no guarantee that it will ever be marketable. Clinical failure can occur at any stage of clinical development. We are required to demonstrate with substantial evidence through well-controlled clinical trials the safety and efficacy of PYX-201, PYX-106 andPYX-107 in a diverse population before we can seek marketing approvals for its commercial sale. Success in preclinical studies for PYX-201, PYX-106 and early-stage clinical trials for PYX-107 does not mean that future larger registration clinical trials will be successful. This is because product candidates in later-stage clinical trials may fail to demonstrate sufficient safety and efficacy to the satisfaction of the FDA, EMA, and other regulatory authorities despite having progressed through preclinical studies and early-stage clinical trials. We do not know whether any clinical trials we may conduct for PYX-201,PYX-106 and PYX-107 will demonstrate consistent or adequate efficacy and safety results sufficient to obtain marketing approval. For example, clinical trial subjects treated with PYX-107 have experienced adverse events that have been considered treatment-related. The majority of these events were mild/moderate in severity, responded to symptomatic treatment and/or were transient and resolved with time. Serious, including sometimes fatal, adverse events, or SAEs, have been reported in clinical studies with PYX-107. The majority of these SAEs were considered unrelated to PYX-107 by the investigators. Some SAEs were considered at least possibly related to PYX-107 as well as possibly to other therapies it was combined with. These possibly related events have included infusion-related reactions, cytokine release syndrome, elevated liver enzymes, bilirubin, fever, and colitis. Less frequent related SAEs reported in one patient each have included kidney injury, hepatic failure, bleeding, immune-mediated encephalitis, myositis, and optic neuritis. Many of these SAEs were also considered possibly related to the chemotherapy, radiation or anti-PD(L)1 agent that were used in combination or were assessed as not related to PYX-107 after a safety review by the trial sponsor.

In addition, even if PYX-107 is approved for commercial sale, the success of PYX-107 would depend on a number of factors beyond our control, including emerging and competing therapies and the market acceptance and adoption of PYX-107 versus actual or perceived competing therapies.

Our product candidates may fail in development or suffer delays that materially and adversely affect their commercial viability. If we or our existing or future collaborators are unable to initiate and complete clinical development of, obtain regulatory approval or licensure for or commercialize our product candidates or experience significant delays in doing so, our business will be materially harmed.

We have no products on the market and only three of our product candidates are currently in clinical development. As a result, the risk of failure for such products is high. Our ability to achieve and sustain profitability depends on obtaining regulatory licensure for and successfully commercializing our product candidates, either alone or with third parties. Before obtaining regulatory licensure for the commercial distribution of our product candidates, we or an existing or future collaborator must conduct extensive preclinical studies and clinical trials to demonstrate the safety, purity and potency in humans of our product candidates. In addition, the development of novel antibodies is complex and difficult. Although our discovery and preclinical programs may initially show promise in identifying potential product candidates, they may not translate into product candidates for clinical development for a number of reasons, including that the target selection methodology we use may not be successful due to our inability to generate an applicable antibody candidate. In addition, several of our product candidates are in-licensed or acquired and we continue to look for additional product candidates to in-license or acquire. Our preclinical studies or clinical trials may not replicate or advance the results of the research programs and pre-clinical studies that were completed prior to our in-licensing or acquisition of product candidates.

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

- negative or inconclusive results from preclinical studies or clinical trials leading to a decision or requirement to conduct additional preclinical studies or clinical trials or abandon a program;
- product-related side effects experienced by participants in our clinical trials or by individuals using therapeutic biological products similar to our product candidates;
- failure in obtaining the necessary approvals from regulators to commence a clinical trial, or a suspension or termination of a clinical trial once commenced;
- conditions imposed by the FDA, EMA or other comparable authorities regarding the scope or design of our clinical trials;
- delays in enrolling patients in clinical trials;
- high drop-out rates of patients;
- inadequate supply or quality of product candidate components or materials or other supplies necessary for the conduct of our clinical trials;
- greater than anticipated clinical trial costs;
- poor effectiveness of our product candidates during clinical trials;
- unfavorable FDA or other comparable regulatory agency inspection and review of a clinical trial site;
- failure of our third party contractors or investigators to comply with regulatory requirements or otherwise meet their contractual obligations in a timely manner, or at all;
- delays and changes in regulatory requirements, policy and guidelines, including the imposition of additional regulatory oversight around clinical testing generally or with respect to our technology in particular; or
- varying interpretations of data by the FDA, the EMA and other comparable foreign regulatory authorities.

If any of the foregoing circumstances occur, we could experience significant delays or an inability to successfully commercialize our product candidates, which could materially harm our business. Moreover, if we do not receive regulatory approvals, we may not be able to continue our operations.

We have no experience as a company completing a clinical trial or submitting a BLA or NDA and may be unable to successfully do so for PYX-201, PYX-106 and PYX-107.

The conduct of a clinical trial is a long, expensive, complicated and highly regulated process. Although certain of our employees have conducted successful clinical trials and made regulatory submissions in the past across many therapeutic areas while employed at other companies, we, as a company, have not completed any clinical trials, or submitted a BLA or NDA, and as a result may require more time and incur greater costs than we anticipate. Failure to commence or complete, or delays in, our clinical trials or planned regulatory submissions would prevent us from, or delay us in, obtaining regulatory approval of and commercializing PYX-201, PYX-106 and PYX-107, which would adversely impact our financial performance. Large-scale clinical trials would require significant additional financial and management resources and reliance on third-party clinical investigators and consultants. Relying on third-party clinical investigators, CROs, and consultants may cause us to encounter delays that are outside of our control. In addition, relying on third parties in the conduct of our preclinical studies or clinical trials exposes us to a risk that they may not adequately comply with good laboratory practice, or GLP, or good clinical practice, or GCP, as required for any studies or trials we plan to submit to a regulatory authority. We may be unable to identify and contract with sufficient investigators, CROs and consultants on terms that are acceptable to us on a timely basis or at all.

We may not be able to submit INDs to commence additional clinical trials on the timelines we expect and, even if we are able to, the FDA may not permit us to proceed.

We may submit additional INDs in the future. We may experience manufacturing delays or other delays with IND-enabling studies. Moreover, we cannot be sure that submission of an IND will result in the FDA allowing us to commence clinical trials or that, once begun, issues will not arise that lead to the suspension or termination of our clinical trials. Additionally, even if the applicable regulatory authorities agree with the design and implementation of the clinical trials set forth in our INDs, we cannot guarantee that those regulatory authorities will not change their requirements in the future, or that circumstances will not arise under which FDA or other regulatory authorities may place our clinical trials on partial or full clinical hold. These considerations apply to the INDs described above and also to new clinical trials we may submit as amendments to existing INDs or as part of new INDs in the future. Any failure to submit INDs on the timelines we expect or to obtain authorization to proceed with our trials may prevent us from completing our clinical trials or commercializing our products on a timely basis, if at all.

Our preclinical studies and clinical trials may fail to demonstrate adequately the safety, purity and potency of any of our product candidates, which would prevent or delay development, regulatory approval or licensure and commercialization.

Before obtaining regulatory licensure for the commercial sale of any of our product candidates, including PYX-201, PYX-106 and PYX-107, we must demonstrate through lengthy, complex and expensive preclinical studies and clinical trials that our product candidates are safe, pure, and potent, as required under a BLA. Preclinical and clinical testing is expensive and can take many years to complete and the outcome of these activities is inherently uncertain. Failure can occur at any time during the preclinical study and clinical trial processes and, because our product candidates are in an early stage of development, there is a high risk of failure. In addition, any failures or adverse outcomes in preclinical or clinical testing seen by other developers of similar product candidates could materially impact the success of our programs. We may never succeed in developing marketable products.

It is also possible that the results of preclinical studies and early clinical trials of our product candidates may not be predictive of the results of later-stage clinical trials. Although product candidates may demonstrate promising results in preclinical studies and early clinical trials, they may not prove to be effective in subsequent clinical trials. For example, testing on animals occurs under different conditions than testing in humans and, therefore, the results of animal studies may not accurately predict human experience. There is typically an extremely high rate of attrition from the failure of product candidates proceeding through preclinical studies and clinical trials. Product candidates in later stages of clinical trials may fail to show the desired safety, purity, and potency profile despite having progressed successfully through preclinical studies and/or initial clinical trials. Likewise, early, smaller-scale clinical trials may not be predictive of eventual safety, purity and potency in large-scale pivotal clinical trials. Many companies in the biopharmaceutical industry have suffered significant setbacks in advanced clinical trials due to lack of potency, insufficient durability of potency or unacceptable safety issues, notwithstanding promising results in earlier trials. Most product candidates that commence preclinical studies and clinical trials are never approved or licensed for commercialization. In addition, preclinical studies or clinical trials we conduct may contradict, undermine or otherwise not replicate or advance the results of the research programs and pre-clinical studies that were completed prior to our in-licensing or acquisition of product candidates, which may materially and adversely affect our business, results of operations and prospects.

Additionally, our PYX-201 and PYX-106 Phase 1 clinical trials are, and we expect that the first clinical trials for our other product candidates may be, open-label studies, where both the patient and investigator know whether the patient is receiving the investigational product candidate or an existing licensed biological product. Most typically, open-label clinical trials test only the investigational product candidate and sometimes do so at different dose levels. Open-label clinical trials are subject to various limitations that may exaggerate any therapeutic effect as patients in open-label clinical trials are aware when they are receiving treatment. In addition, open-label clinical trials may be subject to an “investigator bias” where those assessing and reviewing the physiological outcomes of the clinical trials are aware of which patients have received treatment and may interpret the information of the treated group more favorably given this knowledge. The FDA may also not consider open-label clinical trials to be adequate and well controlled trials sufficient to support BLA licensure.

Any preclinical studies or clinical trials that we may conduct may not demonstrate the safety, purity, and potency necessary to obtain regulatory licensure to market our product candidates. If the results of our ongoing or future preclinical studies and clinical trials are inconclusive with respect to the safety, purity, and potency of our product candidates, if we do not meet the clinical endpoints with statistical and clinically meaningful significance or if there are safety concerns associated with our product candidates, we may be prevented or delayed in obtaining marketing licensure for those product candidates. In some instances, there can be significant variability in safety, purity, and potency results between different preclinical studies and clinical trials of the same product candidate due to numerous factors, including changes in trial procedures set forth in protocols, differences in the size and type of the patient populations, changes in and adherence to the clinical trial protocols and the rate of dropout among clinical trial participants. Results of our trials could reveal a high and unacceptable severity and prevalence of these or other side effects. If that were to occur, or if other developers of similar products were to find an unacceptable severity or prevalence of side effects with their candidates, our trials could be suspended or terminated, and the FDA or comparable foreign regulatory authorities could order us to cease further development of or deny licensure of our product candidates for any or all targeted indications. Product-related side effects could also affect patient recruitment or the ability of enrolled patients to complete an ongoing trial or result in potential product liability claims. See also “The outcome of preclinical testing for PYX-201 and PYX-106 and early clinical trials for PYX-107 may not predict the success of later clinical trials, and the results of clinical trials for PYX-107 may not satisfy the requirements of the FDA, EMA, or comparable foreign regulatory authorities.” Any of these occurrences may significantly harm our business, financial condition and prospects.

Further, our product candidates could cause undesirable side effects in clinical trials related to on-target toxicity. If on-target toxicity is observed or if our product candidates have characteristics that are unexpected, we may need to abandon their development or limit development to more narrow uses or subpopulations in which the undesirable side effects or other characteristics are less prevalent, less severe or more acceptable from a risk-benefit perspective. Many compounds that initially showed promise in early-stage testing for treating cancer have later been found to cause side effects that prevented further development of the compound.

Our preclinical programs may experience delays or may never advance to clinical trials, which would adversely affect our ability to obtain regulatory approval or licensure or commercialize these programs on a timely basis or at all.

In order to obtain FDA, European Commission (based on the opinion of the EMA’s Committee for Human Medicinal Products, or CHMP) or other comparable licensure to market a new biological product, we must demonstrate proof of safety, purity and potency or efficacy in humans. To meet these requirements, we will have to conduct adequate and well-controlled clinical trials. Before we can commence clinical trials for a product candidate, we must complete extensive preclinical studies that support our planned INDs or similar clinical trial applications, or CTAs, in foreign countries. We cannot be certain of the timely completion or outcome of our preclinical studies and cannot predict if the FDA or other comparable foreign authorities and independent ethics committees will accept our proposed clinical programs or if the outcome of our preclinical studies will ultimately support the further development of our programs. As a result, we cannot be sure that we will be able to submit INDs or similar applications for our preclinical programs on the timelines we expect, if at all, and we cannot be sure that submission of INDs or similar applications will result in the FDA or other regulatory authorities or independent ethics committees allowing clinical trials to begin.

Conducting preclinical studies is a lengthy, time-consuming and expensive process. The length of time may vary substantially according to the type, complexity and novelty of the program, and often can be several years or more per program. Any delays in preclinical studies conducted by us or potential future partners may cause us to incur additional operating expenses. The commencement and rate of completion of preclinical studies for a product candidate may be delayed by many factors, including, for example, the inability to generate sufficient preclinical or other *in vivo* or *in vitro* data to support the initiation of clinical trials and delays in reaching a consensus with regulatory agencies on study design.

Moreover, because standards for preclinical assessment are evolving and may change rapidly, even if we reach an agreement with the FDA on a proposal at the pre-IND meeting, the FDA may not accept the IND submission as presented. Even if clinical trials do begin for our preclinical programs, our clinical trials or development efforts may not be successful.

Clinical testing and product development is a lengthy and expensive process with an uncertain outcome. We may incur unexpected costs or experience delays in completing, or ultimately be unable to complete, the clinical testing and the development and commercialization of our product candidates.

Clinical testing is expensive, difficult to design and implement, can take many years to complete and is uncertain as to the timing and outcome. A failure of one or more clinical trials can occur at any stage of the process. We may experience numerous unforeseen events during or as a result of clinical trials, which could delay or prevent our ability to receive marketing licensure or commercialize our product candidates, including:

- delays in reaching, or the failure to reach, a consensus with regulators on clinical trial design;
- the supply or quality of our product candidates or other materials necessary to conduct clinical trials of our product candidates may be insufficient or inadequate, including as a result of delays in the testing, validation, manufacturing and delivery of product candidates to the clinical sites by us or by third parties with whom we have contracted to perform certain of those functions;

•delays in reaching, or the failure to reach, agreement on acceptable clinical trial contracts or clinical trial protocols with prospective trial sites;

•the failure of regulators or institutional review boards to authorize us or our investigators to commence a clinical trial or conduct a clinical trial at a prospective trial site;

•difficulty in designing clinical trials and in selecting endpoints for diseases that have not been well studied and for which the natural history and course of the disease is poorly understood;

•the selection of certain clinical endpoints that may require prolonged periods of clinical observation or analysis of the resulting data;

•we may receive feedback from regulatory authorities that requires us to modify the design of our clinical trials;

•the number of patients required for clinical trials of our product candidates may be larger than we anticipate, enrollment in these clinical trials may be slower than we anticipate, participants may drop out of these clinical trials at a higher rate than we anticipate or fail to return for post-treatment follow-up or the failure to recruit suitable patients to participate in our clinical trials;

•our product candidates may have undesirable side effects or other unexpected characteristics, causing us or our investigators, regulators or institutional review boards to suspend or terminate our clinical trials;

•we may have to suspend or terminate clinical trials of our product candidates for various reasons, including a finding that the participants are being exposed to unacceptable health risks;

•the third parties with whom we contract may fail to comply with regulatory requirements or meet their contractual obligations to us in a timely manner, or at all;

•the requirement from regulators or institutional review boards that we or our investigators suspend or terminate clinical trials for various reasons, including noncompliance with regulatory requirements or unacceptable safety risks;

•clinical trials of our product candidates may produce negative or inconclusive results and we may decide, or regulators may require us, to conduct additional clinical trials or abandon product candidate development and discovery programs;

•the cost of clinical trials of our product candidates may be greater than we anticipate;

•imposition of a clinical hold by regulatory authorities as a result of a serious adverse event, concerns with a class of product candidates or after an inspection of our clinical trial operations, trial sites or manufacturing facilities;

•occurrence of serious adverse events associated with the product candidate that are viewed to outweigh its potential benefits;

•regulators may revise the requirements for approving our product candidates, or such requirements may not be as we anticipate; and

•delays in developing and validating any companion diagnostic to be used in the trial, to the extent we are required to do so.

FDA may modify or enhance clinical trial requirements which may affect enrollment and retention of patients. In August 2023, FDA published a guidance document, Informed Consent, Guidance for IRBs, Clinical Investigators, and Sponsors, which supersedes past guidance and finalizes draft guidance on informed consent. FDA's new guidance presents evolving requirements for informed consent which may affect recruitment and retention of patients in clinical trials. Effects on recruitment and retention of patients may hinder or delay a clinical trial, which may increase costs and delay clinical programs. Further, in December 2023, FDA published a final rule, Institutional Review Board Waiver or Alteration of Consent for Minimal Risk Clinical Investigations, which allows exceptions from informed consent requirements when a clinical investigation poses no more than minimal risk to the human subject and includes appropriate safeguards to protect the rights, safety, and welfare of human subjects.

If we are required to conduct additional clinical trials or other testing of our product candidates beyond those that we currently contemplate, if we are unable to successfully complete clinical trials of our product candidates or other testing, if the results of these trials or tests are not positive or are only modestly positive or if there are safety concerns, we may:

•be delayed in obtaining marketing licenses for our product candidates;

•not obtain marketing licensure at all;

•obtain licensure for indications or patient populations that are not as broad as intended or desired;

•obtain licensure with labeling that includes significant use or distribution restrictions or safety warnings;

•be required to perform additional clinical trials to support marketing licensure;

•have regulatory authorities withdraw or suspend their license, or impose restrictions on distribution of a product candidate in the form of a modified REMS;

•be subject to additional post-marketing testing requirements or changes in the way the product is administered;

•fail to receive approval of any companion diagnostics that may be required by the FDA or comparable foreign regulatory authorities in connection with approval of our therapeutic product candidates; or

•have our product removed from the market after obtaining marketing licensure.

For example, the FDA launched *Project Optimus* in 2021 as an initiative to reform the dose optimization and dose selection paradigm in oncology drug development, which was driven by the FDA's concerns that the current paradigm for dose selection may result in doses and schedules of molecularly targeted therapies that are inadequately characterized before initiating pivotal trials. Through collaboration with the biopharmaceutical industry, academia and other stakeholders, the FDA's goal for this initiative is to advance an oncology dose-finding and dose optimization paradigm that emphasizes dose selections that maximize efficacy as well as safety and tolerability. In support of this initiative and as described in a 2023 draft guidance "*Optimizing the Dosage of Human Prescription Drugs and Biological Products for the Treatment of Oncologic Diseases*" the FDA will likely request sponsors of oncology product candidates to conduct dose optimization studies pre-approval. The FDA also continues to develop and finalize guidance documents and implement initiatives regarding the development and clinical research of oncology product candidates.

Our product development costs also will increase if we experience delays in preclinical studies or clinical trials or in obtaining marketing licenses. We do not know whether any of our preclinical studies or clinical trials will need to be restructured or will be completed on schedule, or at all. Significant preclinical study or clinical trial delays also could shorten any periods during which we may have the exclusive right to commercialize our product candidates, or could allow our competitors to bring products to market before we do and impair our ability to successfully commercialize our product candidates, which may harm our business, results of operations, financial condition and prospects.

Further, cancer therapies sometimes are characterized as first-line, second-line or third-line. The FDA often approves or licenses new oncology therapies initially only for third-line or later use, meaning for use after two or more other treatments have failed. When cancer is detected early enough, first-line therapy, usually hormone therapy, surgery, radiation therapy, immunotherapy or a combination of these, is sometimes adequate to cure the cancer or prolong life without a cure. Second-line and third-line therapies are administered to patients when prior therapy is not effective. Our clinical trials are, and any future clinical trials will be, with patients with difficult to treat cancer. We expect that we would initially seek regulatory licensure for use of these product candidates in appropriate treatment settings. Subsequently, for those products that prove to be sufficiently beneficial, if any, we would expect to seek licensure potentially as a first-line therapy, but any product candidates we develop, even if approved for second-line or third-line therapy, may not be approved for first-line therapy and, prior to seeking and/or receiving any licensures for first-line therapy, we may have to conduct additional clinical trials.

Any failures or setbacks involving the FACT Platform or the APXiMAB Platform, including adverse events, could have a detrimental impact on our research pipeline and future success.

Any failures or setbacks involving the FACT Platform or the APXiMAB Platform, including adverse events, could have a detrimental impact on our research pipeline and future success. For example, we may uncover a previously unknown risk associated with the FACT Platform or the APXiMAB Platform or other issues that may be more problematic than we currently believe, which may prolong the period of observation required for obtaining regulatory approval, necessitate additional clinical testing or result in the failure to obtain regulatory licensure. If the FACT Platform or the APXiMAB Platform or any of their respective components that are used in our product candidates are not safe, we would be required to abandon or redesign other product candidates we develop via the FACT Platform or the APXiMAB Platform, which could have a material adverse effect on our business, financial condition, results of operations and prospects.

We may not be successful in our efforts to use and expand the FACT Platform or the APXiMAB Platform to continue to build a pipeline of product candidates and develop marketable products.

Our business depends not only on our ability to successfully develop, obtain regulatory licensure for, and commercialize our product candidates, but to continue to generate new product candidates through our FACT Platform and APXiMAB Platform. Even if we are successful in continuing to build our pipeline and further progress the development of our current product candidates, any additional product candidates may not be suitable for clinical development, including as a result of harmful side effects, manufacturing issues, limited potency or other characteristics that indicate that they are unlikely to be products that will succeed in clinical development, receive marketing licensure or achieve market acceptance. If we cannot validate our technology platform by successfully commercializing product candidates, we may not be able to obtain product, licensing or collaboration revenue in future periods, which would adversely affect our business, financial condition, results of operations and prospects.

We are parties to and may in the future enter into additional agreements with third parties under which those parties have or will be granted a license to develop product candidates discovered using our APXiMAB platform. If any such programs are not successful or if disputes arise related to such programs, we may not realize the full commercial benefits from such programs.

Our APXiMAB platform has enabled the discovery of several product candidates with potential utility in multiple therapeutic areas and has resulted in five programs that have been licensed to third parties, including larger global biopharmaceutical companies and mid-sized regional or China-focused companies. Our likely counterparties for future licensing and collaboration arrangements include large and mid-size pharmaceutical companies, regional and national pharmaceutical companies, and biotechnology companies. Such arrangements generally allow the licensing parties to control the amount and timing of resources that they dedicate to the development or potential commercialization of any product candidates they develop from the technology we have licensed to them, subject to any territorial or field of use restrictions in the license. In addition, Apexigen had partnered with ESBATech AG, which was acquired by Alcon and later Novartis to provide rabbit monoclonal antibodies in order to develop product candidates for certain diseases.

Apexigen typically negotiated milestone payments and royalty fees from the licensees that will require various levels of success with their product candidate development program in order for us to generate revenue from them. Our ability to generate revenue from these licensing arrangements will depend on our counterparties' abilities to successfully develop and commercialize the product candidates they are developing. We cannot predict the success of any licensing program that we enter into or whether such program will lead to any meaningful milestone or royalty revenue to us.

Licensing programs involving third-party development of product candidates derived from our licensed technology pose the following risks to us:

•counterparties generally have significant discretion, if not total control, in determining the efforts and resources that they will apply to these development efforts;

•counterparties may not properly or adequately obtain, maintain, enforce, or defend intellectual property or proprietary rights relating to our intellectual property or may use our proprietary information in such a way as to expose us to potential litigation or other intellectual property-related proceedings, including proceedings challenging the scope, ownership, validity, and enforceability of our intellectual property;

•counterparties may own or co-own with us intellectual property covering their product candidates, and, in such cases, we typically will not have the exclusive right to commercialize such intellectual property or their product candidates based on the terms of the licensing agreement;

•we may need the cooperation of these counterparties to enforce or defend any intellectual property we contribute to the program;

•counterparties typically will control the interactions with regulatory authorities related to their product candidates, which may impact our ability to obtain and maintain regulatory approval of our own product candidates;

•disputes may arise between the counterparties and us that result in the delay or termination of the research, development, or commercialization of our product candidates or research programs or that result in costly litigation or arbitration that diverts management attention and resources;

•counterparties may decide to not pursue development and commercialization of any product candidates that are derived from our licensed technology, or may elect not to continue or renew development or commercialization programs based on clinical trial results, changes in the counterparties' strategic focus or available funding or external factors such as an acquisition that diverts resources or creates competing priorities, or counterparties may elect to fund or commercialize a competing product;

•counterparties could independently develop, or develop with third parties, products that compete directly or indirectly with our product candidates or research programs if the collaborators believe that competitive products are more likely to be successfully developed or can be commercialized under terms that are more economically attractive than ours;

•counterparties may not commit sufficient resources to the marketing and distribution of their product candidates, resulting in lower royalties to us;

•counterparties may grant sublicenses to our technology or undergo a change of control, and the sublicensees or new owners may decide to pursue a strategy with respect to the program which is not in our best interest;

•counterparties may become bankrupt, which may significantly delay our research or development programs, or may cause us to lose access to valuable technology, know-how, or intellectual property of the counterparty relating to our technology in relation to the terms of the licensing agreement;

•if these counterparties do not satisfy their obligations under our agreements with them, or if they terminate our licensing agreements with them, we may be adversely impacted; and

•licensing agreements may not lead to development or commercialization of product candidates in the most efficient manner or at all.

Beovu® is a drug product developed by Novartis covered under the ESBATech Agreement. Novartis obtained approval for Beovu for use in neovascular (wet) age-related macular degeneration and as a treatment of visual impairment due to diabetic macular edema, Novartis continues to develop Beovu for other indications. Under the terms of the ESBATech agreement, Novartis is obligated to pay us a very low single-digit royalty on worldwide net sales of Beovu. However, Novartis has disputed its obligation to pay royalties to us under the agreement and continues to pay such royalties under protest. As a result, we have determined that any sales-based royalties received from Novartis for Beovu are currently fully constrained, and we have recorded the royalty proceeds as deferred revenue on our consolidated balance sheet, with the amounts totaling $7.7 million as of December 31, 2023. If the dispute with Novartis regarding their royalty obligations is not settled favorably through negotiation or if the parties escalate the dispute through arbitration or litigation, there is no guarantee that we will recognize such historic and future royalty revenue in part or at all, we may be required to return the cash received to date for the constrained royalty payments, we may not receive future payments, and we may incur substantial costs and distraction of management related to such dispute. While this dispute continues, the Beovu royalty rights will be impaired which will limit our ability to exercise ownership over or monetize this royalty stream, all of which could have an adverse effect on our business, financial condition, and results of operations.

Many of the risks relating to product development, intellectual property, regulatory approval, and commercialization described in this "*Risk Factors*" section also apply to the activities of our licensees and any negative impact on these counterparties and their product development programs may adversely affect us.

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

As a result of our limited financial and managerial resources, we must make strategic decisions as to which targets and product candidates to pursue and may forego or delay pursuit of opportunities with other targets or 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. Failure to properly assess potential product candidates could result in our focus on product candidates with low market potential, which would harm our business, financial condition, results of operations and prospects. Our spending on current and future research, product candidates and discovery programs for specific targets or 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 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.

If we reach commercialization for any of our product candidates and the market opportunities for any product candidate that we develop are smaller than we believe they are, our revenue may be adversely affected, and our business may suffer.

The potentially addressable patient population for our current programs or future product candidates may be limited and the number of patients who have the cancers we are targeting may turn out to be lower than expected. Potentially addressable patient populations for our product candidates are only estimates. These estimates could prove to be incorrect, and the estimated number of potential patients in the United States and elsewhere could be lower than expected. It may also be that such patients may not be otherwise amenable to treatment with our product candidates, or patients could become increasingly difficult to identify and access, any of which could materially adversely affect our business, financial condition, results of operations and growth prospects.

Our estimated addressable markets and market opportunities for our product candidates are based on a variety of inputs, including data published by third parties, our own market insights and internal market intelligence, and internally generated data and assumptions. We have not independently verified any third-party information and cannot be assured of its accuracy or completeness. Market opportunity estimates, whether obtained or derived from third-party sources or developed internally, are subject to significant uncertainty and are based on assumptions and estimates that may prove not to be accurate. Although we believe our market opportunity estimates are reasonable, such information is inherently imprecise. In addition, our assumptions and estimates of market opportunities are necessarily subject to a high degree of uncertainty and risk due to a variety of factors, including but not limited to those described in this Annual Report on Form 10-K. If this third-party or internally generated data prove to be inaccurate or if we make errors in our assumptions based on that data, our actual market may be more limited than we estimate it to be. In addition, these inaccuracies or errors may cause us to misallocate capital and other critical business resources, which could harm our business.

The market may not be receptive to some or any of our product candidates because they are based on our novel therapeutic modality, and we may not generate any future revenue from the sale or licensing of product candidates.

Even if regulatory licensure is obtained for a product candidate, we may not generate or sustain revenue from sales of the product due to factors such as whether the product can be sold at a competitive cost and whether the product is otherwise accepted in the market. Some product candidates that we are developing are based on the FACT Platform, which is a new technology and therapeutic approach. Our future success depends on the successful development of this novel therapeutic approach. Additionally, the regulatory licensure process for novel product candidates such as ours can be more expensive and take longer than for other, better-known or extensively-studied product candidates. No regulatory authority has granted licensure for any therapeutic using the FACT Platform. As a result of these factors, it is more difficult for us to predict the time and cost of product candidate development, and we cannot predict whether the FACT Platform will result in the development and marketing licensure of any products. Any development problems we experience in the future related to any of our programs may cause significant delays or unanticipated costs or may prevent the development of a commercially viable product. Advancing our products creates significant challenges for us, including educating medical personnel regarding the potential potency and safety benefits, as well as the challenges, of incorporating our product candidates, if approved, into treatment regimens and establishing the sales and marketing capabilities to gain market acceptance, if approved.

Any of these factors may prevent us from commercializing any of our product candidates we may develop on a timely or profitable basis, if at all.

Market participants with significant influence over acceptance of new treatments, such as physicians and third-party payors, may not adopt a product or treatment based on the FACT Platform and technologies, and we may not be able to convince the medical community and third-party payors to accept and use, or to provide favorable reimbursement for, any product candidates developed by us or our existing or future collaborators. Market acceptance of our product candidates will depend on, among other factors:

- the timing of our receipt of any marketing and commercialization licensures;
- the terms of any licensures and the countries in which licensures are obtained;
- the safety, purity, and potency of our product candidates;
- the prevalence and severity of any adverse side effects associated with our product candidates;
- the limitations or warnings contained in any labeling approved by the FDA, or other comparable foreign regulatory authorities;
- the relative convenience and ease of administration of our product candidates;
- the willingness of patients to accept any new methods of administration;
- the success of our physician education programs;
- the availability of adequate government and third-party payor reimbursement;
- the pricing of our products, particularly as compared to alternative treatments; and
- the availability of alternative effective treatments for the disease indications our product candidates are intended to treat and the relative risks, benefits and costs of those treatments.

If any product candidate we commercialize fails to achieve market acceptance, it could have a material and adverse effect on our business, financial condition, results of operations and prospects.

We are early in our development efforts. Our lead product candidates, PYX-201, PYX-106 and PYX-107, are in the early stages of clinical development. The results of preclinical studies and early-stage clinical trials may not be predictive of future results in later studies or trials. Initial success in clinical trials may not be indicative of results obtained when these trials are completed or in later-stage clinical trials.

The results of preclinical studies may not be predictive of the results of clinical trials, and the results of any early-stage clinical trials that are continuing may not be predictive of the results of the later-stage clinical trials. In addition, initial success in clinical trials may not be indicative of results obtained when such trials are completed on in later stage clinical trials. In particular, the small number of patients in our planned early clinical trials may make the results of these trials less predictive of the outcome of later clinical trials. For example, even if successful, the results of our clinical trials of our product candidates PYX-201, PYX-106 and PYX-107 and other product candidates may not be predictive of the results of further clinical trials of these product candidates or any of our other product candidates. Moreover, preclinical and clinical data often are susceptible to varying interpretations and analyses, and many companies that have believed their product candidates performed satisfactorily in preclinical studies and clinical trials nonetheless have failed to obtain marketing licensure of their products. Our clinical trials may not ultimately be successful or support further clinical development of any of our product candidates. There is a high failure rate for product candidates proceeding through clinical trials. Many companies in the pharmaceutical and biotechnology industries have suffered significant setbacks in clinical development even after achieving encouraging results in earlier studies. Any such setbacks in our clinical development could materially harm our business, results of operations, financial condition and prospects.

Additionally, from time to time, we may publish interim, top-line or preliminary data from our clinical trials. Interim data from clinical trials that we may complete are subject to the risk that one or more of the clinical outcomes may materially change as patient enrollment continues and more patient data become available. Preliminary or top-line data also remain subject to audit and verification procedures that may result in the final data being materially different from the preliminary data we previously announced or published. As a result, interim, top-line and preliminary data should be viewed with caution until the final data are available. Adverse differences between preliminary, top-line or interim data and final data could significantly harm our reputation and business prospects.

If we experience delays or difficulties in the enrollment of patients in our clinical trials, our timelines for submitting applications for and receiving necessary marketing authorizations, if any, could be delayed or prevented.

We may not be able to continue clinical trials for our product candidates if we are unable to locate and enroll a sufficient number of eligible patients to participate in these trials, as required by the FDA or similar regulatory authorities outside of the United States. While we believe that we will be able to enroll a sufficient number of patients into each of these clinical trials, we cannot predict with certainty how difficult it will be to enroll patients for trials in these rare indications. Our ability to identify and enroll eligible patients for clinical trials may turn out to be limited or we may be slower in enrolling these trials than we anticipate. In addition, some of our competitors have ongoing clinical trials for product candidates that treat the same indications as our product candidates and, as a result, patients who would otherwise be eligible for our clinical trials may instead elect to enroll in clinical trials of our competitors' product candidates. Patient enrollment in clinical trials is also affected by other factors including:

- the severity of the disease under investigation;
- the size and nature of the patient population;
- the eligibility criteria for the trial in question;
- the competing clinical trials or approved therapies which present an attractive alternative to patients and their physicians;
- the perceived risks and benefits of the product candidate under study, including as a result of adverse effects observed in similar or competing therapies;
- the efforts to facilitate timely enrollment in clinical trials;
- the patient referral practices of physicians;
- the burden on patients due to the scope and invasiveness of required procedures under clinical trial protocols, some of which may be inconvenient and/or uncomfortable;
- the ability to monitor patients adequately during and after treatment;
- the proximity and availability of clinical trial sites for prospective patients;
- the risk that enrolled patients will drop out or die before completion of the trial;
- patients failing to complete a clinical trial or returning for post-treatment follow-up; and
- our ability to manufacture the requisite materials for a patient and clinical trial.

Our inability to enroll a sufficient number of patients for our clinical trials, or our inability to do so on a timely basis, would result in significant delays and could require us to abandon one or more clinical trials altogether. Enrollment delays in our clinical trials may result in increased development costs for our product candidates, which would cause the value of our company to decline and limit our ability to obtain additional financing.

Our product candidates may cause undesirable and unforeseen side effects or have other properties impacting safety that could halt their clinical development, delay or prevent their regulatory licensure, limit their commercial potential or result in significant negative consequences.

Undesirable side effects caused by our product candidates could cause regulatory authorities to interrupt, delay or halt clinical trials and could result in a more restrictive label or the delay or denial of regulatory licensure or approval by the FDA or other regulatory authorities. As is the case with oncology drugs, it is likely that there may be side effects associated with their use. Results of our trials could reveal a high and unacceptable severity and prevalence of these or other side effects. In such an event, our trials could be suspended or terminated, and the FDA or comparable foreign regulatory authorities could order us to cease further development of or deny licensure or approval of our product candidates for any or all targeted indications. Such side effects could also affect patient recruitment or the ability of enrolled patients to complete the trial or result in potential product liability claims. Any of these occurrences may materially and adversely affect our business, financial condition, results of operations and prospects.

Further, clinical trials by their nature utilize a sample of the potential patient population. With a limited number of patients and limited duration of exposure, rare and severe side effects of our product candidates may only be uncovered with a significantly larger number of patients exposed to the product candidate.

In the event that any of our product candidates receive regulatory licensure or approval and we or others identify undesirable side effects caused by one of our products, any of the following adverse events could occur, which could result in the loss of significant revenue to us and materially and adversely affect our results of operations and business:

•regulatory authorities may withdraw their licensure or approval of the product or seize the product;

•we may be required to recall the product or change the way the product is administered to patients;

•additional restrictions may be imposed on the marketing of the particular product or the manufacturing processes for the product or any component thereof;

•we may be subject to fines, injunctions or the imposition of civil or criminal penalties;

•regulatory authorities may require the addition of labeling statements, such as a “black box” warning or a contraindication;

•we may be required to create a medication guide outlining the risks of such side effects for distribution to patients;

•we could be sued and held liable for harm caused to patients;

•the product may become less competitive; and

•our reputation may suffer.

See also “The outcome of preclinical testing for PYX-201 and PYX-106 and early clinical trials for PYX-107 may not predict the success of later clinical trials, and the results of clinical trials for PYX-107 may not satisfy the requirements of the FDA, EMA, or comparable foreign regulatory authorities.”

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

From time to time, we estimate the timing of the anticipated accomplishment of various scientific, clinical, regulatory and other product development goals, which we sometimes refer to as milestones. These milestones may include the commencement or completion of preclinical studies and clinical trials and the submission of regulatory filings and may be associated with payments from collaborators. From time to time, we may publicly announce the expected timing of some of these milestones. All of these milestones are and will be based on numerous assumptions. The actual timing of these milestones may vary dramatically compared to our estimates, in some cases for reasons beyond our control. If we do not meet these milestones as publicly announced, or at all, our revenue may be lower than expected, the commercialization of our products may be delayed or never achieved and, as a result, our stock price may decline.

We face competition from entities that have developed or may develop product candidates for cancer, including companies developing novel treatments and technology platforms. If these companies develop technologies or product candidates more rapidly than we do or their technologies are more effective, our ability to develop and successfully commercialize product candidates may be adversely affected.

The development and commercialization of therapeutic biological products is highly competitive. We compete with a variety of multinational biopharmaceutical companies and specialized biotechnology companies, as well as technology being developed at universities and other research institutions. Our competitors have developed, are developing or will develop product candidates and processes competitive with our product candidates. Competitive therapeutic treatments include those that have already been approved or licensed and accepted by the medical community and any new treatments that enter the market. We believe that a significant number of products are currently under development, and may become commercially available in the future, for the treatment of conditions for which we may try to develop product candidates. The biotechnology and pharmaceutical industries, including the oncology subsector, are characterized by rapidly evolving technologies, intense competition, and a strong defense of intellectual property and proprietary technologies. Any product candidates that we successfully commercialize may not be competitive with currently marketed therapies and any new therapies commercialized in the future.

We are aware of several companies that are developing cancer immunotherapies and ADCs. Many of these companies are well-capitalized and, in contrast to us, have significant clinical experience, and may include our existing or future collaborators. In addition, these companies compete with us in recruiting scientific and managerial talent and the patient pool available for participation in clinical trials.

Our success will partially depend on our ability to develop and protect therapeutics that are more safe, pure, and potent than competing products. Our commercial opportunity and success will be reduced or eliminated if competing products that are safer, more effective, or less expensive than the therapeutics we develop are commercialized.

If our product candidates are licensed, they will compete with a range of therapeutic treatments that are either in development or currently marketed. Many companies are active across various stages of development in the oncology subsector and are marketing and developing products that employ similar ADC and immunotherapy approaches. As of October 2023, there were approximately 304 ADCs in clinical or preclinical development worldwide, of which the vast majority are being developed for the treatment of various cancer indications. Additionally, there are several large and small companies working on various immunotherapy approaches for treatment of cancer. Multiple companies are also involved in the development of ADC therapeutics and immunotherapies, including, but not limited to, AbbVie Inc., Abcure, Inc., ADC Therapeutics SA, Alligator Bioscience AB, Astellas Pharma, Inc., AstraZeneca plc, Celldex Therapeutics, Inc., Daiichi Sankyo Company, Ltd., Eucure Biopharma, a subsidiary of Biocytogen, Hoffmann-La Roche AG, Genentech, Inc., Gilead Sciences, Inc, GlaxoSmithKline, plc, Lyvgen Biopharma, Nextcure, Inc., Pfizer, Philogen S.p.A., and Rakuten Medical, Inc.

Our preclinical ADC and immunotherapy candidates may face substantial competition from alternative therapeutic modalities, such as CAR-T therapies, bispecific antibodies, and small molecules that are being developed for the same cancer types that we are targeting with our pipeline candidates. These approaches could prove to be more effective, safer, or convey other advantages over any products resulting from our technology. In addition, we also face competition on specific targets, including the target of our PYX-201 candidate, EDB, from Philogen S.p.A., and the target of our PYX-106 product candidate, BSI-060T, from Nextcure, Inc. In addition, each of Alligator Bioscience AB, Celldex Therapeutics, Inc., Lyvgen Biopharma, Eucure Biopharma, a subsidiary of Biocytogen, Hoffmann-La Roche AG, and AbbVie Inc. are developing CD40-based antibody product candidates for solid tumor oncology indications that are in clinical trials, typically in combination therapies. Other companies and institutions also have CD40-based product candidates in development. Additionally, there is a wide array of activity in the development of immunotherapies for oncology which may be competitive with our preclinical discovery programs. Furthermore, if any of our product candidates are approved in oncology indications such as lung, hematological and other cancers, they may compete with existing approaches to treating cancer including surgery, radiation, and drug therapy, including conventional chemotherapy, biological products, and targeted drug small molecule therapies.

Many of our competitors have significantly greater scientific, research and development capabilities, as well as greater financial, technical, manufacturing, marketing, sales and supply resources or experience than we do. If we successfully obtain licensure for any product candidate, we will face competition based on many different factors, including the safety, purity and potency of our products, the ease with which our products can be administered and the extent to which patients accept relatively new routes of administration, the timing and scope of regulatory licenses for these products, the availability and cost of manufacturing, marketing and sales capabilities, price, reimbursement coverage and patent position. Competing products could present superior treatment alternatives, including by being more effective, safer, less expensive or marketed and sold more effectively than any products we may develop. Competitive products may make any products we develop obsolete or noncompetitive before we recover the expense of developing and commercializing our product candidates. Such competitors could also recruit our employees, which could negatively impact our level of expertise and our ability to execute our business plan.

Our biological product candidates for which we intend to seek licensure may face competition sooner than anticipated.

The Affordable Care Act, or ACA, includes a subtitle called the Biologics Price Competition and Innovation Act of 2009, or BPCIA, which created an abbreviated licensure 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 licensure 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. The law is complex and is still being interpreted and implemented by the FDA. As a result, its ultimate impact, implementation, and meaning are subject to uncertainty. While it is uncertain when such processes intended to implement BPCIA may be fully adopted by the FDA, any such processes could have an adverse effect on the future commercial prospects for our product candidates.

There is a risk that any product candidates we may develop that are licensed as a biological product under a BLA would not qualify for the 12-year period of exclusivity or that this exclusivity could be shortened due to congressional action or otherwise, or that the FDA will not consider any product candidates we may develop to be reference products for competing products, potentially creating the opportunity for 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, including litigation challenging the constitutionality of the ACA.

For example, in December 2018, a federal district court ruled that the ACA, without the "individual mandate" penalty (which was repealed by the U.S. Congress as part of the Tax Cuts and Jobs Act), is unconstitutional in its entirety. In December 2019, the U.S. Court of Appeals for the 5th Circuit upheld the district court ruling that the individual mandate provisions are unconstitutional and remanded the case back to the district court for further analysis of whether such provisions could be severed from the remainder of the ACA. On June 17, 2021, the U.S. Supreme Court dismissed the case without specifically ruling on the constitutionality of the ACA. There may, however, be other efforts to challenge, repeal, or replace the ACA in the future. We continue to evaluate the effect that the ACA and its possible repeal and replacement has (or may have) on our business and exclusivity under the BPCIA. It is uncertain the extent to which any such changes may impact our business or financial condition.

Our business entails a significant risk of product liability, and if we are unable to obtain sufficient insurance coverage, such failure could have a material and adverse effect on our business, financial condition, results of operations and prospects.

We expect to be exposed to significant product liability risks inherent in the development, testing and manufacturing of our product candidates and products, if approved. Product liability claims could delay or prevent completion of product candidate development programs. If we succeed in marketing products, such claims could result in an FDA investigation of the safety and effectiveness of our products, our third-party manufacturer's manufacturing processes and facilities or our marketing programs and potentially a recall of our products or more serious enforcement action, including limitations on the approved indications for which our product candidates may be used or suspension or withdrawal of licenses. Regardless of the merits or eventual outcome, liability claims may also result in decreased demand for our products, injury to our reputation, costs to defend the related litigation, a diversion of management's time and our resources, substantial monetary awards to trial participants or patients and a decline in our stock price. In addition, we may be subject to liability based on the actions of our existing or future collaborators in connection with their development of products using the FACT Platform or the APXiMAB Platform. Furthermore, clinical trial and product liability insurance is becoming increasingly expensive. As a result, we may be unable to maintain sufficient insurance at a reasonable cost to protect us against losses caused by product liability claims that could have a material and adverse effect on our business, financial condition, results of operations and prospects.

Risks Related to Regulatory Licensure or Approval and Other Legal Compliance Matters

The regulatory licensure and approval processes of the FDA and other comparable regulatory authorities are lengthy, time-consuming and inherently unpredictable and, if we are ultimately unable to obtain marketing licensure or approval for our product candidates, our business will be substantially harmed.

The time required to obtain approval or licensure by the FDA and other comparable regulatory authorities is unpredictable but typically takes many years following the commencement of clinical trials and depends upon numerous factors, including the substantial discretion of the regulatory authorities. In addition, approval and licensure policies, regulations or the type and amount of clinical data necessary to gain approval or licensure may change during the course of a product candidate's clinical development and may vary among jurisdictions. We have not obtained marketing approval or licensure for any product candidate, and it is possible that none of our existing product candidates, or any product candidates we may seek to develop in the future, will ever obtain marketing approval or licensure.

Our product candidates could fail to receive marketing licensure in the United States for many reasons, including the following:

- the FDA may disagree with the design or implementation of our clinical trials;
- we may be unable to demonstrate to the satisfaction of the FDA that a product candidate is safe, pure, and potent;
- results of clinical trials may not meet the level of statistical significance required by the FDA for licensure;
- we may be unable to demonstrate that a product candidate's clinical and other benefits outweigh its safety risks;
- the FDA may disagree with our interpretation of data from preclinical studies or clinical trials;
- data collected from clinical trials of our product candidates may not be sufficient to support the submission of a BLA to the FDA or other submission or to obtain marketing licensure in the United States;
- the FDA may find deficiencies with or fail to approve the manufacturing processes or facilities of third-party manufacturers with which we contract for clinical and commercial supplies; and
- the licensure policies or regulations of the FDA may significantly change in a manner rendering our clinical data insufficient for licensure.

This lengthy licensure process as well as the unpredictability of future clinical trial results may result in our failing to obtain regulatory licensure to market any of our product candidates, which would significantly harm our business, results of operations, financial condition and prospects. The FDA has substantial discretion in the licensure process and determining when or whether regulatory licensure will be obtained for any of our product candidates. Even if we believe the data collected from clinical trials of our product candidates are promising, such data may not be sufficient to support licensure by the FDA.

In addition, even if we were to obtain licensure, regulatory authorities may approve any of our product candidates for fewer or more limited indications than we request, may not approve the price we intend to charge for our products, may grant a license contingent on the performance of costly post-marketing clinical trials, or may approve or license a product candidate with a label that does not include the labeling claims necessary or desirable for the successful commercialization of that product candidate. Any of the foregoing scenarios could materially harm the commercial prospects for our product candidates.

Even if we obtain FDA licensure for any of our product candidates in the United States, we may never obtain approval or licensure for or commercialize any of them in any other jurisdiction, which would limit our ability to realize their full market potential.

In order to market any products in any particular jurisdiction, we must establish and comply with numerous and varying regulatory requirements on a country-by-country basis regarding safety, purity, potency and efficacy.

Licensure by the FDA in the United States does not ensure approval or licensure by regulatory authorities in other countries or jurisdictions. However, the failure to obtain approval or licensure in one jurisdiction may negatively impact our ability to obtain approval or licensure elsewhere. In addition, clinical trials conducted in one country may not be accepted by regulatory authorities in other countries, and regulatory approval or licensure in one country does not guarantee regulatory approval or licensure in any other country.

Approval or licensure processes vary among countries and can involve additional product testing and validation and additional administrative review periods. Seeking foreign regulatory approval or licensure could result in difficulties and increased costs for us and require additional preclinical studies or clinical trials which could 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. We do not have any product candidates approved or licensed for sale in any jurisdiction, including in international markets, and we do not have experience in obtaining regulatory approval or licensure in international markets. If we fail to comply with regulatory requirements in international markets or to obtain and maintain required approvals or licensures, or if regulatory approvals or licensures in international markets are delayed, our target market will be reduced and our ability to realize the full market potential of any product we develop will be unrealized.

Even if we receive regulatory licensure of any product candidates, we will be subject to ongoing regulatory obligations and continued regulatory review, which may result in significant additional expense, and we may be subject to penalties if we fail to comply with regulatory requirements or experience unanticipated problems with our product candidates.

If any of our product candidates are licensed or approved by regulatory authorities, they will be subject to ongoing regulatory requirements for manufacturing, labeling, packaging, storage, advertising, promotion, sampling, record-keeping, conduct of post-marketing studies, track and trace, serialization, post-market adverse event reporting, and submission of safety, purity, potency, efficacy and other post-market information, including both federal and state requirements in the United States and requirements of comparable foreign regulatory authorities. In addition, we will be subject to continued compliance with Current Good Manufacturing Practices, or cGMP, and GCP requirements for any clinical trials that we conduct post-licensure.

Manufacturers and manufacturers' facilities are required to comply with extensive FDA and comparable foreign regulatory authority requirements, including ensuring that quality control and manufacturing procedures conform to cGMP regulations. As such, we and our contract manufacturers will be subject to continual review and inspections to assess compliance with cGMP and adherence to commitments made in any BLA or other marketing application and previous responses to inspection observations. Accordingly, we and others with whom we work must continue to expend time, money and effort in all areas of regulatory compliance, including manufacturing, production and quality control.

Any regulatory licenses that we receive for our product candidates may be subject to limitations on the approved indications for which the product may be marketed or to the conditions of licensure, or contain requirements for potentially costly post-marketing testing, including Phase 4 clinical trials and surveillance to monitor the safety, purity, and potency of the product candidate. The FDA may also require a REMS program as a condition of licensure of our product candidates, which could entail requirements for long-term patient follow-up, 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. Comparable foreign regulatory authorities may also have programs similar to REMS. In addition, if the FDA or a comparable foreign regulatory authority licenses or approves our product candidates, we will have to comply with requirements including submissions of safety and other post-marketing information and reports and registration.

Clinical trials of our product candidates must be conducted in carefully defined subsets of patients who have agreed to enter into clinical trials. Consequently, it is possible that our clinical trials, or those of any future collaborator, may indicate an apparent positive effect of a product candidate that is greater than the actual positive effect, if any, or alternatively fail to identify undesirable side effects. If one or more of our product candidates receive marketing licensure and we, or others, discover that the biological product is less effective than previously believed or causes undesirable side effects that were not previously identified, a number of potentially significant negative consequences could result, including:

- regulatory authorities may withdraw their licensure of the biological product or seize the biological product;
- we, or any future collaborators, may be required to recall the biological product, change the way the biological product is administered or conduct additional clinical trials;
- additional restrictions may be imposed on the marketing of, or the manufacturing processes for, the particular biological product;
- we may be subject to fines, injunctions or the imposition of civil or criminal penalties;
- regulatory authorities may require the addition of labeling statements, such as a "black box" warning or a contraindication;

•we, or any future collaborators, may be required to create a medication guide outlining the risks of the previously unidentified side effects for distribution to patients;

•we, or any future collaborators, could be sued and held liable for harm caused to patients;

•the biological product may become less competitive in the marketplace; and

•our reputation may suffer.

Any of these events could have a material and adverse effect on our operations and business and could adversely impact our stock price.

The FDA may also impose requirements for costly post-marketing studies or clinical trials and surveillance to monitor the safety, purity, or potency of the product, including the adoption and implementation of REMS. The FDA and other agencies, including the United States Department of Justice, or DOJ, closely regulate and monitor the post-licensure marketing and promotion of biological products to ensure they are marketed and distributed only for the approved indications and in accordance with the provisions of the approved labeling. The FDA and DOJ impose stringent restrictions on manufacturers' communications regarding off-label use, and if we do not market our products only for the approved indications, we may be subject to enforcement action for off-label marketing. Violations of the Federal Food, Drug and Cosmetic Act, or FDCA, and other statutes, including the False Claims Act, relating to the promotion and advertising of prescription drugs may lead to investigations and enforcement actions alleging violations of federal and state healthcare fraud and abuse laws, as well as state consumer protection laws.

We, and any collaborators, must comply with requirements concerning advertising and promotion for any of our product candidates for which we or they obtain marketing licensure. Promotional communications with respect to prescription biological products are subject to a variety of legal and regulatory restrictions and must be consistent with the information in the product's approved labeling. Thus, we, and any collaborators, will not be able to promote any products we develop for indications or uses for which the biological product is not licensed. The FDA strictly regulates marketing, labeling, advertising and promotion of products that are placed on the market. Products may be promoted only for the approved indications and in accordance with the provisions of the approved label. The FDA and other agencies actively enforce the laws and regulations prohibiting the promotion of off-label uses and a company that is found to have improperly promoted off-label uses may be subject to significant liability. However, physicians may, in their independent medical judgment, prescribe legally available products for off-label uses. The FDA does not regulate the behavior of physicians in their choice of treatments, but the FDA does restrict manufacturer's communications on the subject of off-label use of their products. The policies of the FDA and of comparable foreign regulatory authorities may change and additional government regulations may be enacted that could prevent, limit or delay regulatory licensure 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 licensure that we may have obtained and we may not achieve or sustain profitability.

In addition, later discovery of previously unknown side effects or other problems with our products or their manufacturers or manufacturing processes, or failure to comply with regulatory requirements, may yield various results, including:

•restrictions on such products, manufacturers or manufacturing processes;

•restrictions and warnings on the labeling or marketing of a product;

•restrictions on product distribution or use;

•requirements to conduct post-marketing studies or clinical trials;

•warning letters or untitled letters;

•withdrawal of the products from the market;

•refusal to approve pending applications or supplements to approved applications that we submit;

•recall of products;

•fines, restitution or disgorgement of profits or revenues;

•suspension or withdrawal of marketing licenses;

•suspension of any ongoing clinical trials;

•damage to relationships with any potential collaborators;

•unfavorable press coverage and damage to our reputation;

•refusal to permit the import or export of our products;

•product seizure;

•injunctions or the imposition of civil or criminal penalties; or

•litigation involving patients using our products.

The FDA and similar foreign authorities may impose consent decrees or withdraw licensure 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 our product candidates, including adverse events of unanticipated severity or frequency, or with our third-party manufacturers or manufacturing processes, or failure to comply with regulatory requirements, may result in revisions to the approved labeling to add new safety information; imposition of post-market studies or clinical trials to assess new safety risks; or imposition of distribution restrictions or other restrictions under a REMS program. Other potential consequences include, among other things:

•restrictions on the marketing or manufacturing of our products, withdrawal of the product from the market or voluntary or mandatory product recalls;

•fines, warning letters or holds on clinical trials;

•refusal by the FDA and similar foreign authorities to approve pending applications or supplements to approved applications filed by us or suspension or revocation of licenses;

•product seizure or detention or refusal to permit the import or export of our product candidates; and

•injunctions or the imposition of civil or criminal penalties.

Non-compliance with European Union, or EU, requirements regarding safety monitoring or pharmacovigilance, and with requirements related to the development of products for the pediatric population (as explained further below), also can result in significant financial penalties, and non-compliance with pediatric requirements may prevent regulatory approvals from being granted. Similarly, failure to comply with the EU and United Kingdom, or UK, requirements regarding the protection of personal information can lead to significant penalties and sanctions.

A Breakthrough Therapy designation by the FDA, even if granted for any of our product candidates, may not lead to a faster development or regulatory review or licensure process and it does not increase the likelihood that our product candidates will receive marketing licensure.

We may seek Breakthrough Therapy designation for our product candidates and some or all of our future product candidates. A Breakthrough Therapy is defined as a drug that is intended, alone or in combination with one or more other drugs or biological products, to treat a serious or life-threatening disease or condition and for which preliminary clinical evidence indicates that the drug or biological products may demonstrate substantial improvement over existing therapies on one or more clinically significant endpoints, such as substantial treatment effects observed early in clinical development. For product candidates that have been designated as Breakthrough Therapies, interaction and communication between the FDA and the sponsor of the trial can help to identify the most efficient path for clinical development while minimizing the number of patients placed in ineffective control regimens. Drugs designated as Breakthrough Therapies by the FDA may also be eligible for other expedited approval programs, including accelerated approval, if they meet regulatory requirements for those other programs.

Designation as a Breakthrough Therapy is within the discretion of the FDA. Accordingly, even if we believe one of our product candidates meets the criteria for designation as a Breakthrough Therapy, the FDA may disagree and instead determine not to make such designation. In any event, the receipt of a Breakthrough Therapy designation for a product candidate may not result in a faster development process, review or licensure compared to candidate products considered for licensure under non-expedited FDA review procedures and does not assure ultimate licensure by the FDA. In addition, even if one or more of our product candidates qualify as Breakthrough Therapies, the FDA may later decide that the product no longer meets the conditions for qualification. For example, in June 2022, the FDA published a draft guidance document outlining considerations for the FDA in rescinding Breakthrough Therapy designation for products that no longer meet the requirements for that designation. Thus, even though we intend to seek Breakthrough Therapy designation for some or all of our future product candidates for the treatment of various cancers, there can be no assurance that we will receive Breakthrough Therapy designation.

Fast Track designation by the FDA, even if granted for other current or future product candidates, may not lead to a faster development or regulatory review, licensure process and does not increase the likelihood that our product candidates will receive marketing licensure.

We may seek Fast Track designation for one or more of our future product candidates. If a drug or biological product is intended for the treatment of a serious or life-threatening disease or condition and it demonstrates the potential to address unmet medical needs for such a disease or condition, the drug sponsor may apply for FDA Fast Track designation for a particular indication. We may seek Fast Track designation for our product candidates, but there is no assurance that the FDA will grant this designation to any of our proposed product candidates. Marketing applications submitted by sponsors of products in Fast Track development may qualify for priority review under the policies and procedures offered by the FDA, but the Fast Track designation does not assure any such qualification or ultimate marketing licensure by the FDA. The FDA has broad discretion whether or not to grant Fast Track designation, so even if we believe a particular product candidate is eligible for this designation, there can be no assurance that the FDA would decide to grant it. Even if we do receive Fast Track designation, we may not experience a faster development process, review or licensure compared to conventional FDA procedures or pathways and receiving a Fast Track designation does not provide assurance of ultimate FDA licensure. In addition, the FDA may withdraw Fast Track designation if it believes that the designation is no longer supported by data from our clinical development program. The FDA may withdraw any Fast Track designation at any time.

If we decide to seek Orphan Drug Designation for any of our current or future product candidates, we may be unsuccessful or may be unable to maintain the benefits associated with Orphan Drug Designation, including the potential for supplemental market exclusivity.

We may seek Orphan Drug Designation for one or more of our current or future product candidates. For example, in May 2023, the FDA granted Orphan Drug Designation, or ODD, for PYX-201 in pancreatic cancer. Also, the FDA granted ODD for PYX-107 in the treatment of soft tissue carcinoma, esophageal and GEJ cancers. Regulatory authorities in some jurisdictions, including the United States and Europe, may designate drugs or biological products for relatively small patient populations as orphan drugs. Under the Orphan Drug Act, the FDA may grant orphan designation to a drug or biological product intended to treat a rare disease or condition, defined as a disease or condition with a patient population of fewer than 200,000 in the United States, or a patient population greater than 200,000 in the United States when there is no reasonable expectation that the cost of developing and making available the drug in the United States will be recovered from sales in the United States for that drug or biological product. In the United States, Orphan Drug Designation entitles a party to financial incentives such as opportunities for grant funding towards clinical trial costs, tax advantages and user-fee waivers. After the FDA grants Orphan Drug Designation, the identity of the drug or biological product and its potential orphan use are disclosed publicly by the FDA. Orphan Drug Designation does not convey any advantage in, or shorten the duration of, the regulatory review and licensure process.

If a product that has Orphan Drug Designation subsequently receives the first FDA approval or licensure for a particular active ingredient for the disease for which it has such designation, the product is entitled to orphan product exclusivity, which means that the FDA may not approve any other applications, including an NDA or BLA, to market the same drug or biological product for the same indication for seven years, except in limited circumstances such as a showing of clinical superiority to the product with orphan drug exclusivity or if the FDA finds that the holder of the orphan drug exclusivity has not shown that it can assure the availability of sufficient quantities of the orphan drug to meet the needs of patients with the disease or condition for which the biological product was designated. As a result, even if one of our product candidates receives orphan exclusivity, the FDA can still approve or license other drugs or biological products that have a different active ingredient for use in treating the same indication or disease. Further, the FDA can waive orphan exclusivity if we are unable to manufacture sufficient supply of our product.

We may seek Orphan Drug Designation for our product candidates in additional orphan indications in which there is a medically plausible basis for the use of these product candidates. Even if we obtain Orphan Drug Designation, exclusive marketing rights in the United States may be limited if we seek licensure for an indication broader than the orphan designated indication and may be lost if the FDA later determines that the request for designation was materially defective or if we, through our manufacturer, are unable to assure sufficient quantities of the product to meet the needs of patients with the rare disease or condition. In addition, although we intend to seek Orphan Drug Designation for other product candidates, we may never receive these designations.

The U.S. Congress is also considering updates to the orphan drug provisions of the FDCA in response to a recent 11th Circuit decision. Any changes to the orphan drug provisions could change our opportunities for, or likelihood of success in obtaining, orphan drug exclusivity and would materially adversely affect our business, financial condition, results of operations, cash flows and prospects.

Accelerated approval by the FDA, even if granted, may not lead to a faster development or regulatory review or approval process and it does not increase the likelihood that our product candidates will receive marketing licensure. If we are unable to obtain licensure of our products through the Accelerated Approval Program in the United States, we may be required to conduct additional nonclinical and clinical studies and trials beyond those that we currently contemplate, which could increase the expense of obtaining, reduce the likelihood of obtaining and/or delay the timing of obtaining, necessary marketing licensure. Even if we receive accelerated approval from the FDA through the Accelerated Approval Program, if our confirmatory post-marketing trial does not verify clinical benefit, or if we do not comply with rigorous post-marketing requirements, the FDA may seek to withdraw accelerated approval.

We plan to seek accelerated approval of PYX-201 and PYX-106 and may seek approval of future product candidates using the FDA's accelerated approval pathway. For any licensure to market a biological product, we must provide the FDA and foreign regulatory agencies with clinical data that adequately demonstrate the safety, purity, and potency of the product for the indication applied for in the NDA or BLA or other respective regulatory filings. The Accelerated Approval Program is one of several approaches used by the FDA to make prescription drugs or biological products more rapidly available for the treatment of serious or life-threatening diseases. Section 506(c) of the FDCA provides that the FDA may grant accelerated approval to "a product for a serious or life-threatening condition upon a determination that the product has an effect on a surrogate endpoint that is reasonably likely to predict clinical benefit, or on a clinical endpoint that can be measured earlier than irreversible morbidity or mortality, that is reasonably likely to predict an effect on irreversible morbidity or mortality or other clinical benefit, taking into account the severity, rarity, or prevalence of the condition and the availability or lack of alternative treatments." Licensure through the Accelerated Approval Program is subject, however, to the requirement that a sponsor perform adequate and well controlled post-marketing clinical trials to verify and describe the drug's clinical benefit, where there is uncertainty as to the relationship of the surrogate endpoint to the clinical benefit, or of the observed clinical endpoint to ultimate outcome. Typically, clinical benefit is verified when post-marketing clinical trials show that the biological products provide a clinically meaningful positive therapeutic effect, that is, an effect on how a patient feels, functions, or survives. If required, these confirmatory trials must be completed with due diligence and, pursuant to the Food and Drug Omnibus Reform Act of 2022, or FDORA, enacted in 2022, may require that such studies be underway prior to approval. If such confirmatory post-marketing trials fail to confirm the product's clinical profile or risks and benefits, the FDA may withdraw accelerated approval of the product.

The FDA has broad discretion with regard to licensure through the Accelerated Approval Program, and even if we believe that the Accelerated Approval Program is appropriate for one of our products, we cannot assure you that the FDA will ultimately agree. The FDA may also change its policies with respect over Accelerated Approval over time. For example, in March 2023, the FDA announced the availability of draft guidance on "Clinical Trial Considerations to Support Accelerated Approval of Oncology Therapeutics," in which the Agency outlined, and invited public comment on, its "preferred approach" of randomized controlled trials, including those that provide for longer term follow-up that could fulfill a postmarketing requirement to verify clinical benefit. In that draft guidance, the FDA acknowledged that historically, single-arm trial designs and response endpoints have most commonly been used in oncology, but noted that such trials have limitations. Furthermore, even if we do obtain licensure through the Accelerated Approval Program, we may not experience a faster development process, review, or licensure compared to conventional FDA procedures.

Even if the FDA reviews a BLA seeking accelerated approval, there can be no assurance that licensure will be granted on a timely basis, or at all. The FDA may disagree that the design of, or results from, our studies support accelerated approval. Additionally, the FDA could require us to conduct further studies or trials prior to granting licensure of any type, including by determining that licensure through the Accelerated Approval Program is not appropriate and that our clinical trials may not be used to support licensure through the conventional pathway. We might not be able to fulfill the FDA's requirements in a timely manner, which would cause delays, or licensure might not be granted because our submission is deemed incomplete by the FDA. There also can be no assurance that after subsequent FDA feedback we will continue to pursue licensure through the Accelerated Approval Program. A failure to obtain licensure through the Accelerated Approval Program could result in a longer time period to obtain licensure of our products, could increase the cost of our products' development, could delay our ability to commercialize our products and could significantly harm our financial position and competitive position in the marketplace.

Even if we receive licensure for one of our products through the Accelerated Approval Program, we will be subject to rigorous post-marketing requirements, including the completion of one or more confirmatory post-marketing trials as the FDA may require, to verify the clinical benefit of the product, and submission to the FDA of all promotional materials prior to their dissemination. These requirements could adversely impact the timing of the commercial launch of the product. Even if we do receive accelerated approval, we may not experience a faster development or regulatory review or licensure process. Further, receiving accelerated approval does not provide assurance of ultimate full FDA licensure.

The FDA could seek to withdraw accelerated approval for multiple reasons, including if we fail to conduct any required confirmatory post-marketing trial with due diligence, our confirmatory post-marketing trial does not confirm the predicted clinical benefit, other evidence shows that the product is not safe, pure, or potent under the conditions of use, or we disseminate promotional materials that are found by the FDA to be false and misleading.

Any delay in obtaining, or inability to obtain, licensure through the Accelerated Approval Program, or any issues in maintaining approval granted under the Accelerated Approval Program, would delay or prevent commercialization of our products, and would materially adversely affect our business, financial condition, results of operations, cash flows and prospects.

If foreign regulatory authorities approve biosimilar versions of any of our product candidates that receive marketing approval, or such authorities do not grant our product candidates appropriate periods of data or market exclusivity before approving generic versions of our product candidates, the sales of our product candidates could be adversely affected.

In the EU and the UK, innovative medicinal products are authorized based on a full marketing authorization application and conditional authorization (as opposed to an application for marketing authorization that relies on data in the marketing authorization dossier for another, previously approved medicinal product). Applications for marketing authorization for innovative medicinal products must contain, *inter alia*, the results of pharmaceutical tests, preclinical tests and clinical trials conducted with the medicinal product for which marketing authorization is sought (and where applicable the results of the pediatric studies unless a waiver or a deferral has been obtained— as described further below).

A marketing authorization can be obtained via the centralized procedure or the national procedure. The centralized procedure results in a single marketing authorization, issued by the European Commission (based on the opinion of the EMA), which is valid across the entire European Economic Area, or EEA, which comprises the EU, Iceland, Liechtenstein and Norway. The centralized procedure is compulsory for human drugs that are (i) derived from biotechnology processes, such as genetic engineering; (ii) contain a new active substance indicated for the treatment of certain diseases, such as HIV/AIDS, cancer, diabetes, neurodegenerative diseases, autoimmune and other immune dysfunctions and viral diseases; (iii) designated orphan medicines; and (iv) advanced-therapy medicines, such as gene therapy, somatic cell therapy or tissue-engineered medicines. The centralized procedure may at the request of the applicant also be used in certain other cases. The centralized procedure would be mandatory for the product candidates we are developing.

Where an applicant for a marketing authorization submits a full dossier containing its own pharmaceutical, preclinical tests and clinical trials data, and where the application does not fall within the 'global marketing authorization' of an existing medicinal product, reference product candidates may receive eight years of data exclusivity and an additional two years of market exclusivity, upon grant of the marketing authorization. If granted, during the data exclusivity period, applicants for approval of biosimilars cannot rely on data contained in the marketing authorization dossier submitted for the already authorized, or reference product candidate, to support their application. The market exclusivity period prevents a successful biosimilar applicant from commercializing its product in the EU until 10 years have elapsed from the initial marketing authorization of the reference product in the EU, but a biosimilar marketing authorization application can be submitted during this time. The overall 10-year market exclusivity period can further be extended by one more year if, during the first eight years of those 10 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, even if a compound is considered to be a new active substance and the innovator is able to gain the period of data and market exclusivity, provided that no other intellectual property or regulatory exclusivities apply, another unrelated company could also apply for a marketing authorization and market another competing medicinal product for the same therapeutic indication if such company obtained its own marketing authorization based on a separate marketing authorization application based on a full self-standing scientific data package supporting the application.

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

In the EU, marking authorization applications for new medicinal products must include the results of clinical trials conducted in pediatric population, in compliance with a pediatric investigation plan, or PIP, agreed with the EMA's Pediatric Committee, or PDCO. The PDCO can grant waivers or deferrals to these requirements in certain circumstances (for example, a waiver may be obtained if the condition only occurs in adult populations). Where required, pediatric studies must cover all sub-sets of the pediatric population for both existing and new indications, pharmacological forms and route of administrations. Limited further exclusions apply, including in relation to biosimilar applications. Certain incentives may be available for completion of pediatric studies. For example, once the marketing authorization is obtained in all countries in the European Union, or EU Member States, and study results are included in the product information, even when negative, the product is eligible for a six-months supplementary protection certificate extension (if any is in effect at the time of approval) or, in the case of orphan pharmaceutical products, a two year extension of the orphan market exclusivity is granted.

In the EU, the criteria for designating an “orphan medicinal product” are similar in principle to those in the United States. A medicinal product may be designated as orphan if (1) it is intended for the diagnosis, prevention or treatment of a life-threatening or chronically debilitating condition (2) either (a) such condition affects no more than five in 10,000 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 investment and (3) there exists no satisfactory method of diagnosis, prevention or treatment of such condition authorized for marketing in the EU, or if such a method exists, the product will be of significant benefit to those affected by the condition. The application for Orphan Drug Designation must be submitted before the marketing authorization application. Orphan Drug Designations entitle a party to financial incentives such as reduction of fees or fee waivers and are, upon grant of a marketing authorization, entitled to 10 years of market exclusivity. During the 10-year market exclusivity period, the EMA cannot accept another marketing authorization application, or grant a marketing authorization or accept an application to extend an existing marketing authorization, for the same therapeutic indication, in respect of a similar medicinal product. An orphan medicinal product can also obtain an additional two years of market exclusivity in the EU for pediatric studies. No extension to any supplementary protection certificate can be granted on the basis of pediatric studies for orphan indications. Orphan Drug Designation does not convey any advantage in, or shorten the duration of, the regulatory review and approval process.

The ten-year market exclusivity may be reduced to six years if, at the end of the fifth year, it is established that the product no longer meets the criteria for Orphan Drug Designation, for example, if the product is sufficiently profitable not to justify maintenance of market exclusivity. At any time, a marketing authorization may be granted to a similar product for the same indication if:

1.the second applicant can establish that its product, although similar, is safer, more effective or otherwise clinically superior;

2.the holder of the marketing authorization for the original orphan medicinal product has given his consent to the second applicant; or

3.the holder of the marketing authorization for the original orphan medicinal product is unable to supply sufficient quantities of the medicinal product.

Although the UK has left the EU, its regulatory legal framework provides for similar periods of protection (namely regulatory data exclusivity, marketing protection and market exclusivity).

Competition that our product candidates may face from biosimilar versions of our product candidates could materially and adversely impact our future revenue, profitability and cash flows and substantially limit our ability to obtain a return on the investments we have made in those product candidates. Our future revenues, profitability and cash flows could also be materially and adversely affected and our ability to obtain a return on the investments we have made in those product candidates may be substantially limited if our product candidates, if and when approved, are not afforded the appropriate periods of non-patent exclusivity.

The failure to obtain required regulatory clearances or approvals for any companion diagnostic tests that we may pursue may prevent or delay approval of any of our product candidates. Moreover, the commercial success of any of our product candidates that require a companion diagnostic will be tied to the receipt of any required regulatory clearances or approvals and the continued availability of such tests.

In connection with the clinical development of our product candidates for certain indications, we may work with collaborators to develop or obtain access to companion diagnostic tests to identify appropriate patients for our product candidates. We may rely on third parties for the development, testing and manufacturing of these companion diagnostics, the application for and receipt of any required regulatory clearances or approvals, and the commercial supply of these companion diagnostics. The FDA and foreign regulatory authorities regulate companion diagnostics as medical devices that will likely be subject to clinical trials in conjunction with the clinical trials for product candidates, and which will require separate regulatory clearance or approval prior to commercialization. This process could include additional meetings with health authorities, such as a pre-submission meeting and the requirement to submit an investigational device exemption, or IDE. In the case of a companion diagnostic that is designated as “significant risk device,” approval of an IDE by the FDA and an Institutional Review Board, or IRB, is required before such diagnostic is used in conjunction with the clinical trials for a corresponding product candidate. We or our third-party collaborators may fail to obtain the required regulatory clearances or approvals, which could prevent or delay approval of our product candidates. In addition, the commercial success of any of our product candidates that requires a companion diagnostic will be tied to and dependent upon the receipt of required regulatory clearances or approvals and the continued ability of such third parties to make the companion diagnostic commercially available to us on reasonable terms in the relevant geographies.

If we are required to in the future and if we are unable to successfully develop companion diagnostic tests for our product candidates that require such tests, or experience significant delays in doing so, we may not realize the full commercial potential of these product candidates.

We may be required by the FDA to develop, either by ourselves or with collaborators, companion diagnostic tests for our product candidates for certain indications. To be successful, we or our collaborators will need to address a number of scientific, technical, regulatory and logistical challenges. We have no prior experience with medical device or diagnostic test development. If we choose to develop and seek FDA clearance or approval for companion diagnostic tests on our own, we will require additional personnel with medical device knowledge and expertise. We may rely on third parties for the design, development and manufacture of companion diagnostic tests for our therapeutic product candidates that require such tests. These third parties may be laboratories that develop companion diagnostic tests. Recently, FDA published a proposed rule announcing its intention to regulate laboratory-developed tests (LDTs) as medical devices subject to existing device regulatory requirements. If these parties are unable to successfully develop companion diagnostics for these therapeutic product candidates, meet FDA regulatory requirements, or experience delays in doing so, we may be unable to enroll enough patients for our current and planned clinical trials, the development of these therapeutic product candidates may be adversely affected, these therapeutic product candidates may not obtain marketing approval, and we may not realize the full commercial potential of any of these therapeutics that obtain marketing approval. Any failure to successfully develop this companion diagnostic may cause or contribute to delayed enrollment of this trial and may prevent us from initiating or completing further clinical trials to support marketing approval for our product candidates. As a result, our business, results of operations and financial condition could be materially harmed.

Our relationships with customers, physicians and third-party payors are subject, directly or indirectly, to federal and state healthcare fraud and abuse laws, false claims laws, and other healthcare laws and regulations. If we are unable to comply or have not fully complied with these laws, we could face substantial penalties.

Healthcare providers, physicians and third-party payors in the United States and elsewhere will play a primary role in the recommendation and prescription of any product candidates for which we obtain marketing licensure. Our current and future arrangements with healthcare professionals, principal investigators, consultants, customers, drug wholesalers/distributors, pharmacy benefit managers, and third-party payors subject us to various federal and state fraud and abuse laws and other healthcare laws that may constrain the business or financial arrangements and relationships through which we research, develop, sell, market and distribute our product candidates, if we obtain marketing licensure. In particular, the research of our product candidates, as well as the promotion, sales and marketing of healthcare items and services, as well as certain business arrangements in the healthcare industry, are subject to extensive laws designed to prevent fraud, kickbacks, self-dealing and other abusive practices. These laws and regulations may restrict or prohibit a wide range of pricing, discounting, marketing and promotion, structuring and commission(s), certain customer incentive programs and other business or financial arrangements.

Ensuring that our business arrangements with third parties comply with applicable healthcare laws and regulations will likely be costly. The shifting compliance environment and the need to build and maintain robust and expandable systems to comply with multiple jurisdictions with different compliance or reporting requirements increases the possibility that a healthcare company may run afoul of one or more of the requirements. It is possible that governmental authorities will conclude that our business practices may not comply with current or future statutes, regulations, or case law involving applicable fraud and abuse or other healthcare laws and regulations. If our operations are found to be in violation of any of these laws or any other governmental regulations that may apply to us, we may be subject to significant civil, criminal and administrative penalties, damages, fines, disgorgement, imprisonment, or exclusion from participating in government-funded healthcare programs, such as Medicare and Medicaid; 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; contractual damages; reputational harm; and/or the curtailment or restructuring of our operations.

If the physicians or other providers or entities with whom we expect to do business are found not to be in compliance with applicable laws, they may be subject to significant criminal, civil or administrative sanctions, including exclusion from government-funded healthcare programs. Even if resolved in our favor, litigation or other legal proceedings relating to healthcare laws and regulations may cause us to incur significant expenses and could distract our technical and management personnel from their normal responsibilities. In addition, there could be public announcements of the results of hearings, motions or other interim proceedings or developments. If securities analysts or investors perceive these results to be negative, it could have a substantial adverse effect on the price of our common stock. Such litigation or proceedings could substantially increase our operating losses and reduce the resources available for development, manufacturing, sales, marketing or distribution activities. Uncertainties resulting from the initiation and continuation of litigation or other proceedings relating to applicable healthcare laws and regulations could have an adverse effect on our ability to compete in the marketplace.

The successful commercialization of our product candidates in the United States and elsewhere will depend in part on the extent to which third-party payors, including governmental authorities and private health insurers, provide coverage and adequate reimbursement levels, as well as implement pricing policies favorable for our product candidates. Failure to obtain or maintain coverage and adequate reimbursement for our product candidates, if approved, could limit our ability to market those products and decrease our ability to generate revenue.

Significant uncertainty exists as to the coverage and reimbursement status of any products for which we may obtain regulatory licensure. In the United States and in other countries, patients who are provided medical treatment for their conditions generally rely on third-party payors to reimburse all or part of the costs associated with their treatment. The availability of coverage and adequacy of reimbursement for our products by third-party payors, including government health care programs (e.g., Medicare, Medicaid or TRICARE), managed care providers, private health insurers, health maintenance organizations and other organizations is essential for most patients to be able to afford medical services and pharmaceutical products such as our product candidates. Third-party payors decide which medications they will pay for and establish reimbursement levels.

Our ability to successfully commercialize our product candidates will depend, in part, on the extent to which coverage and adequate reimbursement for any products for which we obtain marketing authorization will be available from third-party payors. In the United States, no uniform policy for coverage and reimbursement for pharmaceutical products exists among third-party payors. Third-party payors often rely upon Medicare coverage policy and payment limitations in setting reimbursement policies, but also have their own methods and approval processes apart from Medicare coverage and reimbursement determinations. Therefore, coverage and reimbursement for products for which we may obtain marketing authorization could differ significantly from payor to payor. One payor's determination to provide coverage for a product does not assure that other payors will also provide coverage and reimbursement for the product. Payors consider a number of factors when determining whether to cover a new product, including, for example, whether the 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. Third-party payors may also limit coverage to specific products on an approved list, or formulary, which might not include all of the FDA-approved products for a particular indication.

Moreover, a payor's decision to provide coverage for a product does not imply that an adequate reimbursement rate will be approved. The process for determining whether a payor will provide coverage for a product may be separate from the process for setting the reimbursement rate that the payor will pay for the product. Even if coverage is provided, the approved reimbursement amount may not be high enough to allow us to establish or maintain pricing sufficient to realize a sufficient return on our investment. A decision by a third-party payor not to cover or not to separately reimburse for any products for which we may obtain marketing authorization could reduce physician utilization of such products. If coverage and adequate reimbursement are not available, or are available only to limited levels, we may not be able to successfully commercialize our product candidates. We cannot be sure that coverage and reimbursement in the United States will be available for our current or future product candidates or for any procedures using our current or future product candidates, and any reimbursement that may become available may not be adequate or may be decreased or eliminated in the future. Moreover, for products administered under the supervision of a physician, obtaining coverage and adequate reimbursement may be particularly difficult because of the higher prices often associated with such drugs. Additionally, separate reimbursement for the product itself may or may not be available. Instead, the hospital or administering physician may be reimbursed only for providing the treatment or procedure in which our product is used.

Further, increasing efforts by third-party payors in the United States and abroad to cap or reduce healthcare costs may cause payor organizations to limit both coverage and the level of reimbursement for newly approved products and, as a result, they may not cover or provide adequate payment for our product candidates. In order to secure coverage and reimbursement for any product that might be approved for sale, we may need to conduct expensive pharmacoeconomic studies in order to demonstrate the medical necessity and cost-effectiveness of our products, in addition to the costs required to obtain FDA or comparable marketing authorizations or approvals. Additionally, we may also need to provide permissible discounts to purchasers, private health plans or government healthcare programs. Our product candidates may nonetheless not be considered medically necessary or cost-effective. If third-party payors do not consider a product to be cost-effective compared to other available therapies, they may not cover the product after marketing authorization or approval as a benefit under their plans or, if they do, the level of payment may not be sufficient to allow a company to sell its products at a profit. We expect to experience pricing pressures from third-party payors in connection with the potential sale of any of our product candidates.

Lastly, in some foreign countries, the proposed pricing for a drug must be approved before the drug may be lawfully marketed. The requirements governing drug pricing vary widely from country to country. For example, EU Member States can restrict the range of medicinal products for which their national health insurance systems provide reimbursement and they can control the prices of medicinal products for human use. To obtain reimbursement or pricing approval, some of these Member States may require the completion of clinical trials that compare the cost effectiveness of a particular product candidate to currently available therapies. An EU Member State may approve a specific price for the medicinal product, or it may instead adopt a system of direct or indirect controls on the profitability of the company placing the medicinal product on the market. Approaches between EU Member States are diverging. For example, in France, effective market access will be supported by agreements with hospitals and products may be reimbursed by the Social Security Fund. The price of medicines is negotiated with the Economic Committee for Health Products. There can be no assurance that any country that has price controls or reimbursement limitations for pharmaceutical products will allow favorable reimbursement and pricing arrangements for any of our product candidates. Historically, products launched in the EU do not follow price structures of the United States and generally prices in the EU tend to be significantly lower than prices in the United States.

Enacted and future healthcare legislation may increase the difficulty and cost for us to progress our clinical programs and obtain marketing licensure or approval of and commercialize our product candidates and may affect the prices we may set.

In the United States and other jurisdictions, there have been, and we expect there will continue to be, a number of legislative and regulatory changes and proposed changes to the healthcare system that could affect results of our future operations. In particular, there have been and continue to be a number of initiatives at the U.S. federal and state levels that seek to reduce healthcare costs and improve the quality of healthcare. For example, the Inflation Reduction Act (IRA), which was signed into law on August 16, 2022, allows Medicare to: beginning in 2026, establish a "maximum fair price" for a fixed number of pharmaceutical and biological products covered under Medicare Parts B and D following a price negotiation process with the Centers for Medicare and Medicaid Services (CMS); and, beginning in 2023, penalize drug companies that raise prices for products covered under Medicare Parts B and D faster than inflation, among other reforms. CMS has recently taken steps to implement the IRA, including:

- On June 30, 2023, issuing guidance detailing the requirements and parameters of the first round of price negotiations, to take place during 2023 and 2024, for products subject to the "maximum fair price" provision that would become effective in 2026;
- On August 29, 2023, announcing the initial list of 10 drugs subject to price negotiations (including one product for oncologic indications);
- On November 17, 2023, releasing guidance outlining further details in implementing the Medicare Part D Discount Program; and
- On December 14, 2023, updating a list of 48 Medicare Part B products that had adjusted coinsurance rates based on the inflationary rebate provisions of the IRA for the time period of January 1, 2024 to March 31, 2024.

It is unclear how future regulatory actions to implement the IRA, as well as the outcome of pending litigation against the IRA, may affect our products and future profitability. See Part I, Item 1, Government Regulation – Other Healthcare Laws - Healthcare Reform of this Annual Report on Form 10-K for additional detail on recent healthcare reform efforts that could affect our operations.

We expect that additional state and federal healthcare reform measures will be adopted in the future, any of which could limit the extent to which state and federal governments cover particular healthcare products and services and could limit the amounts that federal and state governments will pay for healthcare items and services. This could result in reduced demand for any product candidate we develop or could result in additional pricing pressures.

In markets outside of the United States, reimbursement and healthcare payment systems vary significantly by country and many countries have instituted price ceilings on specific products and therapies. The price control regulations outside of the United States can have a significant impact on the profitability of a given market, and further uncertainty is introduced if and when these laws change. For example, in Canada, price control legislation for patented medicines is currently undergoing significant changes that may have significant effects on profitability for companies selling products in Canada.

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

Actual or perceived failures to comply with applicable data protection, privacy and security laws, regulations, standards and other requirements could adversely affect our business, operations, and financial condition.

The global data protection landscape is rapidly evolving, and we may be or become subject to or affected by numerous federal, state and foreign laws and regulations, as well as regulatory guidance, governing the collection, use, disclosure, transfer, security and processing of personal information, such as information that we collect about participants and healthcare providers in connection with clinical trials. Implementation standards and enforcement practices are likely to remain uncertain for the foreseeable future, which may create uncertainty in our business, affect our or our service providers' ability to operate in certain jurisdictions or to collect, store, transfer use and share personal data, result in liability or impose additional compliance or other costs on us. Any failure or perceived failure by us to comply with federal, state or foreign laws or self-regulatory standards could result in negative publicity, diversion of management time and effort and proceedings against us by governmental entities or others.

As our operations and business grow, we may become subject to or affected by new or additional data protection laws and regulations and face increased scrutiny or attention from regulatory authorities. In the United States, most healthcare providers, including certain research institutions from which we may obtain patient health information, are subject to privacy and security regulations promulgated under the Health Insurance Portability and Accountability Act of 1996, as amended by the Health Information Technology for Economic and Clinical Health Act, which we collectively refer to as HIPAA. We are not currently acting as a covered entity or business associate under HIPAA and therefore are not directly regulated under HIPAA. However, any person may be prosecuted under HIPAA's criminal provisions either directly or under aiding-and-abetting or conspiracy principles. Consequently, depending on the facts and circumstances, we could face substantial criminal penalties if we knowingly receive individually identifiable health information from a HIPAA-covered healthcare provider or research institution that has disclosed individually identifiable health information in a manner that is not authorized or permitted under HIPAA. In addition, in the future, we may maintain sensitive personal information, including health-related information, that we receive throughout the clinical trial process, in the course of our research collaborations and/or directly from individuals (or their healthcare providers) who may enroll in patient assistance programs if we choose to implement these types of programs. As a result, we may be subject to data privacy and security laws protection such information, including state laws requiring notification of affected individuals and state regulators in the event of a breach of personal information, which is a broader class of information than the health information protected by HIPAA.

Other federal and state laws establish additional requirements for protecting the privacy and security of personal information, including health information. In addition, certain states have proposed or enacted legislation. For instance, Washington state recently passed the "My Health My Data" Act, which will regulate "consumer health data," which is defined as "personal information that is linked or reasonably linked to a consumer and that identifies a consumer's past, present, or future physical or mental health." The "My Health My Data" Act provides exemptions for personal data used or shared in research, including data subject to 45 C.F.R. Parts 46, 50 and 56. Nevada also recently enacted a consumer health data privacy bill, and additional states may adopt health-specific privacy laws that could impact our business activities depending on how they are interpreted.

The Federal Trade Commission, or the FTC, and many state attorney generals are interpreting existing federal and state consumer protection laws to impose evolving standards for the collection, use, dissemination and security of health-related and other personal information. Privacy laws require us to publish statements that describe how we handle personal information and choices individuals may have about the way we handle their personal information. Violating individuals' privacy rights, publishing false or misleading information about security practices, or failing to take appropriate steps to keep individuals' personal information secure may constitute unfair or deceptive acts or practices in violation of Section 5 of the FTC Act. Additionally, the FTC recently published an advance notice of proposed rule making on "commercial surveillance" and data security, and is seeking comment on whether it should implement new trade regulation rules or other regulatory alternatives concerning the ways in which companies (2) collect, aggregate, protect, use, analyze, and retain consumer data, as well as (2) transfer, share, sell, or otherwise monetize that data in ways that are unfair or deceptive. Federal regulators, state attorneys general and plaintiffs' attorneys have been and will likely continue to be active in this space, and if we do not comply with existing or new laws and regulations related to patient health information, we could be subject to criminal or civil sanctions. Further, the California Consumer Privacy Act of 2018, or the CCPA, went into effect in January 2020, which creates individual data privacy rights for consumers and operational requirements for companies, including placing increased privacy and security obligations on entities handling certain personal information of consumers or households. These requirements could increase our compliance costs and potential liability. The CCPA gives California residents expanded rights to access and delete their personal information, opt out of certain personal information sharing and receive detailed information about how their personal information is used. The CCPA provides for civil penalties for violations, as well as a private right of action for data breaches that is expected to increase data breach litigation. While there is currently an exception for protected health information maintained by a business associate or covered entity as well as an exception for clinical trial data, as currently written, the CCPA may impact certain of our business activities. Further, the California Privacy Rights Act, or CPRA, was passed in California in 2020 and modifies the CCPA. The CCPA (as modified by the CPRA) imposes additional data protection obligations on covered businesses, including additional consumer rights processes, limitations on data uses, new audit requirements for higher risk data, and opt outs for certain uses of sensitive data. It also creates a new California data protection agency authorized to issue substantive regulations and could result in increased privacy and information security enforcement. The majority of the provisions went into effect on January 1, 2023, and additional compliance investment and potential business process changes may be required. Similar laws have been adopted in other states or proposed in other states and at the federal level, and if passed, such laws may have potentially conflicting requirements that would make compliance challenging. While these new laws may include exemptions for health-related data such as clinical trial data, they add layers of complexity to compliance in the U.S. market, and could increase our compliance costs and adversely affect our business. In the event that we are subject to or affected by HIPAA, the CCPA (as modified by the CPRA), or other privacy and data protection laws, any liability from failure to comply with the requirements of these laws could adversely affect our financial condition.

In addition, the European Union, or EU, General Data Protection Regulation, or EU GDPR, imposes strict requirements for the processing of personal data (i.e., data which identifies an individual or from which an individual is identifiable). The UK has implemented the EU GDPR into its national law by virtue of Section 3 of the European Union (Withdrawal) Act 2018 (known as the UK GDPR, and, together with the EU GDPR, the GDPR), which sits alongside the UK Data Protection Act 2018.

The GDPR imposes a number of compliance obligations on controllers including *inter alia*: (i) accountability and transparency requirements, which require controllers to demonstrate and record compliance with the GDPR and to provide more detailed information to data subjects regarding processing; (ii) requirements to process personal data lawfully, including specific requirements for obtaining valid consent where consent is the lawful basis for processing; (iii) obligations to consider data protection as any new products or services are developed and designed, including to limit the amount of personal data processed; (iv) obligations to implement appropriate technical and organizational security measures to safeguard personal data and to report certain personal data breaches to the relevant supervisory authority without undue delay (and, in any event, no later than 72 hours, where feasible) and affected individuals where the personal data breach is likely to result in a high risk to their rights and freedoms; (v) obligations to comply with data protection rights of data subjects, including a right of access to and rectification of personal data, a right to obtain restriction of processing or to withdraw consent to processing, or to object to processing of personal data and a right to ask for a copy of personal data to be provided to a third party in a useable format and a right to erasure of personal data in certain circumstances; and (vi) additional requirements around the processing of special categories of personal data (including health data and genetic data).

In addition, the EU GDPR also prohibits transfers of personal data subject to the EU GDPR to countries outside of the EEA, unless such transfers are made to a country deemed to have adequate data privacy laws by the European Commission or specific safeguards have been implemented in accordance with the EU GDPR or a derogation under the EU GDPR can be relied on. The Court of Justice of the European Union issued a decision in July 2020 invalidating the EU-U.S. Privacy Shield framework as a data transfer mechanism (*Schrems II*) and imposing further restrictions on the use of EU standard contractual clauses, or EU SCCs, including a requirement for companies to carry out a transfer impact assessment, or TIA. A TIA, among other things, assesses laws governing access to personal data in the recipient country and considers whether supplementary measures that provide privacy protections additional to those provided under the EU SCCs will need to be implemented to ensure an "essentially equivalent" level of data protection to that afforded in the EU. The UK GDPR imposes similar restrictions on transfers of personal data from the UK to jurisdictions that the UK does not consider adequate. This may have implications for our cross-border data flows and may result in compliance costs.

Further, on October 7, 2022, the U.S. President introduced an Executive Order to facilitate a new Trans-Atlantic Data Privacy Framework, or DPF, which will act as a successor to the invalidated Privacy Shield. On July 10, 2023, the European Commission adopted its Final Implementing Decision granting the U.S. adequacy, or Adequacy Decision, for EU-US transfers of personal data for entities self-certified to the DPF. Entities relying on EU SCCs for transfers to the U.S. are also able to rely on the analysis in the Adequacy Decision as support for their TIA regarding the equivalence of U.S. national security safeguards and redress.

It should also be noted that the UK Government has published its own form of EU SCCs, known as the International Data Transfer Agreement and International Data Transfer Addendum to the new EU SCCs. The UK Information Commissioner's Office has also published its own version of the TIA and revised guidance on international transfers, although entities may choose to adopt either the EU or UK style TIA. Further, on September 21, 2023, the UK Secretary of State for Science, Innovation and Technology established a UK-US data bridge (i.e., a UK equivalent of the Adequacy Decision) and adopted UK regulations to implement the UK-US data bridge, or UK Adequacy Regulations. Personal data may now be transferred from the UK under the UK-US data bridge through the UK extension to the DPF to organizations self-certified under the UK extensions to the DPF.

Companies subject to the EU GDPR may be subject to robust regulatory enforcement of data protection requirements and potential fines for noncompliance of up to €20 million (under the EU GDPR) or £17.5 million (under the UK GDPR) or 4% of the annual global turnover of the noncompliant company, whichever is greater. In addition, the EU GDPR confers a private right of action on data subjects and consumer associations to lodge complaints with supervisory authorities, seek judicial remedies and obtain compensation for damages resulting from violations of the EU GDPR.

Although we work to comply with applicable laws, regulations and standards, our contractual obligations and other legal obligations, these requirements are evolving and may be modified, interpreted and applied in an inconsistent manner from one jurisdiction to another, and may conflict with one another or other legal obligations with which we must comply. Any failure or perceived failure by us or our employees, representatives, contractors, consultants, collaborators, or other third parties to comply with such requirements or adequately address privacy and security concerns, even if unfounded, could result in additional cost and liability to us, damage our reputation, and adversely affect our business and results of operations.

If we or our third-party manufacturers and suppliers 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 an adverse effect on the success of our business.

We are subject to numerous environmental, health and safety laws and regulations, including those governing laboratory procedures and the handling, use, storage, treatment and disposal of hazardous materials and wastes. Our research and development activities involve the use of biological and hazardous materials and 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, which could cause an interruption of our commercialization efforts, research and development efforts and business operations, environmental damage resulting in costly clean-up and liabilities under applicable laws and regulations governing the use, storage, handling and disposal of these materials and specified waste products. Although we believe that the safety procedures utilized by our third-party manufacturers for handling and disposing of these materials generally comply with the standards prescribed by these laws and regulations, we cannot guarantee that this is the case or eliminate the risk of accidental contamination or injury from these materials. Upon an event of this nature, we may be held liable for any resulting damages and such liability could exceed our resources and state or federal or other applicable authorities may curtail our use of certain materials and/or interrupt our business operations. Further, environmental laws and regulations are complex, change frequently and have tended to become more stringent. We cannot predict the impact of any changes of this nature and cannot be certain of our future compliance. 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, development or production efforts. Failure to comply with these laws and regulations also may result in substantial fines, penalties or other sanctions.

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 or other work-related injuries, this insurance may not provide adequate coverage against potential liabilities. We do not carry specific biological waste or hazardous waste insurance coverage, workers' compensation or property and casualty and general liability insurance policies that include coverage for damages and fines arising from biological or hazardous waste exposure or contamination.

We are subject to U.S. and certain foreign export and import controls, sanctions, embargoes, anti-corruption laws and anti-money laundering laws and regulations. Compliance with these legal standards could impair our ability to compete in domestic and international markets. We can face criminal liability and other serious consequences for violations, which can harm our business.

We are subject to export control and import laws and regulations, including the U.S. Export Administration Regulations, U.S. Customs regulations, various economic and trade sanctions regulations administered by the U.S. Treasury Department's Office of Foreign Assets Controls, the U.S. Foreign Corrupt Practices Act of 1977, as amended, or the FCPA, the U.S. domestic bribery statute contained in 18 U.S.C. § 201, the U.S. Travel Act, the USA PATRIOT Act of 2001 and other state and national anti-bribery and anti-money laundering laws in the countries in which we conduct activities. Anti-corruption laws are interpreted broadly and prohibit companies and their employees, agents, contractors and other collaborators from authorizing, promising, offering or providing, directly or indirectly, improper payments or anything else of value to recipients in the public or private sector. We may engage third parties for clinical trials outside of the United States, to sell our products abroad once we enter a commercialization phase and/or to obtain necessary permits, licenses, patent registrations and other regulatory approvals. We may also have direct or indirect interactions with officials and employees of government agencies or government-affiliated hospitals, universities and other organizations. We can be held liable for the corrupt or other illegal activities of our employees, agents, contractors and other collaborators, even if we do not explicitly authorize or have actual knowledge of these activities. Any violations of the laws and regulations described above may result in substantial civil and criminal fines and penalties, imprisonment, the loss of export or import privileges, debarment, tax reassessments, breach of contract and fraud litigation, reputational harm and other consequences.

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

If we fail to attract and retain qualified senior management and key scientific personnel, our business may be materially and adversely affected.

Our success depends in part on our continued ability to attract, retain and motivate highly qualified management and clinical and scientific personnel. We are highly dependent upon members of our senior management, including Lara Sullivan, M.D., our President and Chief Executive Officer, and Pamela Connealy, our Chief Financial Officer and Chief Operating Officer, as well as our senior scientists and other members of our senior management team. The loss of services of any of these individuals could delay or prevent the successful development of our product pipeline, the initiation and completion of our clinical trials or the commercialization of product candidates or any future product candidates.

Competition for qualified personnel in the pharmaceutical, biopharmaceutical and biotechnology field is intense due to the limited number of individuals who possess the skills and experience required by our industry. We will need to hire additional personnel as we expand our clinical development and if we initiate commercial activities. We may not be able to attract and retain quality personnel on acceptable terms, or at all. In addition, to the extent we hire personnel from competitors, we may be subject to allegations that they have been improperly solicited or that they have divulged proprietary or other confidential information, or that their former employers own their research output.

As our product candidates advance into clinical trials, we may experience difficulties in managing our growth and expanding our operations.

As of March 20, 2024, we had 50 full-time employees. As our development and commercialization plans and strategies develop, and as we continue to operate as a public company, we expect to expand our employee base for managerial, operational, financial and other resources. In addition, we have limited experience in product development. As our product candidates enter and advance through preclinical studies and clinical trials, we will need to expand our development, regulatory and manufacturing capabilities or contract with other organizations to provide these capabilities for us. In the future, we expect to have to manage additional relationships with collaborators or partners, suppliers and other organizations. Our ability to manage our operations and future growth will require us to integrate products and technology from the Merger and continue to improve our operational, financial and management controls, reporting systems and procedures. We may not be able to implement improvements to our management information and control systems in an efficient or timely manner and may discover deficiencies in existing systems and controls. Our inability to successfully manage our growth and expand our operations could have a material and adverse effect on our business, financial condition, results of operations and prospects.

We currently have no marketing, sales, or distribution infrastructure and we intend to either establish a sales and marketing infrastructure or outsource this function to a third party. Either of these commercialization strategies carries substantial risks to us.

We currently have no marketing, sales, and distribution capabilities because all our product candidates are still in preclinical or clinical development. If any of our product candidates complete clinical development and are approved, we intend to either establish a sales and marketing organization with technical expertise and supporting distribution capabilities to commercialize our product candidates in a legally compliant manner, or to outsource this function to a third party. There are risks involved if we decide to establish our own sales and marketing capabilities or enter into arrangements with third parties to perform these services. To the extent that we enter into collaboration agreements with respect to marketing, sales or distribution, our product revenue may be lower than if we directly marketed or sold any approved products. Such collaborative arrangements with partners may place the commercialization of our products outside of our control and would make us subject to a number of risks, including that we may not be able to control the amount or timing of resources that our collaborative partner devotes to our products or our collaborator's willingness or ability to complete its obligations, and our obligations under our arrangements may be adversely affected by business combinations or significant changes in our collaborators' business strategy.

If we are unable to enter into these arrangements on acceptable terms or at all, we may not be able to successfully commercialize any approved products. If we are not successful in commercializing any approved products, either on our own or through collaborations with one or more third parties, our future product revenue will suffer and we may incur significant additional losses, which would have a material adverse effect on our business, financial condition, and results of operations.

Our internal computer systems, or those of any of our existing or future CROs, manufacturers, other contractors, consultants, or collaborators, may fail or suffer security or data privacy breaches or other unauthorized or improper access to, use of or destruction of our proprietary and confidential data, employee data or personal data, which could result in additional costs, significant liabilities, harm to our reputation and material disruption of our operations.

In the ordinary course of our business, we collect, process, and store proprietary, confidential, and sensitive information, including personal information (including health information), intellectual property, trade secrets, and proprietary business information owned or controlled by ourselves or other parties.

Despite the implementation of security measures, our internal computer systems and those of our current and any future CROs, manufacturers, other contractors, consultants, existing or future collaborators and other third-party service providers are vulnerable to damage from various methods, including cybersecurity attacks, breaches, intentional or accidental mistakes or errors, or other technological failures, which can include, among other things, computer viruses, unauthorized access attempts, including third parties gaining access to systems using stolen or inferred credentials, ransomware attacks, denial-of-service attacks, phishing attempts, service disruptions, natural disasters, fire, terrorism, war and telecommunication and electrical failures. As the cyber-threat landscape evolves, these attacks are growing in frequency, sophistication and intensity, and are becoming increasingly difficult to detect. Furthermore, because the techniques used to obtain unauthorized access to, or to sabotage, systems change frequently and often are not recognized until launched against a target, we may be unable to anticipate these techniques or implement adequate preventative measures. We may also experience security breaches that may remain undetected for an extended period.

If such an event were to occur and cause interruptions in our operations or result in the unauthorized acquisition of or access to personally identifiable information or individually identifiable health information, it could result in a material disruption of our product candidate development programs and our business operations including without limitation, disruptions of our drug development programs, delays in our regulatory approval efforts, regulatory investigations or enforcement actions, litigation, indemnity obligations, negative publicity, and financial loss and significant liabilities. In addition, system failures could cause the loss, theft, exposure, or unauthorized access or use of valuable clinical trial data as a result of accidents, errors or malfeasance by our employees, independent contractors or others working with us or on our behalf or otherwise disrupt our clinical activities and be expensive and time-consuming to remedy. Some of the federal, state and foreign government legal requirements include obligations of companies to notify individuals of security breaches involving particular personally identifiable information, which could result from breaches experienced by us or by our vendors, contractors or organizations with which we have formed strategic relationships. Notifications and follow-up actions related to a security breach could impact our reputation and cause us to incur significant costs, including legal expenses and remediation costs. For example, the loss of clinical trial data from completed, ongoing or future clinical trials involving our product candidates could result in delays in our regulatory licensure efforts and significantly increase our costs to recover or reproduce the lost data. Any breach of our computer systems may result in a loss of data or compromised data integrity across many of our programs in various stages of development.

We may be required to expend resources, modify our business activities and practices, or modify our operations (including our development program activities) or information technology in an effort to comply with applicable data protection laws, privacy policies and data protection obligations.

While we have implemented security measures designed to protect against security breaches, there can be no assurance that our security measures or those of our service providers, partners and other third parties, will be effective in protecting against all security breaches and material adverse effects on our business that may arise from such breaches. The recovery systems, security protocols, network protection mechanisms and other security measures that we (and our third parties) have integrated into our platform, systems, networks and physical facilities, which are designed to protect against, detect and minimize security breaches, may not be adequate to prevent or detect service interruption, system failure, or data loss.

We will also rely on third parties to manufacture our product candidates, and similar events relating to their computer systems could also have a material adverse effect on our business. To the extent that any disruption or security breach were to result in a loss of, or damage to, our data, or inappropriate disclosure of confidential or proprietary information, we could be exposed to litigation and governmental investigations, the further development and commercialization of our product candidates could be delayed and we could be subject to significant fines or penalties for any noncompliance with certain state, federal or international privacy and security laws.

Our insurance policies may not be adequate to compensate us for the potential losses arising from any such disruption, failure or security breach. In addition, such insurance may not be available to us in the future on economically reasonable terms, or at all. Further, our insurance may not cover all claims made against us and could have high deductibles in any event, and defending a suit, regardless of its merit, could be costly and divert management attention.

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

Any unplanned event, such as flood, fire, explosion, earthquake, extreme weather condition, medical epidemics or pandemics, power shortage, telecommunication failure or other natural or manmade accidents or incidents that result in us being unable to fully utilize our facilities, or the manufacturing facilities of our third-party contract manufacturers, may have a material and adverse effect on our ability to operate our business, particularly on a daily basis, and have significant negative consequences on our financial and operating conditions. Loss of access to these facilities may result in increased costs, delays in the development of our product candidates or interruption of our business operations. Earthquakes, wildfires or other natural disasters could further disrupt our operations, and have a material and adverse effect on our business, financial condition, results of operations and prospects. If a natural disaster, power outage or other event prevented us from using all or a significant portion of our headquarters, damaged critical infrastructure, such as our research facilities or the manufacturing facilities of our third-party contract manufacturers, or otherwise disrupted operations, it may be difficult or, in certain cases, impossible, for us to continue our business for a substantial period of time. The disaster recovery and business continuity plans we have in place may prove inadequate in the event of a serious disaster or similar event. We may incur substantial expenses as a result of the limited nature of our disaster recovery and business continuity plans, which could have a material adverse effect on our business. As part of our risk management policy, we maintain insurance coverage at levels that we believe are appropriate for our business. However, in the event of an accident or incident at these facilities, we cannot assure you that the amounts of insurance will be sufficient to satisfy any damages and losses. If our facilities, or the manufacturing facilities of our third-party contract manufacturers, are unable to operate because of an accident or incident or for any other reason, even for a short period of time, any or all of our research and development and discovery programs may be harmed. Any business interruption may have a material and adverse effect on our business, financial condition, results of operations and prospects.

Our business is subject to economic, political, regulatory and other risks associated with conducting business internationally.

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

•differing regulatory requirements and reimbursement regimes in foreign countries;

•unexpected changes in tariffs, trade barriers, price and exchange controls and other regulatory requirements;

•economic weakness, including inflation, or political instability in particular foreign economies and markets;

•compliance with tax, employment, immigration and labor laws for employees living or traveling abroad;

•foreign taxes, including withholding of payroll taxes;

•foreign currency fluctuations, which could result in increased operating expenses and reduced revenue, and other obligations incident to doing business in another country;

•difficulties staffing and managing foreign operations;

•workforce uncertainty in countries where labor unrest is more common than in the United States;

•potential liability under the FCPA or comparable foreign regulations;

•challenges enforcing our contractual and intellectual property rights, especially in those foreign countries that do not respect and protect intellectual property rights to the same extent as the United States;

•production shortages resulting from any events affecting raw material supply or manufacturing capabilities abroad; and

•business interruptions resulting from geo-political actions, including war and terrorism.

These and other risks associated with our international operations may materially adversely affect our ability to attain or maintain profitable operations.

Disruptions at the FDA, the SEC and other government agencies caused by funding shortages or global health concerns could hinder their ability to hire and retain key leadership and other personnel, prevent new products and services from being developed or commercialized in a timely manner or otherwise prevent those agencies from performing normal business functions on which the operation of our business may rely, which could negatively impact our business.

The ability of the FDA to review and approve new products can be affected by a variety of factors, including government budget and funding levels, ability to hire and retain key personnel and accept the payment of user fees, and statutory, regulatory and policy changes. Average review times at the agency have fluctuated in recent years as a result. In addition, government funding of the SEC, and other government agencies on which our operations may rely, including those that fund research and development activities is subject to the political process, which is inherently fluid and unpredictable.

Disruptions at the FDA and other agencies may also slow the time necessary for new drugs to be reviewed and/or approved by necessary government agencies, which would adversely affect our business. For example, in recent years, including in 2018 and 2019, the U.S. government shut down several times and certain regulatory agencies, such as the FDA and the SEC, had to furlough critical employees and stop critical activities. 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. Further, future government shutdowns could impact our ability to access the public markets and obtain necessary capital in order to properly capitalize and continue our operations.

If a prolonged government shutdown occurs, or if global health concerns prevent the FDA or other regulatory authorities from conducting their regular inspections, reviews, or other regulatory activities, it could significantly impact the ability of the FDA or other regulatory authorities to timely review and process our regulatory submissions, which could have a material adverse effect on our business.

Risks Related to Our Dependence on Third Parties

If we fail to comply with our obligations under any license, collaboration or other agreements, we may be required to pay damages and could lose intellectual property rights that are necessary for developing and protecting our product candidates or we could lose certain rights to grant sublicenses.

We are a party to license agreements with Pfizer, Biosion, and the University of Chicago, pursuant to which we in-license patents and technology for certain of our product candidates, pursuant to which we may license patents and technology for future product candidates. Our current license agreements and our collaboration agreement impose, and any future license agreements or collaboration agreements we enter into are likely to impose, various development, commercialization, funding, milestone, royalty, diligence, sublicensing, insurance, patent prosecution and enforcement and/or other obligations on us. If we breach any of these obligations, or use the intellectual property licensed to us in an unauthorized manner, we may be required to pay damages and the licensor may have the right to terminate the license, which could result in us being unable to develop, manufacture and sell products that are covered by the licensed technology or enable a competitor to gain access to the licensed technology. Moreover, our licensors may own or control intellectual property that has not been licensed to us and, as a result, we may be subject to claims, regardless of their merit, that we are infringing or otherwise violating the licensor's rights. In addition, while we cannot 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.

We have already entered into collaborations with third parties for the research, development and commercialization of certain of the product candidates we may develop. We may form or seek additional collaborations or strategic alliances or enter into additional licensing arrangements in the future. If any of these collaborations, strategic alliances or additional licensing arrangements are not successful, we may not be able to capitalize on the market potential of those product candidates.

We may in the future form or seek strategic alliances, create joint ventures or collaborations or enter into additional licensing arrangements with third parties that we believe will complement or augment our development and commercialization efforts with respect to our product candidates and any future product candidates that we may develop. Any of these relationships may require us to incur non-recurring and other charges, increase our near and long-term expenditures, issue securities that dilute our existing stockholders or disrupt our management and business.

In addition, we face significant competition in seeking appropriate strategic partners and the negotiation process for these sorts of transactions is time-consuming, complex and expensive. Moreover, 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, potency, purity and efficacy and obtain marketing approval. Additionally, our existing partners may decide to acquire or partner with other companies developing oncology therapeutics, which may have an adverse impact on our business prospects, financial condition and results of operations.

Further, if we enter into additional collaboration agreements and strategic partnerships or license our product candidates, we may not be able to realize the benefit of those 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 prospects, financial condition and results of operations. We also cannot be certain that, following a strategic transaction or license, we will achieve the revenue or specific net income that justifies the entry into the transaction in the first place. Any delays in entering into new collaborations or strategic partnership agreements related to our product candidates could delay the development and commercialization of our product candidates in certain geographies for certain indications, which would harm our business prospects, financial condition and results of operations.

We rely on third parties to manufacture our product candidates. Any failure by a third party manufacturer to produce acceptable raw materials or product candidates for us or to obtain authorization from the FDA or comparable foreign regulatory authorities relating thereto may delay or impair our ability to initiate or complete our clinical trials, obtain regulatory licensure or approvals or commercialize approved products.

We rely on third-party contract manufacturers to manufacture our preclinical trial product supplies and clinical product supplies, and if we receive authorization to market our product candidates, we will rely on such manufacturers for commercial supplies. We do not own or operate manufacturing facilities for producing such supplies. There can be no assurance that our preclinical and clinical development product supplies will not be limited, interrupted, or of satisfactory quality or continue to be available at acceptable prices, whether as a result of inflationary pressures or otherwise. In particular, any replacement of any of our manufacturers could require significant effort and expense because there may be a limited number of qualified replacements and could take a significant amount of time to complete.

The manufacturing process for a product candidate is subject to FDA and foreign regulatory authority review. Suppliers and manufacturers must meet applicable manufacturing requirements and undergo rigorous facility and process validation tests required by regulatory authorities in order to comply with regulatory standards, such as cGMPs. In the event that any of our manufacturers fail 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 reasonable terms, if at all. In some cases, the technical skills or technology required to manufacture our product candidates may be unique or proprietary to the original manufacturer and we may have difficulty transferring such skills or technology to another third party and a feasible alternative may not exist. 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 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. The delays associated with the verification of a new manufacturer could negatively affect our ability to develop product candidates in a timely manner or within budget.

We expect to continue to rely on third party manufacturers if we receive regulatory licensure for any product candidate. To the extent that we have existing, or enter into future, manufacturing arrangements with third parties, we will depend on these third parties to perform their obligations in a timely manner consistent with contractual and regulatory requirements, including those related to quality control and assurance. If we are unable to obtain or maintain third party manufacturing for product candidates, or to do so on commercially reasonable terms, we may not be able to develop and commercialize our product candidates successfully. Our or a third party's failure to execute on our manufacturing requirements and comply with cGMP or similar foreign requirements could adversely affect our business in a number of ways, including:

•an inability to initiate or continue clinical trials of product candidates under development;

•delay in submitting regulatory applications, or receiving regulatory licenses, for product candidates;

•loss of the cooperation of an existing or future collaborator;

•subjecting third party manufacturing facilities or our manufacturing facilities to additional inspections by regulatory authorities;

•requirements to cease distribution or to recall batches of our product candidates; and

•the inability to commercialize a product candidate, and an inability to meet commercial demands for such products.

We may be unable to establish agreements with third party CDMOs, or to do so on acceptable terms. Even if we are able to establish agreements with CDMOs, reliance on them entails additional risks, including:

•reliance on the CDMO for regulatory, compliance and quality assurance;

•the possible breach of the manufacturing agreement by the CDMO;

•the possible misappropriation of our proprietary information, including our trade secrets and know-how; and

•the possible termination or nonrenewal of the agreement by the CDMO at a time that is costly or inconvenient for us.

We have only limited technology transfer agreements in place with respect to our product candidates, and these arrangements do not extend to commercial supply and, in some instances, to clinical supply. We acquire many key materials on a purchase order basis. As a result, we do not have long-term committed arrangements with respect to our product candidates and other materials. If we receive marketing licensure for any of our product candidates, we will need to establish an agreement for commercial manufacture with a third party.

The CDMOs we retain may not be able to comply with cGMP regulations or similar regulatory requirements outside of the United States. Our failure, or the failure of our CDMOs, to comply with applicable regulations could result in sanctions being imposed on us, including clinical holds, fines, injunctions, civil penalties, delays, suspension or withdrawal of license, license revocation, seizures or recalls of product candidates or products, operating restrictions and criminal prosecutions, any of which could significantly and adversely affect supplies of our products.

The facilities used by our contract manufacturers to manufacture our product candidates must be approved by the FDA or the EU Member States in coordination with the EMA pursuant to inspections that will be conducted after we submit our BLA to the FDA or our marketing authorization application to the EMA. We do not have complete control over all aspects of the manufacturing process of, and are dependent on, our contract manufacturing partners for compliance with cGMP regulations for manufacturing. Third-party manufacturers may not be able to comply with cGMP regulations or similar regulatory requirements outside of the United States. If our contract manufacturers cannot successfully manufacture material that conforms to our specifications and the strict regulatory requirements of the FDA or comparable foreign regulatory bodies, they will not be able to secure and/or maintain marketing licensure for their manufacturing facilities. In addition, we do not have complete control over the ability of our contract manufacturers to maintain adequate quality control, quality assurance and qualified personnel. If the FDA, EU Member States and the EMA or other comparable regulatory authorities do not approve these facilities for the manufacture of our product candidates or if they withdraw any such licensure in the future, we may need to find alternative manufacturing facilities, which would significantly impact our ability to develop, obtain marketing licensure for or market our product candidates, if approved or licensed.

Our failure, or the failure of our third-party manufacturers, to comply with applicable regulations could result in sanctions being imposed on us, including fines, injunctions, civil penalties, delays, suspension or withdrawal of licensure, license revocation, seizures or recalls of products or product candidates, operating restrictions and criminal prosecutions, any of which could significantly and adversely affect supplies of our product candidates and harm our business and results of operations. Our product candidates and any products that we may develop may compete with other product candidates and products for access to suitable manufacturing facilities. As a result, we may not obtain access to these facilities on a priority basis or at all. There are a limited number of manufacturers that operate under cGMP regulations and that might be capable of manufacturing for us.

Any performance failure on the part of our existing or future manufacturers could delay clinical development or marketing licensure. We do not currently have arrangements in place for redundant supply or a second source for bulk drug substance. If our current CDMOs cannot perform as agreed, we may be required to replace such manufacturers. Although we believe that there are several potential alternative manufacturers who could manufacture our product candidates, we may incur added costs and delays in identifying and qualifying any such replacement manufacturer or be able to reach agreement with any alternative manufacturer.

Our current and anticipated future dependence upon others for the manufacture of our product candidates or products may adversely affect our future profit margins and our ability to commercialize any products that receive marketing licensure on a timely and competitive basis.

A portion of our manufacturing of our product candidates takes place in China, through third-party manufacturers. A significant disruption in the operation of those manufacturers could materially adversely affect our business, financial condition and results of operations.

We currently contract manufacturing operations to third parties, and large quantities of our product candidates are manufactured by these third parties globally, including in China. Any disruption in production or inability of our manufacturers to produce adequate quantities to meet our needs could impair our ability to operate our business on a day-to-day basis and to continue our development of our product candidates. Furthermore, since certain of these manufacturers are located in China, we are exposed to the possibility of product supply disruption and increased costs in the event of changes in the policies of the U.S. or Chinese governments, political unrest or unstable economic conditions in China. For example, a trade dispute between the U.S. and China could lead to tariffs on the chemical intermediates we use that are manufactured in China. Any of these matters could materially and adversely affect our business and results of operations. Any recall of the manufacturing lots or similar action regarding our product candidates used in clinical trials could delay the trials or detract from the integrity of the trial data and its potential use in future regulatory filings.

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

In order to conduct clinical trials of our product candidates, we will need to manufacture them in large quantities. Quality issues may arise during scale-up activities. Our reliance on a limited number of CDMOs, the complexity of drug manufacturing and the difficulty of scaling up a manufacturing process could cause the delay of clinical trials, regulatory submissions, required licensure, or commercialization of our product candidates, cause us to incur higher costs and prevent us from commercializing our product candidates successfully. Furthermore, if our CDMOs fail to deliver the required commercial quality and quantities of materials on a timely basis and at commercially reasonable prices, and we are unable to secure one or more replacement CDMOs capable of production in a timely manner at a substantially equivalent cost, then testing and clinical trials of that product candidate may be delayed or infeasible, and regulatory licensure or commercial launch of any resulting product may be delayed or not obtained, which could significantly harm our business.

If we are unable to obtain sufficient raw and intermediate materials on a timely basis or if we experience other manufacturing or supply difficulties, our business may be adversely affected.

The manufacture of certain of our product candidates requires the timely delivery of sufficient amounts of raw and intermediate materials. We work closely with our suppliers to ensure the continuity of supply but cannot guarantee these efforts will always be successful. Further, while efforts are made to diversify our sources of raw and intermediate materials, in certain instances we acquire raw and intermediate materials from a sole supplier. While we believe that alternative sources of supply exist where we rely on sole supplier relationships, there can be no assurance that we will be able to quickly establish additional or replacement sources for some materials. A reduction or interruption in supply, and an inability to develop alternative sources for such supply, could adversely affect our ability to manufacture our product candidates in a timely or cost-effective manner.

We expect to rely on third parties to conduct our clinical trials, and those third parties may not perform satisfactorily, including failing to meet deadlines for completing such trials.

We will rely on third-party CROs to conduct clinical trials for our biological product candidates. We currently do not plan to conduct any clinical trials independently. Agreements with these CROs might terminate for a variety of reasons, including for their failure to perform. Entry into alternative arrangements, if necessary, could significantly delay our product development activities.

Our reliance on these CROs for research and development activities will reduce our control over these activities but will not relieve us of our responsibilities. For example, we will remain responsible for ensuring that each of our clinical trials is conducted in accordance with the general investigational plan and protocols in the applicable IND. Moreover, the FDA requires compliance with standards, commonly referred to as GCPs for conducting, recording and reporting the results of clinical trials to assure that data and reported results are credible and accurate and that the rights, integrity and confidentiality of trial participants are protected.

If these CROs 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 licenses for our product candidates and will not be able to, or may be delayed in our efforts to, successfully commercialize our product candidates.

Risks Related to Our Intellectual Property

If we are unable to obtain and maintain patent protection for our product candidates, or if the scope of the patent protection obtained is not sufficiently broad, or if our patents are insufficient to protect our product candidates for an adequate amount of time, or if we are unable to obtain adequate protection for our proprietary know-how, we may not be able to compete effectively in our markets.

We rely upon a combination of patents, proprietary know-how, trade secret protection and confidentiality agreements to protect the intellectual property related to our product candidates and discovery programs. Our success depends in large part on our ability to obtain and maintain patent protection in the United States and other countries with respect to our current and any future product candidates. We seek to protect our proprietary position by, among other methods, licensing and filing patent applications in the United States and abroad related to our current and future product candidates and discovery programs. The patent prosecution process is expensive and time-consuming, and we may not be able to file and prosecute all necessary or desirable patent applications at a reasonable cost or in a timely manner. We may also rely on trade secrets, know-how and continuing technological innovation to develop and maintain our proprietary and intellectual property position.

We in-license and file patent applications directed to our product candidates in an effort to establish intellectual property positions directed to their compositions of matter as well as uses of these product candidates in the treatment of diseases. Our intellectual property includes patents and patent applications that we own, as well as patents and patent applications that we in-license. For example, our license agreements with Pfizer and Biosion grant us exclusive rights to certain patents and patent applications relating to our product candidates.

We or our licensors have not pursued or maintained, and may not pursue or maintain in the future, patent protection for our product candidates in every country or territory in which we may sell our products, if approved. In addition, we cannot be sure that any of our pending patent applications will issue or that, if issued, they have or will issue in a form that will be advantageous to us. The United States Patent and Trademark Office, or the USPTO, international patent offices or judicial bodies may deny, or significantly narrow claims made under our patent applications and our issued patents may be successfully challenged, may be designed around, or may otherwise be of insufficient scope to provide us with protection for our commercial products.

It is possible that we will fail to identify patentable aspects of our research and development output before it is too late to obtain patent protection. Moreover, patent prosecution is a lengthy process, during which the scope of the claims initially submitted for examination by the USPTO may be significantly narrowed by the time they issue, or claims may not issue at all. The claims of our issued patents or patent applications when issued may not cover our current or future product candidates, or even if such patents provide coverage, the coverage obtained may not provide any competitive advantage. The patent applications that we own, or in-license may fail to result in issued patents with claims that cover our current or any future product candidates in the United States or in other foreign countries. There is no assurance that all of the potentially relevant prior art relating to our patents and patent applications has been found, which can invalidate a patent or prevent a patent from issuing from a pending patent application. Even if patents do successfully issue and even if such patents cover our current or any future product candidates, third parties may challenge their validity, enforceability or scope, which may result in such patents being narrowed, invalidated, or held unenforceable. Any successful opposition to these patents or any other patents owned by or licensed to us could deprive us of rights necessary for the successful commercialization of any product candidates that we may develop. Further, if we encounter delays in regulatory licensure or approvals, the period of time during which we could market a product candidate under patent protection could be reduced.

If the patent applications we own or have in-licensed with respect to our product candidates and discovery programs fail to issue, if their breadth or strength of protection is threatened, or if they fail to provide meaningful exclusivity for our current or any future product candidates, it could dissuade companies from collaborating with us to develop and commercialize product candidates and future drugs and threaten our ability to commercialize future drugs. Any such outcome could have a negative effect on our business.

The patent position of biotechnology and pharmaceutical companies generally is highly uncertain, involves complex legal and factual questions and has in recent years been the subject of much litigation. In addition, the laws of foreign countries may not protect our intellectual property rights to the same extent as the laws of the United States. For example, European patent law restricts the patentability of methods of treatment of the human body more than United States law does. Furthermore, other parties may have developed or may develop technologies that may be related to, or competitive with, our technologies, and such parties may have filed, or may file, patent applications, or may have received, or may receive, patents, claiming inventions that may overlap or conflict with those claimed in our patent applications or issued patents, and that we may rely upon to establish exclusivity for our products in the market. Publications of discoveries in the scientific literature often lag behind the actual discoveries, and patent applications in the United States and other jurisdictions are typically not published until 18 months after filing, or in some cases not at all. Therefore, we cannot know with certainty whether we were the first to make the inventions claimed in our owned or licensed patents or pending patent applications, or that we were the first to file for patent protection of such inventions. As a result, the issuance, scope, validity, enforceability and commercial value of our patent rights are highly uncertain. Our pending and future patent applications may not result in patents being issued which protect our technology or drugs, in whole or in part, or which effectively prevent others from commercializing competitive technologies and drugs. Changes in either the patent laws or interpretation of the patent laws in the United States and other countries may diminish the value of our patents or narrow the scope of our patent protection.

We may be subject to a third-party submission of prior art to the USPTO, or other patent offices, in our pending patent applications. Such a submission may preclude the granting of any of our pending patent applications, or may result in patents granting with narrow claims, which could limit our ability to stop others from using or commercializing similar or identical technology and products. The issuance of a patent is not conclusive as to its inventorship, scope, validity or enforceability, and our owned and licensed patent rights may be challenged in the courts or patent offices in the United States and abroad. For example, we may become involved in opposition, derivation, reexamination, inter partes review, post-grant review, or interference proceedings challenging our patent rights or the patent rights of others. An adverse determination in any such proceeding, or in litigation, could reduce the scope of our patent claims, result in our patent rights being held invalid, in whole or in part, or unenforceable, or limit the duration of the patent protection of our technology and products, and allow third parties to commercialize our technology or products and compete directly with us without payment to us, or result in our inability to manufacture or commercialize products without infringing third-party patent rights. In addition, if the breadth or strength of protection provided by our patents and patent applications is threatened, it could dissuade companies from collaborating with us to license, develop or commercialize our current or any future product candidates.

Moreover, patents have a limited lifespan. In the United States, a patent generally expires 20 years after the earliest filing date of a non-provisional patent application. Various extensions may be available; however, the life of a patent, and the protection it affords, is limited. Without patent protection for our current or any future product candidates, we may be open to competition from generic and/or biosimilar versions of such products. Given the amount of time required for the development, testing and regulatory review of new product candidates, patents protecting such candidates might expire before or shortly after such candidates are commercialized. As a result, our owned and licensed patent rights may not provide us with sufficient rights to exclude others from commercializing drugs similar or identical to ours.

Even if our patent rights are unchallenged, our issued patents and our pending patent applications, if issued, may not provide us with any meaningful protection or prevent competitors from designing around our patent claims to circumvent our owned patent rights by developing similar or alternative technologies or products in a non-infringing manner. For example, a third-party may develop a competitive product that provides benefits similar to one or more of our product candidates, but that has a different composition that falls outside the scope of our patent protection. If the protection provided by our patent rights with respect to our product candidates is not sufficiently broad to impede such competition, or if the breadth, strength or term (including any extensions or adjustments) of protection provided by our patent rights with respect to our product candidates or any future product candidates is successfully challenged, our ability to successfully commercialize our product candidates could be negatively affected, which would harm our business. Further, if we encounter delays in our clinical trials, the period of time during which we could market our product candidates or any future product candidates under patent protection would be reduced.

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

The USPTO and various foreign governmental patent agencies require compliance with a number of procedural, documentary, fee payment and other similar provisions during the patent application process. In addition, periodic maintenance fees, renewal fees, annuity fees and various other government fees on patents and/or patent applications will have to be paid to the USPTO and various government patent agencies outside of the United States over the lifetime of our owned and licensed patents and/or applications and any patent rights we may own or license in the future. We rely on a combination of in-house employees, service providers and our licensors to pay these fees. The USPTO and various non-U.S. government patent agencies require compliance with several procedural, documentary, fee payment and other similar provisions during the patent application process. We employ a combination of in-house employees, reputable law firms and other professionals to help us comply, and we are also dependent on our licensors to take the necessary action to comply with these requirements with respect to our licensed intellectual property. 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 or our licensors fail to maintain the patents and patent applications covering our products or technologies, we may not be able to stop a competitor from marketing products that are the same as, or similar to, our product candidates, which would have a material adverse effect on our business. In many cases, an inadvertent lapse can be cured by payment of a late fee or by other means in accordance with the applicable rules. There are situations, however, in which non-compliance can result in abandonment or lapse of the patent or patent application, resulting in partial or complete loss of patent rights in the relevant jurisdiction. In such an event, potential competitors might be able to enter the market and this circumstance could harm our business.

In addition, if we fail to apply for, or are unsuccessful in our application for, applicable patent term extensions or adjustments, we will have a more limited time during which we can enforce our granted patent rights. In addition, if we are responsible for patent prosecution and maintenance of patent rights in-licensed to us, any of the foregoing could expose us to liability to the applicable patent owner.

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

Given the amount of time required for the development, testing and regulatory review of new product candidates such as PYX-201 and PYX-106, patents protecting such candidates might expire before or shortly after such candidates are commercialized. We expect to seek extensions of patent terms in the United States and, if available, in other countries where we have or will obtain patent rights. In the United States, the Drug Price Competition and Patent Term Restoration Act of 1984 permits a patent term extension of up to five years beyond the normal expiration of the patent, provided that the patent is not enforceable for more than 14 years from the date of licensure, which is limited to the approved indication (or any additional indications approved during the period of extension). However, the applicable authorities, including the FDA and the USPTO in the United States, and any equivalent regulatory authority in other countries, may not agree with our assessment of whether such extensions are available, and may refuse to grant extensions to our patents, or may grant more limited extensions than we request. If this occurs, our competitors may be able to take advantage of our investment in development and clinical trials by referencing our clinical and preclinical data and launch their drug earlier than might otherwise be the case.

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

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. The following examples are illustrative:

- others may be able to make compounds or formulations that are similar to our product candidates but that are not covered by the claims of any patents, should they issue, that we own or license;
- we or our licensors might not have been the first to make the inventions covered by the issued patents or pending patent applications that we own or license;
- we or our licensors might not have been the first to file patent applications covering certain of our inventions;
- others may independently develop similar or alternative technologies or duplicate any of our technologies without infringing our intellectual property rights;
- it is possible that our pending patent applications will not lead to issued patents;
- issued patents that we own or license may not provide us with any competitive advantages, or may be held invalid or unenforceable as a result of legal challenges;
- our competitors might conduct research and development activities in the United States and other countries that provide a safe harbor from patent infringement claims for certain research and development activities, as well as in countries where we do not have patent rights and then use the information learned from such activities to develop competitive drugs for sale in our major commercial markets;
- we may not develop additional proprietary technologies that are patentable;

•we may not be successful in enforcing our patents against potential infringers or recovering meaningful damages; and

•the patents of others may have an adverse effect on our business.

Third parties may initiate legal proceedings alleging that we are infringing their intellectual property rights, the outcome of which would be uncertain and could have a negative impact on the success of our business.

Our commercial success depends, in part, upon our ability and the ability of others with whom we may collaborate to develop, manufacture, market and sell our current and any future product candidates and use our proprietary technologies without infringing the proprietary rights and intellectual property of third parties. The biotechnology and pharmaceutical industries are characterized by extensive and complex litigation regarding patents and other intellectual property rights. We may in the future become party to, or be threatened with, adversarial proceedings or litigation regarding intellectual property rights with respect to our current and any future product candidates and technology, including interference proceedings, post grant review and inter partes review before the USPTO. In addition, there are third-party patents and, if issued as patents, patent applications, relating to: the engineering of antibodies, including with respect to CD40 and Fc domains; and methods for treating cancers, including those expressing siglec-15; that may be construed to cover our product candidates or methods of using our product candidates, including PYX-107 and PYX-106, respectively. The third parties that control these patents may allege that our product candidates, including PYX-107 and PYX-106, infringe these patents. Parties making infringement, misappropriation, or other intellectual property claims against us may obtain injunctive or other equitable relief, which could effectively block our ability to further develop and commercialize one or more of our product candidates. Defense of these claims, regardless of their merit, would involve substantial litigation expense and would be a substantial diversion of management and employee resources from our business. Third parties may assert infringement claims against us based on existing patents or patents that may be granted in the future, regardless of their merit. There is a risk that third parties may choose to engage in litigation with us to enforce or to otherwise assert their patent rights against us. Even if we believe such claims are without merit, a court of competent jurisdiction could hold that these third-party patents are valid, enforceable and infringed, which could have a negative impact on our ability to commercialize our current and any future product candidates. In order to successfully challenge the validity of any such U.S. patent in federal court, we would need to overcome a presumption of validity. As this burden is a high one requiring us to present clear and convincing evidence as to the invalidity of any such U.S. patent claim, there is no assurance that a court of competent jurisdiction would invalidate the claims of any such U.S. patent. Moreover, given the vast number of patents in our field of technology, we cannot be certain that we do not infringe existing patents or that we will not infringe patents that may be granted in the future. Other companies and research institutions have filed, and may file in the future, patent applications related to antibodies or antibody-drug conjugates and their therapeutic use. Some of these patent applications have already been allowed or issued, and others may issue in the future. While we may decide to initiate proceedings to challenge the validity of these or other patents in the future, we may be unsuccessful, and courts or patent offices in the United States and abroad could uphold the validity of any such patent. Furthermore, because patent applications can take many years to issue and may be confidential for 18 months or more after filing, and because pending patent claims can be revised before issuance, there may be applications now pending which may later result in issued patents that may be infringed by the manufacture, use or sale of our product candidates. Regardless of when filed, we may fail to identify relevant third-party patents or patent applications, or we may incorrectly conclude that a third-party patent is invalid or not infringed by our product candidates or activities. If a patent holder believes our product candidate infringes its patent, the patent holder may sue us even if we have received patent protection for our technology. Moreover, we may face patent infringement claims from non-practicing entities that have no relevant drug revenue and against whom our own patent portfolio may thus have no deterrent effect. If a patent infringement suit were threatened or brought against us, we could be forced to stop or delay research, development, manufacturing or sales of the therapeutic or product candidate that is the subject of the actual or threatened suit.

If we are found to infringe a third party's valid and enforceable intellectual property rights, we could be required to obtain a license from such third party to continue developing, manufacturing and marketing our product candidate(s) and technology. Under any such license, we would most likely be required to pay various types of fees, milestones, royalties or other amounts. Moreover, we may not be able to obtain any required license on commercially reasonable terms or at all. Our business could be harmed if in litigation the prevailing party does not offer us a license, and such a license may not be on commercially reasonable terms.

The licensing or acquisition of third-party intellectual property rights is a competitive area, and more established companies may also pursue strategies to license or acquire third-party intellectual property rights that 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. We also may be unable to license or acquire third-party intellectual property rights on terms that would allow us to make an appropriate return on our investment or at all. 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 program or product candidate(s), which could have a material adverse effect on our business, financial condition, results of operations and prospects. Furthermore, even if we were able to obtain a license, it could be non-exclusive, thereby giving our competitors and other third parties access to the same technologies licensed to us, and it could require us to make substantial licensing and royalty payments. We could be forced, including by court order, to cease developing, manufacturing and commercializing the infringing technology or product candidate. 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 or other intellectual property right. We may be required to indemnify collaborators or contractors against such claims. A finding of infringement could prevent us from manufacturing and commercializing our current or any future product candidates or force us to cease some or all of our business operations, which could materially harm our business. Even if we are successful in defending against such claims, litigation can be expensive and time consuming and would divert management's attention from our core business. Claims that we have misappropriated the confidential information or trade secrets of third parties could have a similar negative impact on our business, financial condition, results of operations and prospects.

We may be subject to claims asserting that our employees, consultants or advisors have wrongfully used or disclosed alleged trade secrets of their current or former employers or claims asserting ownership of what we regard as our own intellectual property.

Certain of our employees, consultants or advisors are currently, or were previously, employed at universities or other biotechnology or pharmaceutical companies, including our competitors or potential competitors. Although we try to ensure that our employees, consultants and advisors do not use the proprietary information or know-how of others in their work for us, we may be subject to claims that these individuals have used or disclosed intellectual property, including trade secrets or other proprietary information, of any such individual's current or former employer. Litigation may be necessary to defend against these claims. If we fail in defending any such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights or personnel. Even if we are successful in defending against such claims, litigation could result in substantial costs and be a distraction to management.

In addition, we may in the future be subject to claims by our former employees or consultants asserting an ownership right in our patents or patent applications, as a result of the work they performed on our behalf. Although 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, and we cannot be certain that our agreements with such parties will be upheld in the face of a potential challenge or that they will not be breached, for which we may not have an adequate remedy. 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.

Licensing of intellectual property is of critical importance to our business and involves complex legal, business and scientific issues. If we breach our University of Chicago, Pfizer, or Biosion license agreements or any of the other agreements under which we acquired, or will acquire, intellectual property rights covering our product candidates, we could lose the ability to continue the development and commercialization of the related product candidates(s).

The licensing of intellectual property is of critical importance to our business and to our current and future product candidates, and we expect to enter into additional such agreements in the future.

In particular, the rights to the intellectual property covering PYX-201 are in-licensed from Pfizer and the rights to the intellectual property covering our product candidate PYX-106 are in-licensed from Biosion. We may acquire the rights to the intellectual property covering future product candidates from other third-party licensors.

If we fail to meet our obligations under any of our in-license agreements, including the amended and restated license agreement with Pfizer, dated October 6, 2022, as further amended, or the Biosion License Agreement, as further amended, then the licensor may terminate the license agreement. If one of our material in-license agreements is terminated, we will lose the right to continue to develop and commercialize the product candidate(s) covered by such in-license agreement. While we would expect to exercise all rights and remedies available to us, including seeking to cure any breach by us, and otherwise seek to preserve our rights under our in-license agreements, we may not be able to do so in a timely manner, at an acceptable cost or at all.

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

Competitors may infringe or otherwise violate our patents, the patents of our licensors or our other intellectual property rights. To counter infringement or unauthorized use, we may be required to file legal claims, which can be expensive and time consuming and is likely to divert significant resources from our core business, including distracting our technical and management personnel from their normal responsibilities. In addition, in an infringement proceeding, a court may decide that a patent of ours or our licensors is not valid or is unenforceable, or may refuse to stop the other party from using the technology at issue on the grounds that our patents do not cover the technology in question. An adverse result in any litigation or defense proceedings could put one or more of our owned or licensed patents at risk of being invalidated or interpreted narrowly and could put our owned or licensed patent applications at risk of not issuing. The initiation of a claim against a third party might also cause the third party to bring counter claims against us, such as claims asserting that our patent rights are invalid or unenforceable. In patent litigation in the United States, defendant counterclaims alleging invalidity or unenforceability are commonplace. Grounds for a validity challenge could be an alleged failure to meet any of several statutory requirements, including lack of novelty, obviousness, non-enablement or lack of statutory subject matter. Grounds for an unenforceability assertion could be an allegation that someone connected with prosecution of the patent withheld relevant material information from the USPTO, or made a materially misleading statement, during prosecution. Third parties may also raise similar validity claims before the USPTO in post-grant proceedings such as ex parte reexaminations, inter partes review, or post-grant review, or oppositions or similar proceedings outside the United States, in parallel with litigation or even outside the context of litigation. The outcome following legal assertions of invalidity and unenforceability is unpredictable. We cannot be certain that there is or will be no invalidating prior art, of which we and the patent examiner were unaware during prosecution. For the patents and patent applications that we have licensed, we may have limited or no right to participate in the defense of any licensed patents against challenge by a third party. If a defendant were to prevail on a legal assertion of invalidity or unenforceability, we would lose at least part, and perhaps all, of any future patent protection on our current or future product candidates. Such a loss of patent protection could harm our business.

We may not be able to prevent, alone or with our licensors, misappropriation of our intellectual property rights, particularly in countries where the laws may not protect those rights as fully as in the United States. Any litigation or other proceedings to enforce our intellectual property rights may fail, and even if successful, may result in substantial costs and distract our management and other employees.

Furthermore, because of the substantial amount of discovery required in connection with intellectual property litigation, there is a risk that some of our confidential information could be compromised by disclosure during this type of litigation. There could also be public announcements of the results of hearings, motions or other interim proceedings or developments. If securities analysts or investors perceive these results to be negative, it could have an adverse effect on the price of our common stock.

We may not have sufficient financial or other resources to adequately conduct such litigation or proceedings. Some of our competitors may be able to sustain the costs of such litigation or proceedings more effectively than we can because of their greater financial resources and more mature and developed intellectual property portfolios. Accordingly, despite our efforts, we may not be able to prevent third parties from infringing upon or misappropriating or from successfully challenging our intellectual property rights. Uncertainties resulting from the initiation and continuation of patent litigation or other proceedings could have a material adverse effect on our ability to compete in the marketplace.

Changes in U.S. patent law or the patent law of other countries or jurisdictions could diminish the value of patents in general, thereby impairing our ability to protect our current and any future product candidates.

The United States has recently enacted and implemented wide ranging patent reform legislation. 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. In addition to increasing uncertainty with regard to our ability to obtain patents in the future, this combination of events has created uncertainty with respect to the value of patents, once obtained. Depending on actions by the U.S. Congress, the federal courts, and the USPTO, the laws and regulations governing patents could change in unpredictable ways that could weaken our ability to obtain new patents or to enforce patents that we own, have licensed or that we might obtain in the future. Similarly, changes in patent law and regulations in other countries or jurisdictions, changes in the governmental bodies that enforce them or changes in how the relevant governmental authority enforces patent laws or regulations may weaken our ability to obtain new patents or to enforce patents that we own or have licensed or that we may obtain in the future.

We may not be able to protect our intellectual property rights throughout the world, which could negatively impact our business.

Filing, prosecuting and defending patents covering our current and any future product candidates in all countries throughout the world would be prohibitively expensive. Competitors may use our technologies in jurisdictions where we or our licensors have not obtained patent protection to develop their own products and, further, may export otherwise infringing products to territories where we may obtain patent protection but where patent enforcement is not as strong as that in the United States. These products may compete with our products in jurisdictions where we do not have any issued or licensed patents and any future patent claims, or other intellectual property rights may not be effective or sufficient to prevent them from so competing.

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

In addition to seeking patent and trademark protection for our product candidates, we may also rely on trade secrets, including unpatented know-how, technology and other proprietary information, to maintain our competitive position. We seek to protect our trade secrets, in part, by entering into non-disclosure and confidentiality agreements with parties who have access to them, such as our employees, corporate collaborators, outside scientific collaborators, contract manufacturers, consultants, advisors and other third parties. We also enter into confidentiality and invention or patent assignment agreements with our employees, advisors and consultants. Despite these efforts, any of these parties may breach the agreements and disclose our proprietary information, including our trade secrets. Monitoring unauthorized uses and disclosures of our intellectual property is difficult, and we do not know whether the steps we have taken to protect our intellectual property will be effective. In addition, we may not be able to obtain adequate remedies for any such breaches. Enforcing a claim that a party illegally disclosed or misappropriated a trade secret is difficult, expensive and time-consuming, and the outcome is unpredictable. In addition, some courts inside and outside the United States are less willing or unwilling to protect trade secrets.

Moreover, our competitors may independently develop knowledge, methods and know-how equivalent to our trade secrets. Competitors could purchase our products and replicate some or all of the competitive advantages we derive from our development efforts for technologies on which we do not have patent protection. If any of our trade secrets were to be lawfully obtained or independently developed by a competitor, we would have no right to prevent them, or those to whom they communicate it, from using that technology or information to compete with us. If any of our trade secrets were to be disclosed to or independently developed by a competitor, our competitive position would be harmed.

We also seek to preserve the integrity and confidentiality of our data and other confidential information by maintaining physical security of our premises and physical and electronic security of our information technology systems. While we have confidence in these individuals, organizations and systems, agreements or security measures may be breached and detecting the disclosure or misappropriation of confidential information and enforcing a claim that a party illegally disclosed or misappropriated confidential information is difficult, expensive and time-consuming, and the outcome is unpredictable. Further, we may not be able to obtain adequate remedies for any breach. In addition, our confidential information may otherwise become known or be independently discovered by competitors, in which case we would have no right to prevent them, or those to whom they communicate it, from using that technology or information to compete with us.

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.

Since we rely on third parties to help us discover, develop, manufacture or commercialize our current and any future product candidates, or if we collaborate with third parties for the development, manufacturing or commercialization of our current or any future product candidates, we must, at times, share trade secrets with them. We may also conduct joint research and development programs that may require us to share trade secrets under the terms of our research and development partnerships or similar agreements. 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 discovery of our trade secrets or other unauthorized use or disclosure could have an adverse effect on our business and results of operations.

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. Despite our efforts to protect our trade secrets, we may not be able to prevent the unauthorized disclosure or use of our technical know-how or other trade secrets by the parties to these agreements. Moreover, we cannot guarantee that we have entered into such agreements with each party that may have or have had access to our confidential information or proprietary technology and processes. Monitoring unauthorized uses and disclosures is difficult, and we do not know whether the steps we have taken to protect our proprietary technologies will be effective. If any of the collaborators, scientific advisors, employees, contractors and consultants who are parties to these agreements breaches or violates the terms of any of these agreements, we may not have adequate remedies for any such breach or violation, and we could lose our trade secrets as a result. Moreover, if confidential information that is licensed or disclosed to us by our partners, collaborators, or others is inadvertently disclosed or subject to a breach or violation, we may be exposed to liability to the owner of that confidential information. Enforcing a claim that a third-party illegally or unlawfully obtained and is using our trade secrets, like patent litigation, is expensive and time consuming, and the outcome is unpredictable. In addition, courts outside the United States are sometimes less willing to protect trade secrets.

Any trademarks we may obtain may be infringed or successfully challenged, resulting in harm to our business.

We expect to rely on trademarks as one means to distinguish any of our product candidates that are approved for marketing from the products of our competitors. We have not yet selected trademarks for our product candidates and have not yet begun the process of applying to register trademarks for our current or any future product candidate. Once we select trademarks and apply to register them, our trademark applications may not be approved. Third parties may oppose our trademark applications or otherwise challenge our use of the trademarks. In the event that our trademarks are successfully challenged, we could be forced to rebrand our products, which could result in loss of brand recognition and could require us to devote resources to advertising and marketing new brands. Our competitors may infringe our trademarks, and we may not have adequate resources to enforce our trademarks.

In addition, any proprietary name we propose to use with our current or any other 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. The FDA typically conducts a review of proposed product names, including an evaluation of the potential for confusion with other product names. If the FDA objects to any of our proposed proprietary product names, we may be required to expend significant additional resources in an effort to identify a suitable proprietary product name that would qualify under applicable trademark laws, not infringe the existing rights of third parties and be acceptable to the FDA.

Risks Related to Our Common Stock

Our operating results may fluctuate significantly or may fall below the expectations of investors or securities analysts, each of which may cause our stock price to fluctuate or decline.

We expect our operating results may be subject to annual and quarterly fluctuations. Our net loss and other operating results may be affected by numerous factors, including:

- results of preclinical studies, IND submissions, clinical trials, or the addition or termination of clinical trials or funding support by us, or existing or future collaborators or licensing partners;
- variations in the level of expense related to the ongoing development of the FACT Platform, the APXiMAB Platform, our product candidates or future development programs;
- our execution of any additional collaboration, licensing or similar arrangements, and the timing of payments we may make or receive under existing or future arrangements or the termination or modification of any such existing or future arrangements;
- any intellectual property infringement lawsuit or opposition, interference or cancellation proceeding in which we may become involved;
- additions and departures of key personnel;
- strategic decisions by us or our competitors, such as acquisitions, divestitures, spin-offs, joint ventures, strategic investments or changes in business strategy;
- if any of our product candidates receive regulatory licensure, the terms of such licensure and market acceptance and demand for such product candidates;
- regulatory developments affecting our product candidates or those of our competitors; and
- changes in general market and economic conditions.

If our operating results fall below the expectations of investors or securities analysts, the price of our common stock could decline substantially. Furthermore, any fluctuations in our operating results may, in turn, cause the price of our stock to fluctuate substantially.

Our stock price is volatile, and you could lose all or part of your investment.

Our stock price is highly volatile. As a result of this volatility, investors may not be able to sell their common stock at or above the price they purchased their common stock. The market price for our common stock may be influenced by many factors, including the other risks described in this section of the Annual Report on Form 10-K titled “Risk Factors” as well as and the following:

- results of our preclinical studies, IND submissions and clinical trials, if any, of our product candidates, or those of our competitors or our existing or future collaborators;
- regulatory or legal developments in the U.S. and other countries, especially changes in laws or regulations applicable to our products;
- the success of competitive products or technologies;
- introductions and announcements of new products by us, our future commercialization partners, or our competitors, and the timing of these introductions or announcements;

•actions taken by regulatory agencies with respect to our products, our product candidates, preclinical studies, clinical trials, manufacturing process or sales and marketing terms;

•actual or anticipated variations in our financial results or those of companies that are perceived to be similar to us;

•the success of our efforts to acquire or in-license additional technologies, products or product candidates;

•developments concerning any future collaborations, including but not limited to those with our sources of manufacturing supply and our commercialization partners;

•market conditions in the pharmaceutical and biotechnology sectors;

•announcements by us or our competitors of significant acquisitions, strategic collaborations, joint ventures or capital commitments;

•developments or disputes concerning patents or other proprietary rights, including patents, litigation matters and our ability to obtain patent protection for our products;

•our ability or inability to raise additional capital and the terms on which we raise it;

•the recruitment or departure of key personnel;

•changes in the structure of healthcare payment systems;

•actual or anticipated changes in earnings estimates or changes in stock market analyst recommendations regarding our common stock, other comparable companies or our industry generally;

•our failure or the failure of our competitors to meet analysts' projections or guidance that we or our competitors may give to the market;

•fluctuations in the valuation of companies perceived by investors to be comparable to us;

•announcement and expectation of additional financing efforts;

•speculation in the press or investment community;

•trading volume of our common stock;

•sales of our common stock by us, our insiders or our other stockholders;

•the concentrated ownership of our common stock;

•changes in accounting principles;

•terrorist acts, acts of war or periods of widespread civil unrest;

•the impact of any natural disasters or public health emergencies and other calamities; and

•general economic, industry and market conditions.

In addition, the stock markets in general, and the markets for pharmaceutical, biopharmaceutical and biotechnology stocks in particular, have experienced extreme volatility that has been often unrelated to the operating performance of the issuer. These broad market and industry factors may seriously harm the market price of our common stock, regardless of our operating performance.

The future issuance of equity or of debt securities that are convertible into equity will dilute our share capital.

We will need to raise additional capital in the future. To the extent we raise additional capital through the issuance of equity or convertible debt securities in the future, there will be dilution to our existing investors and the terms of these securities may include liquidation or other preferences that adversely affect our stockholders' rights. Future issuances of our common stock or other equity securities, or the perception that such sales may occur, could adversely affect the trading price of our common stock and impair our ability to raise capital through future offerings of shares or equity securities. We may choose to raise additional capital through the issuance of equity or convertible debt securities due to market conditions or strategic considerations even if we believe we have sufficient funds for our current or future operating plans. No prediction can be made as to the effect, if any, that future sales of common stock or the availability of common stock for future sales will have on the trading price of our common stock.

If securities or industry analysts do not publish research or reports about our business, or if they issue adverse or misleading research or reports regarding us, our business or our market, our stock price and trading volume could decline.

The trading market for our common stock is influenced by the research and reports that industry or securities analysts publish about us, our business or our market. If no or few securities or industry analysts commence or maintain coverage of us, the trading price for our stock would be negatively impacted. If any of the analysts who cover us issue adverse or misleading research or reports regarding us, our business model, our intellectual property, our product candidates, our stock performance or our market, or if our operating results fail to meet the expectations of analysts, our stock price would likely decline. If one or more of these analysts cease coverage of us or fail to publish reports on us regularly, we could lose visibility in the financial markets, which in turn could cause our stock price or trading volume to decline.

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 and their interests may conflict with your interests as an owner of our common stock.

As of March 20, 2024, our executive officers and directors, together with holders of five percent or more of our outstanding common stock and their respective affiliates, beneficially own approximately 44.7% of our outstanding common stock. As a result, these stockholders, if acting together, have significant influence over the outcome of corporate actions requiring stockholder approval, including the election of directors, any merger, consolidation or sale of all or substantially all of our assets and any other significant corporate transaction. The interests of these stockholders may not be the same as or may even conflict with interests of our other stockholders. For example, these stockholders could delay or prevent a change of control of our company, even if such a change of control would benefit our other stockholders, which could deprive our stockholders of an opportunity to receive a premium for their common stock as part of a sale of our company or our assets and might affect the prevailing market price of our common stock. The significant concentration of stock ownership may adversely affect the trading price of our common stock due to investors' perception that conflicts of interest may exist or arise.

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

Our common stock price could decline as a result of sales of a large number of shares of common stock or the perception that these sales could occur. These sales, or the possibility that these sales may occur, might also make it more difficult for us to sell equity securities in the future at a time and price that we deem appropriate.

Shares issued upon the exercise of stock options and warrants outstanding under our equity incentive plans or pursuant to future awards granted under those plans will become available for sale in the public market to the extent permitted by the provisions of applicable vesting schedules, market stand-off agreements and/or lock-up agreements, as well as Rules 144 and 701 under the Securities Act.

We are an "emerging growth company" and a "smaller reporting company," and the reduced disclosure requirements applicable to emerging growth companies and smaller reporting companies may make our common stock less attractive to investors.

We are an "emerging growth company," as defined in the JOBS Act. We will remain an emerging growth company until the earlier of (i) the last day of the fiscal year (a) following the fifth anniversary of the completion of our initial public offering, or IPO, (b) in which we have total annual gross revenue of at least $1.235 billion or (c) in which we are deemed to be a large accelerated filer, which means the market value of our common stock that is held by non-affiliates exceeded $700 million as of the prior June 30th and (ii) the date on which we have issued more than $1.0 billion in non-convertible debt during the prior three-year period.

An emerging growth company may take advantage of specified reduced reporting requirements and other burdens that are otherwise applicable generally to public companies. These provisions include:

- being permitted to present only two years of audited financial statements and only two years of related management's discussion and analysis of financial condition and results of operations in this Annual Report on Form 10-K;
- not being required to comply with the auditor attestation requirements of Section 404 of the Sarbanes-Oxley Act of 2002, or the Sarbanes-Oxley Act;
- an exemption from compliance with any new requirements adopted by the Public Company Accounting Oversight Board regarding mandatory audit firm rotations;
- reduced disclosure obligations regarding executive compensation in our periodic reports, proxy statements and registration statements; and
- exemptions from the requirement to hold a nonbinding advisory vote on executive compensation and to obtain stockholder approval of any golden parachute payments not previously approved.

We have elected to take advantage of certain reduced disclosure obligations and may elect to take advantage of other reduced reporting requirements in future filings. As a result, the information that we provide to our investors may be different from the information you might receive from other public reporting companies that are not emerging growth companies in which you hold equity interests. The JOBS Act provides that an emerging growth company can take advantage of an extended transition period for complying with new or revised accounting standards applicable to public companies until those standards would otherwise apply to private companies. We have irrevocably elected not to avail ourself of this extended transition period, and, as a result, we will adopt new or revised accounting standards on the relevant dates on which adoption of such standards is required for other public companies.

We are also a “smaller reporting company,” and will continue to be a smaller reporting company as long as (i) the market value of our shares held by non-affiliates is less than $250 million or (ii) our annual revenue was less than $100 million during the most recently completed fiscal year and the market value of our shares held by non-affiliates is less than $700 million. If we are a smaller reporting company at the time, we cease to be an emerging growth company, we may continue to rely on exemptions from certain disclosure requirements that are available to smaller reporting companies. Specifically, as a smaller reporting company, we may choose to present only the two most recent fiscal years of audited financial statements in our Annual Report on Form 10-K and have reduced disclosure obligations regarding executive compensation, and, similar to emerging growth companies, if we are a smaller reporting company with less than $100 million in annual revenue, we would not be required to obtain an attestation report on internal control over financial reporting issued by our independent registered public accounting firm.

Anti-takeover provisions in our charter documents and under Delaware law would make an acquisition of us, which may be beneficial to our stockholders, more difficult and may prevent attempts by our stockholders to replace or remove our current management.

Provisions in the amended and restated certificate of incorporation and our amended and restated bylaws may delay or prevent an acquisition of us or a change in our management. In addition, these provisions may frustrate or prevent any attempts by our stockholders to replace or remove our current management by making it more difficult for stockholders to replace members of our board of directors. Because our board of directors is responsible for appointing the members of our management team, these provisions could in turn affect any attempt by our stockholders to replace current members of our management team. These provisions include:

- a prohibition on actions by our stockholders by written consent;
- a requirement that special meetings of stockholders be called only by the chairman of our board of directors, our chief executive officer, or our board of directors pursuant to a resolution adopted by a majority of the total number of authorized directors;
- advance notice requirements for election to our board of directors and for proposing matters that can be acted upon at stockholder meetings;
- a requirement that directors may only be removed “for cause” and only with 66 2/3% voting stock of our stockholders;
- a requirement that only the board of directors may change the number of directors and fill vacancies on the board;
- division of our board of directors into three classes, serving staggered terms of three years each; and
- the authority of the board of directors to issue preferred stock with such terms as the board of directors may determine.

Moreover, because we are incorporated in Delaware, we are governed by the provisions of Section 203 of the Delaware General Corporation Law, as amended, which prohibits a person who owns in excess of 15% of our outstanding voting stock from merging or combining with us for a period of three years after the date of the transaction in which the person acquired in excess of 15% of our outstanding voting stock, unless the merger or combination is approved in a prescribed manner. These provisions would apply even if the proposed merger or acquisition could be considered beneficial by some stockholders.

We have incurred and will continue to incur increased costs as a result of operating as a public company, and our management has and will be required to devote substantial time to new compliance initiatives and corporate governance practices. Additionally, if we fail to maintain proper and effective internal controls, our ability to produce accurate financial statements on a timely basis could be impaired.

As a public company, we have incurred and, particularly after we are no longer an emerging growth company or a smaller reporting company, we will continue to incur significant legal, accounting and other expenses that we did not incur as a private company. The Sarbanes-Oxley Act, the Dodd-Frank Wall Street Reform and Consumer Protection Act, the listing requirements of Nasdaq and other applicable securities rules and regulations impose various requirements on public companies, including establishment and maintenance of effective disclosure and financial controls and corporate governance practices. Also, the Exchange Act requires, among other things, that we file annual, quarterly and current reports with respect to our business and operating results. Our management and other personnel devote a substantial amount of time to these compliance initiatives. Moreover, these rules and regulations have increased and will continue to increase our legal and financial compliance costs and will make some activities more time-consuming and costly. For example, these rules and regulations may make it more difficult and more expensive for us to obtain director and officer liability insurance, and we may be required to accept reduced policy limits and coverage or to incur substantial costs to maintain the same or similar coverage. These rules and regulations could also make it more difficult for us to attract and retain qualified members of our board of directors or our board committees or as executive officers. These rules and regulations are also often subject to varying interpretations, in many cases due to their lack of specificity, and, as a result, their application in practice may evolve over time as new guidance is provided by regulatory and governing bodies. This could result in continuing uncertainty regarding compliance matters and higher costs necessitated by ongoing revisions to disclosure and governance practices.

In addition, as a public company, we incur additional costs and obligations in order to comply with SEC rules that implement Section 404 of the Sarbanes-Oxley Act. Under these rules, we are required to make a formal assessment of the effectiveness of our internal control over financial reporting, and once we cease to be an emerging growth company or a smaller reporting company, we will be required to include an attestation report on internal control over financial reporting issued by our independent registered public accounting firm. To achieve compliance with Section 404 within the prescribed period, we are engaged in a process to document and evaluate our internal control over financial reporting, which is both costly and challenging. In this regard, we will need to continue to dedicate internal resources, potentially engage outside consultants and adopt a detailed work plan to assess and document the adequacy of our internal control over financial reporting, continue steps to improve control processes as appropriate, validate through testing that controls are designed and operating effectively, and implement a continuous reporting and improvement process for internal control over financial reporting.

The rules governing the standards that must be met for management to assess our internal control over financial reporting are complex and require significant documentation, testing and possible remediation to meet the detailed standards under the rules. During the course of its testing, our management may identify material weaknesses or deficiencies which may not be remedied in time to meet the deadline imposed by the Sarbanes-Oxley Act. Our internal control over financial reporting will not prevent or detect all errors and all fraud.

If we are not able to comply with the requirements of Section 404 of the Sarbanes-Oxley Act in a timely manner, or if we are unable to maintain proper and effective internal controls, we may not be able to produce timely and accurate financial statements. If that were to happen, the market price of our stock could decline and we could be subject to sanctions or investigations by the stock exchange on which our common stock is listed, the SEC or other regulatory authorities. In addition, if we are not able to continue to meet these requirements, we may not be able to remain listed on Nasdaq.

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 facts that judgments in decision-making can be faulty and that breakdowns can occur because of simple error or mistake. Additionally, controls can be circumvented by the individual acts of some persons, by collusion of two or more people or by an unauthorized override of the controls. Accordingly, because of the inherent limitations in our control system, misstatements due to error or fraud may occur and not be detected.

Because we do not anticipate paying any cash dividends on our capital stock in the foreseeable future, your ability to achieve a return on your investment will depend on appreciation of the value of our common stock.

We have never declared or paid cash dividends on our capital stock. We currently intend to retain all of our future earnings, if any, to finance the growth and development of our business and do not anticipate declaring or paying any cash dividends for the foreseeable future. Any return to stockholders will therefore be limited to any appreciation in the value of our common stock, which is not certain.

We may be subject to securities litigation, which is expensive and could divert our management's attention.

In the past, companies that have experienced volatility in the market price of their securities have been subject to securities class action litigation. We may be the target of this type of litigation in the future. In addition, securities class action lawsuits and derivative lawsuits are often brought against public companies that have entered into merger agreements. Even if the lawsuits are without merit, defending against these claims could result in substantial costs and divert management time and resources. We may be a target for securities and shareholder lawsuits in the future. Regardless of the merits or the ultimate results of such litigation, securities litigation brought against us could result in substantial costs and divert our management's attention from other business concerns.

Our certificate of incorporation and bylaws designate the Court of Chancery of the State of Delaware as the sole and exclusive forum for certain types of actions and proceedings that may be initiated by our stockholders, which could limit our stockholders' ability to obtain a favorable judicial forum for disputes with us or our directors, officers or employees.

Our amended and restated certificate of incorporation provides that, unless we consent in writing to the selection of an alternative forum, the Court of Chancery of the State of Delaware (or, if the Court of Chancery of the State of Delaware does not have jurisdiction, another state court located within the State of Delaware, or the federal district court for the District of Delaware) shall be the sole and exclusive forum for the following types of proceedings: (1) any derivative action or proceeding brought on our behalf under Delaware law, (2) any action asserting a claim of breach of a fiduciary duty owed by any of our directors, officers or other employees to us or our stockholders, (3) any action arising pursuant to any provision of the Delaware General Corporation Law or our amended and restated certificate of incorporation or bylaws, (4) any other action asserting a claim that is governed by the internal affairs doctrine or (5) any other action asserting an "internal corporate claim," as defined in Section 115 of the Delaware General Corporation Law. This provision would not apply to suits brought to enforce a duty or liability created by the Securities Act, the Exchange Act or any other claim for which the U.S. federal courts have exclusive jurisdiction. 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. Our amended and restated bylaws further provide that the federal district courts of the United States of America will be the exclusive forum to the fullest extent permitted by law, for resolving any complaint asserting a cause of action arising under the Securities Act or the Exchange Act. This choice of forum provision may limit a stockholder's ability to bring a claim in a judicial forum that it finds favorable for disputes with us or our directors, officers or other employees, which may discourage such lawsuits against us and our directors, officers and employees. Alternatively, if a court were to find these provisions of our amended and restated certificate of incorporation and amended and restated bylaws inapplicable to, or unenforceable in respect of, one or more of the specified types of actions or proceedings, we may incur additional costs associated with resolving such matters in other jurisdictions, which could adversely affect our business and financial condition. Any person or entity purchasing or otherwise acquiring any interest in shares of our capital stock shall be deemed to have notice of and to have consented to the provisions of our amended and restated certificate of incorporation and amended and restated bylaws described above.

Our ability to use net operating loss carryforwards and other tax attributes may be subject to limitations.

We have incurred substantial losses during our history, do not expect to become profitable in the near future and may never achieve profitability. To the extent that we continue to generate taxable losses, unused losses will carry forward to offset future taxable income, if any, subject to certain limitations (including the limitations described below) until such unused losses expire (if at all). As of December 31, 2023, our federal and state net operating losses in the United States were $56.4 million ($268.5 million before tax) and $11.2 million ($167.4 million before tax) respectively. The federal net operating loss carryforwards in the United States can be carried forward indefinitely but may be subject to annual usage limitations to the extent certain substantial changes our ownership occur. The federal net operating loss carryforward relating to tax years prior to 2017 of $5.9 million ($28.3 million before tax), acquired with Apexigen, begin to expire in 2033. The state net operating loss carryforwards begin expiring in 2035. In addition, as of December 31, 2023, the Company had $7.8 million and $3.6 million of federal and state credit carryovers which begin to expire in 2030. These loss and credit carryforwards are subject to review and possible adjustment by the relevant taxing authorities.

Our NOL and credit carryforwards are subject to review and possible adjustment by the IRS, and state tax authorities. Under Section 382 of the Internal Revenue Code of 1986, as amended, or the Code, our federal NOL and credit carryforwards may become subject to an annual limitation in the event of certain cumulative changes in the ownership of our company. An "ownership change" pursuant to Section 382 of the Code generally occurs if one or more stockholders or groups of stockholders who own at least 5% of a company's stock increase their ownership by more than 50 percentage points over their lowest ownership percentage within a rolling three-year period. Our ability to utilize our NOL carryforwards and other tax attributes to offset future taxable income or tax liabilities may be limited as a result of ownership changes, including potential changes in connection with our IPO. Similar rules may apply under state tax laws. We have not yet determined the amount of the cumulative change in our ownership resulting from our IPO or other transactions, or any resulting limitations on our ability to utilize our NOL carryforwards and other tax attributes. In addition, we may experience ownership changes in the future due to subsequent shifts in our stock, some of which are outside of our control. If we earn taxable income, such limitations could result in increased future income tax liability to us, and our future cash flows could be adversely affected. We have recorded a full valuation allowance related to our NOL carryforwards and other deferred tax assets due to the uncertainty of the ultimate realization of the future benefits of those assets.

Item 1B. Unresolved Staff Comments.

None.

Item 1C. Cybersecurity

Risk Management and Strategy

We take a risk-based approach in implementing and maintaining 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 information related to our clinical trials, products in development, and proprietary technologies ("IT Systems and Data").

Our information security function, supported by members of our IT department and our third-party IT service providers, helps identify, assess and manage our cybersecurity threats and risks. This team helps to identify and assess risks from cybersecurity threats by monitoring and evaluating our threat environment using various methods including, for example: automated tools, subscribing to reports and services that identify cybersecurity threats and analyzing such reports of threats and actors, conducting scans of our threat environment, evaluating threats reported to us, conducting vulnerability assessments, and working with third parties to conduct certain tests of our environment.

Depending on the environment and systems, 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 IT Systems and Data, including, for example: incident detection and response procedures; an incident response policy; a disaster recovery plan; conducting risk assessments; maintaining network security controls, encrypting certain of our data; maintaining access and physical security controls; systems monitoring; assessing vendor risk; employee training; and maintaining cybersecurity insurance.

The cybersecurity risk management and mitigation measures we implement for certain of our IT Systems and Data including for example (1) cybersecurity risk is addressed as a component of our enterprise risk management assessment processes; (2) the information security function works with senior management 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 to the Audit Committee of the Board, which evaluates our overall enterprise risk, (4) policies and procedures to manage how Information Systems and Data are collected, maintained and stored, (5) communicating with and training personnel on cybersecurity risks and trends.

We use third-party service providers to assist us from time to time to identify, assess, and manage material risks from cybersecurity threats.

For a description of the risks from cybersecurity threats that may materially affect us and how they may do so, see our risk factors under Part I. Item 1A. Risk Factors in this Annual Report on Form 10-K, including *"Our internal computer systems, or those of any of our existing or future CROs, manufacturers, other contractors, consultants, or collaborators, may fail or suffer security or data privacy breaches or other unauthorized or improper access to, use of or destruction of our proprietary and confidential data, employee data or personal data, which could result in additional costs, significant liabilities, harm to our reputation and material disruption of our operations."*

Governance

Our Board of Directors, or Board, addresses our cybersecurity risk management as part of its general oversight function. The Audit Committee of the Board is responsible for overseeing our cybersecurity risk management processes, including oversight and mitigation of risks from cybersecurity threats. The Audit Committee receive scheduled updates from senior management. The Audit Committee also receives various reports, summaries or presentations related to cybersecurity threats, risk and mitigation.

Our Chief Financial Officer, or CFO, is primarily responsible for assessing and managing cybersecurity risks across the company based on the assessments by our Senior Director of IT and third-party IT specialists. Additionally, our cybersecurity risk assessment and management processes are implemented and maintained by our Senior Director of IT with assistance from third-party IT specialists. Our CFO has extensive experience managing risks at our company and at similar companies in the past, including risks arising from cybersecurity threats. Our Senior Director of IT has over 25 years of experience in IT security, and data analytics.

Our CFO is responsible for approving budgets and our Senior Director of IT is responsible for preparing for cybersecurity incidents, approving cybersecurity processes, and conducting regular reviews of security assessments and other security-related reports.

Our cybersecurity incident response is designed to escalate certain cybersecurity incidents to members of management. In addition, our cybersecurity incident response and vulnerability management policies and procedures include reporting to the Audit Committee of the Board for certain cybersecurity incidents.

Item 2. Properties.

Our headquarters are located at 321 Harrison Avenue, Boston, MA 02118, where we lease approximately 31,659 rentable square feet of office and laboratory space under a lease that terminates on December 31, 2032, with an additional five-year option to extend the lease beyond December 31, 2032. We also entered into a sublease for 17,729 square feet of this office and laboratory space commencing on March 24, 2023. The sublease agreement will continue through March 31, 2026, with an option for the sublessee to extend the sublease for a one-year period. We continue to be responsible for performance under this lease until it expires on December 31, 2032.

We believe that our existing facilities are adequate to meet our current needs, and that suitable additional alternative spaces will be available in the future on commercially reasonable terms.

Item 3. Legal Proceedings.

From time to time, we may become involved in legal proceedings arising in the ordinary course of our business. As of the date of this Annual Report on Form 10-K, we were not a party to any material legal matters or claims and we are not aware of any pending or threatened legal proceeding against us that we believe could have a material adverse effect on our business, operating results or financial condition.

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 is trading on The Nasdaq Global Select Market under the symbol "PYXS".

Holders of Our Common Stock

Broadridge Corporate Issuer Solutions, Inc is our transfer agent and registrar for our common stock. As of the close of business on March 20, 2024, there were approximately 62 holders of record of shares of our common stock. These numbers were derived from our stockholder records and do not include beneficial owners of our common stock whose shares are held in "street" name with various dealers, clearing agencies, banks, brokers and other fiduciaries.

Dividends

We have never declared or paid cash dividends on our capital stock. We currently intend to retain all available funds and future earnings, if any, for use in the operation of our business and do not anticipate paying any cash dividends on our common stock in the foreseeable future. Any future determination to declare and pay dividends will be made at the discretion of our board of directors and will depend on various factors, including applicable laws, our results of operations, our financial condition, our capital requirements, general business conditions, our future prospects and other factors that our board of directors may deem relevant. Our ability to pay cash dividends on our capital stock in the future may also be limited by the terms of any preferred securities we may issue or agreements governing any additional indebtedness we may incur.

Recent Sales of Unregistered Equity Securities

On February 26, 2024, we entered into a securities purchase agreement, or the Securities Purchase Agreement, for a private placement, or the Private Placement, with certain institutional and accredited investors, each, a Purchaser and collectively, the Purchasers.

Pursuant to the Securities Purchase Agreement, we agreed to issue and sell to the Purchasers an aggregate of (i) 8,849,371 shares, or the Shares, of our common stock, par value $0.001 per share, or the Common Stock, at a purchase price of $4.78 per share, and (ii) pre-funded warrants, or the Pre-Funded Warrants, to purchase up to an aggregate of 1,611,215 shares of Common Stock at a purchase price of $4.779 per Pre-Funded Warrant, which represents the per share purchase price of the Shares less the $0.001 per share exercise price for each Pre-Funded Warrant. The Pre-Funded Warrants will be exercisable at any time after the date of issuance and will not expire.

Leerink Partners LLC acted as the lead placement agent and LifeSci Capital LLC acted as co-placement agent for the Private Placement. We have agreed to pay customary placement fees and reimburse certain expenses of the placement agents.

The Private Placement closed on February 29, 2024. We received aggregate gross proceeds from the Private Placement of approximately $50 million, before deducting placement agent fees and offering expenses. We intend to use the net proceeds from this proposed financing for working capital and general corporate purposes.

The shares of Common Stock issued in connection with the Private Placement were not registered under the Securities Act, in reliance upon the exemption provided in Section 4(a)(2) of the Securities Act.

On February 26, 2024, we also entered into a registration rights agreement, or the Registration Rights Agreement, with the Purchasers, which we agreed to register for the resale of the Shares and Pre-Funded Warrants, together, the Registrable Securities. Under the Registration Rights Agreement, we agreed to prepare and file a registration statement with the SEC, no later than March 27, 2024, or the Filing Deadline. We also agreed to use reasonable efforts to cause such registration statement to become effective as soon as practicable, but in any event no later than the fifth calendar day following the filing of the registration statement (or, in the event of a "review" by the SEC, the 75th day, following such filing date).

Under the terms of the Registration Rights Agreement, we also agreed to be responsible for all fees and expenses incurred in connection with the registration of the Registrable Securities. In addition, certain liquidated damages provisions will apply to the Company in the event of registration failures, as described in the Registration Rights Agreement. We have granted the Purchasers customary indemnification rights in connection with the registration statement. The Purchasers have also granted the Company customary indemnification rights in connection with the registration statement.

Use of Proceeds from Initial Public Offering

Our initial public offering of common stock, or the IPO, was effected through a Registration Statement on Form S-1 (File No. 333-259627) that was declared effective by the SEC on October 7, 2021. We issued and sold in aggregate 10,500,000 shares of common stock, at a public offering price of $16.00 per share, for net proceeds of $152.3 million after deducting underwriting discounts, commissions and other offering costs of $15.7 million. BofA Securities, Inc., Jefferies LLC, Credit Suisse Securities (USA) LLC, William Blair & Company, L.L.C. and LifeSci Capital LLC acted as underwriters for the offering. None of the underwriting discounts and commissions or offering expenses were incurred or paid to directors or officers of ours or their associates or to persons owning 10% or more of our common stock or to any of our affiliates. We have invested the net proceeds from the IPO in a money market fund.

Our planned use of the net proceeds from the IPO as described in our final prospectus filed with the SEC on October 8, 2021 has changed due to the re-prioritization of our pipeline contemplated in connection with our reorganization. As a result, we currently expect to use our cash and cash equivalents, which include the net proceeds from our IPO, to advance the clinical development of PYX-201 and PYX-106, as well as for general corporate purposes.

Securities authorized for issuance under equity incentive plans

Refer to “Item 12. Security ownership of certain beneficial owners and management and related stockholder matters” in this Annual Report on Form 10-K for information on securities authorized for issuance under equity compensation plans.

Issuer Purchases of Equity Securities

None.

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 of our financial condition and results of operations together with our audited consolidated financial statements and related notes thereto included elsewhere in this Annual Report on Form 10-K. Unless the context requires otherwise, references in this Annual Report on Form 10-K to "Pyxis Oncology," the "Company," "we," "us," and "our" refer to Pyxis Oncology, Inc. and its subsidiaries.

Overview

We are a clinical stage company focused on defeating difficult-to-treat cancers. We are efficiently building next generation therapeutics that hold the potential for mono and combination therapies. We develop our product candidates with the objective to kill tumor cells, and to address the underlying pathologies created by cancer that enable its uncontrollable proliferation and immune evasion. Since our launch in 2019, we have developed a broad portfolio that includes antibody-drug conjugates, or ADC, product candidates, and immuno-oncology, or IO, product candidates. Our ADC and IO programs employ novel and emerging strategies to target a broad range of solid tumors resistant to current standards of care.

Our pipeline is balanced across programs with an emphasis on solid tumors. We in-licensed two ADC programs in March 2021 from Pfizer and one IO program from Biosion in March 2022. Additionally, upon the acquisition of Apexigen Inc., or Apexigen, in August 2023, we added another IO program to our pipeline. We have additional preclinical monoclonal antibody, or mAb, discovery programs derived from the work at the laboratory of Dr. Thomas Gajewski. We retain full worldwide development and commercialization rights to all our product candidates, with the exception of PYX-106 in Greater China (mainland China, Hong Kong, Macau and Taiwan).

Our clinical development pipeline focused on multiple difficult-to-treat tumors is displayed below:

Our Clinical Program Portfolio

PYX-201

Our lead ADC product candidate is PYX-201, an investigational, novel ADC consisting of human Immunoglobulin G1, or IgG1, site-specifically conjugated with a next generation auristatin derivative via proteases-cleavable linker. PYX-201 is an ADC that uniquely targets Extradomain-B Fibronectin, or EDB+FN, in the tumor stroma. EDB+FN regulates blood vessel morphogenesis, which provides the tumor access to nutrition and oxygen, a means to remove waste, and a pathway for metastasizing cells.

We believe EDB+FN within the tumor stroma may be an ideal target to address in many cancers with high unmet need. The stroma plays a major role in the initiation, growth, survival, invasion and drug-resistance of solid tumors, yet few therapeutics specifically target tumor-associated stroma. By targeting EDB+FN and specifically attacking the stroma, our goal is to destabilize the barrier that protects, feeds and provides structure to the tumor in addition to killing tumor cells directly. EDB+FN is overexpressed in many malignancies and is minimally expressed in most normal adult tissues, making it a potentially attractive means to target tumors while sparing healthy cells.

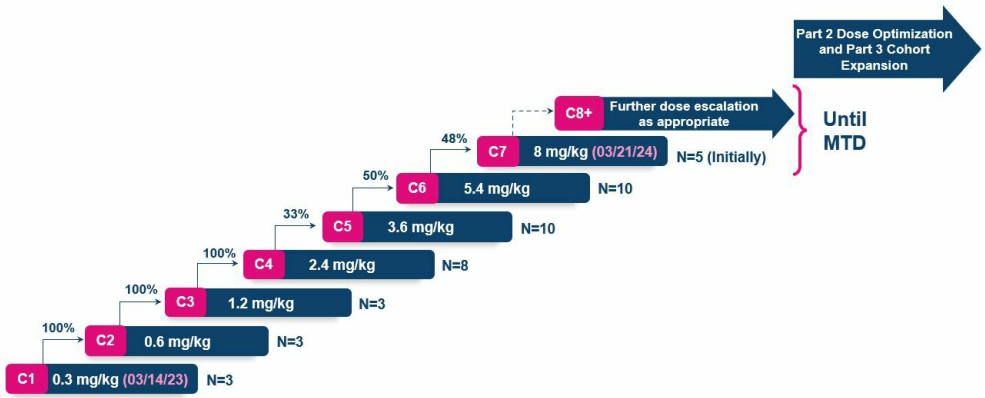
In preclinical models of patient-derived xenograft, or PDX models, we observed tumor regression with single agent PYX-201 in a dose-dependent manner. In addition, we observed that the treatment of preclinical syngeneic tumor models with PYX-201 resulted in enhanced T-cell infiltration into the tumor microenvironment, or TME, suggesting that PYX-201 may have caused immunogenic cell death, or ICD, and could potentially trigger downstream anti-tumor immune response.

In December 2022, we announced clearance of our investigational new drug application, or IND, by the U.S. Food and Drug Administration, or FDA, to initiate a Phase 1 clinical trial. During the first quarter of 2023, we announced dosing of the first subject in a Phase 1 trial of PYX-201, referred to as PYX-201-101. PYX-201-101 is an open-label, multicenter, dose-escalation trial designed to evaluate the safety, tolerability, pharmacokinetics, or PK, pharmacodynamics, or PD, and preliminary efficacy of PYX-201 and identify recommended doses for further study. Patients with relapsed or refractory solid tumors, including non-small cell lung cancer, or NSCLC, locally advanced/metastatic breast cancer, hormone receptor and human epidermal growth factor receptor 2 positive and negative, or HR+ HER- and HR- HER2+, breast cancers, triple negative breast cancer, or TNBC, ovarian cancer, thyroid cancer, pancreatic ductal adenocarcinoma, or PDAC, soft tissue sarcoma, or STS, hepatocellular carcinoma, or HCC, head and neck squamous cell carcinoma, or HNSCC, and kidney cancer are eligible to enroll in this study. In May 2023, the FDA granted Orphan Drug Designation, or ODD, for use of PYX-201 in the treatment of pancreatic cancer.

In the Phase 1 portion of the trial, the starting dose of PYX-201 was 0.3 mg/kg. The Dose Escalation Steering Committee, or DESC, approved escalating the dose after each cohort. PYX-201 is administered once every three weeks. Dose escalation follows the Bayesian Optimal Interval, or BOIN, design until the recommended Part 2 dose(s), or RP2D, is determined.

To date, 37 subjects in six cohorts have been dosed with PYX-201 in this Phase 1 trial. PYX-201 recently cleared the 21-day Dose Limiting Toxicity, or DLT, observation period for ten subjects in Cohort 6 at a dose of 5.4 mg/kg. The DESC met on March 19, 2024, and voted to escalate dosing into Cohort 7 at a dose of 8 mg/kg and we are now enrolling subjects in Cohort 7 at this dose. PYX-201 has been well tolerated to date, with no significant evidence of target mediated toxicities experienced by the 37 subjects enrolled and dosed to date. Approximately 54% of subjects have experienced grade 2, and 6% of subjects have experienced grade 3 treatment emergent adverse events, or TEAEs. No subjects have reported TEAEs leading to dosing delay or study drug discontinuation. We anticipate enrolling and dosing another 10-15 subjects at Cohort 7 with a dose of 8 mg/kg or future higher dose level cohorts, should PYX-201's profile continue to support further dose escalation.

The dose escalation and number of subjects enrolled and dosed to date with PYX-201 in the PYX-201-101 trial, for each cohort since initiating the trial in March 2023, are provided below.



As we continue to analyze the data generated, we anticipate that the data from the dose finding studies will guide the selection for the RP2D for subsequent multi-dosing and potential combination studies. We believe the encouraging PYX-201 safety profile observed to date likely reflects the specificity of target expression within tumor tissue and the potential for a wider TI given the novel mechanism of action within the TME. We anticipate reporting efficacy, safety, and PK/PD data from this Phase 1 clinical trial, in the fall of 2024. We also anticipate reporting pre-clinical insights along with the plan for the next phase of development at that time.

PYX-106

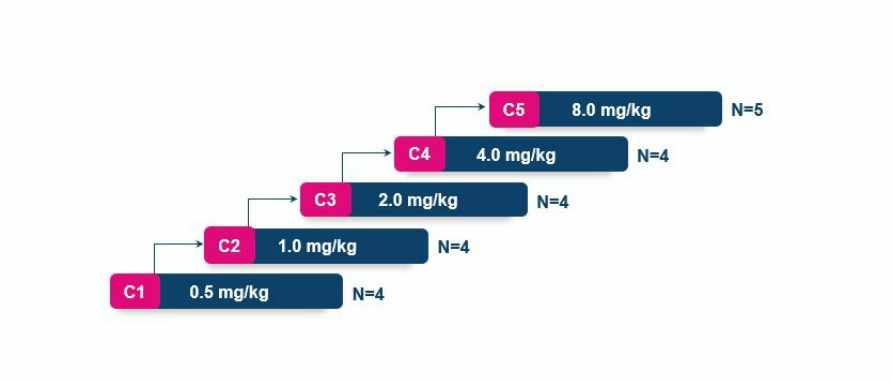
Our lead IO product candidate is PYX-106, an investigational, fully human IgG1 Siglec-15-targeting antibody designed to block Siglec-15 mediated suppression of T-cell proliferation and function. PYX-106 has high binding affinity to a unique epitope and high potency. Overall, by binding and blocking Siglec-15 activity on myeloid cells and tumors, our Siglec-15 targeting antibody is designed to enhance immune cell mediated tumor cell killing. We are developing this asset for the treatment of solid tumors and believe that PYX-106 has the potential to provide additional benefit to patients either alone or in combination with other therapies, including other immuno-therapies.

Preclinical studies provided us sufficient scientific rationale about the effect of blocking Siglec-15 in various animal models. PYX-106 was observed as well tolerated with no evidence of anti-drug antibodies. Further, PYX-106 was observed to have 7 days of half-life in monkeys in our preclinical studies. If the half-life of 7 days were observed in humans, it would allow for less frequent dosing, maintain exposure and target engagement.

In December 2022, we announced clearance of our IND by the FDA for PYX-106 to initiate a Phase 1 clinical trial. During the second quarter of 2023, we announced dosing of the first subject in a Phase 1 trial of PYX-106, referred to as PYX-106-101. PYX-106-101 is a first-in-human, Phase 1, multicenter, open-label dose escalation trial designed to evaluate the safety, tolerability, PK, PD, and preliminary efficacy of PYX-106 and identify recommended doses for further study. Patients with relapsed or refractory solid tumors, including non-small cell lung cancer without driver mutations/translocations, breast cancer, endometrial cancer, thyroid cancer, kidney cancer, cholangiocarcinoma, bladder cancer, colorectal cancer, and HNSCC are eligible to enroll in this study.

In the Phase 1 portion of the trial, the starting dose of PYX-106 was 0.5 mg/kg. The DESC approved escalating the dose after each cohort. We are currently dosing subjects in fifth cohort at a dose of 8 mg/kg. To date, 21 subjects have been dosed with PYX-106 in the Phase 1 trial. PYX-106 is administered once every two weeks. Dose escalation will follow the BOIN design until the RP2D is determined.

The dose escalation and number of subjects enrolled and dosed to date with PYX-106 in the PYX-106-101 trial, for each cohort since initiating the trial in May 2023, are provided below.



We anticipate reporting preliminary data from this Phase 1 clinical trial, including PK/PD data and early signs of potential clinical activity, in the second half of 2024.

PYX-107

On August 23, 2023, we completed the acquisition contemplated by that Agreement and Plan of Merger, or the Merger Agreement, by and among the Company, Ascent Merger Sub Corp., a Delaware corporation and wholly-owned subsidiary of the Company, or the Merger Sub, and Apexigen, a Delaware corporation and a clinical-stage biopharmaceutical company focused on discovering and developing innovative antibody therapeutics for oncology.

Pursuant to the Merger Agreement, Merger Sub merged with and into Apexigen, with Apexigen surviving as a wholly owned subsidiary of the Company, or the Merger. As consideration for the Merger, we delivered to Apexigen common stockholders 4,344,435 shares of our common stock and replaced stock options, restricted stock units and warrants to Apexigen's former employees and warrant-holders, for an aggregate purchase price of $10.7 million.

The Merger expanded our existing pipeline with the addition of sotigalimab (now PYX-107), a CD40 agonist with demonstrated anti-cancer activity in patients who previously progressed on PD-(L)1 inhibitors. PYX-107 has been evaluated in more than 500 patients in clinical trials and demonstrated strong activity, including rapid, deep and durable responses and a favorable tolerability profile, across multiple difficult-to-treat tumor types. In a Phase II trial, PYX-107 in combination with nivolumab has demonstrated strong activity in melanoma patients who are refractory to anti-PD-(L)1, with a 15.2% partial response rate and a 30.3% stable disease rate along with a favorable tolerability profile. Opportunity to advance clinical development of PYX-107 will be further assessed as part of portfolio evaluation.

Since our inception, we have focused substantially all of our resources on conducting research and development activities, undertaking preclinical studies and clinical trials, organizing and staffing our company, business planning, raising capital, establishing and maintaining our intellectual property portfolio and identifying potential product candidates. We do not have any products approved for sale and have not generated any revenue from product sales or from any other sources. We have incurred significant operating losses since our inception. We reported net losses of $73.8 million and $120.7 million for the years ended December 31, 2023 and 2022, respectively. As of December 31, 2023, we had an accumulated deficit of $286.2 million, net equity of $125.7 million, and cash, cash equivalents and short-term investments of $119.3 million. We expect to continue to incur significant expenses and operating losses for the foreseeable future. We expect that our expenses and capital expenditures will increase substantially in connection with our ongoing activities. Our operations to date have been financed primarily through sales of convertible preferred stock and sale of equity securities and additional funding may be necessary to fund future clinical and preclinical activities.

Components of Our Results of Operations

Operating Expenses

Research and Development Expenses

Research and development expenses consist of costs incurred for our research activities, including our discovery efforts and research work to support clinical development, and the development of our programs. Research and development expenses are presented among program-specific costs and unallocated costs.

Program-specific costs include:

•direct third-party costs, which include expenses incurred under agreements with contract research organizations, or CROs, and the cost of consultants who assist with the development of our product candidates on a program-specific basis, investigator grants, sponsored research, and any other third-party expenses directly attributable to the development of the product candidates;

•costs of acquiring, developing, and manufacturing and testing clinical and preclinical materials, including costs incurred under agreements with CDMOs to the extent they can be allocated to a specific program;

•license fees and milestone payments related to the acquisition and retention of certain licensed technology and intellectual property rights for a specific product candidate; and

•costs associated with preclinical activities that are directly attributable to the development of the product candidates.

Unallocated costs include:

•employee-related expenses for research and development personnel, including salaries, bonus, payroll taxes, related benefits, severance and other staff-related expenses;

•stock-based compensation expenses for employees engaged in research and development activities;

•facilities and other costs, which include allocated expenses for rent and maintenance of facilities, depreciation of leasehold improvements and equipment, laboratory supplies, third-party cost for discovery research and the cost of consultants who assist with our research and development and costs related to contract manufacturing, but are not allocated to a specific program.

We expense research and development costs as incurred. Non-refundable advance payments that we make for goods or services to be received in the future for use in research and development activities are recorded as prepaid expenses. The prepaid amounts are expensed as the related goods are delivered or the services are performed, or when it is no longer expected that the goods will be delivered, or the services rendered.

We expect that our research and development expenses will increase substantially in connection with our ongoing and planned preclinical and clinical development activities in the near term and in the future. The successful development of our product candidates is highly uncertain. At this time, we cannot accurately estimate or know the nature, timing and costs of the efforts that will be necessary to complete the preclinical and clinical development of any of our product candidates and we may never succeed in obtaining regulatory approval for any of our product candidates.

General and Administrative Expenses

General and administrative expenses consist primarily of salaries and personnel-related costs, including stock-based compensation, and severance for our personnel in executive, legal, finance and accounting, human resources and other administrative functions. General and administrative expenses also include professional fees for auditing, tax, and legal services, as well as insurance, board of director compensation, consulting, other administrative expenses and facility costs not otherwise included in research and development expenses.

Other Income, Net

Other income, net primarily consists of interest earned on our invested cash and cash equivalent balances, accretion of discounts associated with our marketable debt securities and sublease income under our sublease.

Income Taxes

Since our inception, we have not recognized any income tax benefits for the net losses we have incurred or for the research and development tax credits earned in each year and interim period, as we believe, based upon the weight of available evidence, that it is more likely than not that all of our net operating losses, or NOLs, carryforwards and tax credit carryforwards will not be realized. As of December 31, 2023, our federal and state net operating losses in the United States were $56.4 million ($268.5 million before tax) and $11.2 million ($167.4 million before tax) respectively. respectively. The federal net operating loss carryforwards in the United States can be carried forward indefinitely but may be subject to annual usage limitations to the extent certain substantial changes our ownership occur. The federal net operating loss carryforward relating to tax years prior to 2017 of $5.9 million ($28.3 million before tax), acquired with Apexigen, begin to expire in 2033. The state net operating loss carryforwards begin expiring in 2035. In addition, as of December 31, 2023, the Company had $7.8 million and $3.6 million of federal and state credit carryovers which begin to expire in 2030. These loss and credit carryforwards are subject to review and possible adjustment by the relevant taxing authorities.

Results of Operations

Comparison of the Years Ended December 31, 2023 and 2022

The following table summarizes our results of operations for the years ended December 31, 2023 and 2022 (in thousands):

	Year Ended December 31,		
	2023	**2022**	**Change**
Operating expenses:			
Research and development	$ 49,586	$ 86,129	$ (36,543)
General and administrative	32,610	37,352	(4,742)
Total operating expenses	82,196	123,481	(41,285)
Loss from operations	(82,196)	(123,481)	41,285
Other income, net:			
Interest and investment income	6,630	2,764	3,866
Sublease income	1,776	—	1,776
Total other income, net	8,406	2,764	5,642
Net loss	**$ (73,790)**	**$ (120,717)**	**$ 46,927**

Research and Development Expenses

The following table summarizes our research and development expenses for the years ended December 31, 2023 and 2022 (in thousands):

	Year Ended December 31,		
	2023	**2022**	**Change**
Program-specific costs:			
PYX-201	$ 8,649	$ 37,730	$ (29,081)
PYX-106	4,645	14,563	(9,918)
Other program costs	677	8,674	(7,997)
Total program costs	**13,971**	**60,967**	**(46,996)**
Unallocated costs:			
Personnel-related expenses including stock-based compensation	26,294	18,975	7,319
Other costs	9,321	6,187	3,134
Total research and development expenses	**$ 49,586**	**$ 86,129**	**$ (36,543)**

Research and development expenses decreased by $36.5 million, from $86.1 million for the year ended December 31, 2022 to $49.6 million for the year ended December 31, 2023.

PYX-201 program-specific research and development costs decreased by $29.1 million, primarily due to a decrease in licensing fees related to a one-time payment of $17.3 million in the prior year related to the Pfizer A&R Agreement, a $10.4 million decrease in contract manufacturing costs for drug products and drug substances, which were manufactured in 2022, and a $4.3 million decrease in pre-clinical research costs. This decrease was partially offset by a $2.8 million increase in clinical trial related expenses for our ongoing Phase 1 clinical trial for PYX-201.

PYX-106 program-specific research and development costs decreased by $9.9 million, primarily due to a decrease in licensing fees related to a one-time payment of $10.0 million in the prior year, related to the Biosion License Agreement, and a $2.1 million decrease in contract manufacturing costs for drug products and drug substances. This decrease was partially offset by a $2.1 million increase in clinical trial related expenses for our ongoing Phase 1 clinical trial for PYX-106.

Other program costs decreased by $8.0 million, primarily due to pre-clinical and contract manufacturing costs incurred in the prior year related to pre-clinical programs we voluntarily paused through our pipeline reprioritization announced in the second quarter of 2022 to refocus development efforts and spending on PYX-201 and PYX-106.

Unallocated research and development costs increased by $10.4 million, primarily due to higher personnel-related expenses, including stock-based compensation, by $7.3 million due to an increase in headcount to support our research and development activities and $3.1 million increase in costs related to facilities rent, laboratory expenses, depreciation and amortization.

General and Administrative Expenses

The following table summarizes our general and administrative expenses for the years ended December 31, 2023 and 2022 (in thousands):

	Year Ended December 31,		
	2023	**2022**	**Change**
Personnel-related expenses including stock-based compensation	$ 21,090	$ 18,732	$ 2,358
Professional and consultant fees	8,573	13,061	(4,488)
Facilities, insurance and other costs	2,947	5,559	(2,612)
Total general and administrative expenses	**$ 32,610**	**$ 37,352**	**$ (4,742)**

General and administrative expenses decreased by $4.7 million, from $37.4 million for the year ended December 31, 2022 to $32.6 million for the year ended December 31, 2023. The decrease was primarily related to a reduction in professional and consultant fees of $4.5 million and facilities and other costs of $2.6 million due to higher spend in the prior year, mainly related to the build-out of our general and administrative function. This decrease was partially offset by increased personnel-related expenses of $2.3 million, primarily related to stock-based compensation.

Other Income, net

Other income, net for the years ended December 31, 2023 and 2022 was $8.4 million and $2.8 million, respectively. The increase of $5.6 million was primarily due to higher interest rates on our deposits and money market funds, accretion of discounts on our marketable debt securities by $3.9 million, and sublease income of $1.8 million.

Liquidity and Capital Resources

We had cash, cash equivalents, and short-term investments of $119.3 million as of December 31, 2023. For the year ended December 31, 2023 and 2022, we had net losses of $73.8 million and $120.7 million, respectively. As of December 31, 2023, we had an accumulated deficit of $286.2 million.

On November 1, 2022, we filed a registration statement on Form S-3 with the SEC for the issuance of common stock, preferred stock, warrants, debt securities, rights and units up to an aggregate of $250.0 million. On November 14, 2022, the registration statement was declared effective by the SEC. The registration statement includes an at-the-market, or ATM, offering program for the sale of up to $125.0 million of shares of our common stock.

During the year ended December 31, 2023, we completed the sale of an aggregate of 1,001,208 shares of common stock under the ATM offering program, with an average gross sale price of $6.30 per share, resulting in gross proceeds of $6.3 million. We paid commissions of $0.2 million to the placement agent under the ATM offering program.

On January 30, 2024, we completed the sale of an aggregate of 3,600,000 shares of our common stock under the ATM offering program, with an average sale price of $3.00 per share, resulting in gross proceeds of $10.8 million, before the placement agent fees.

On February 29, 2024, we completed the private placement with certain accredited investors and issued and sold to the purchasers an aggregate of (i) 8,849,371 shares of Common Stock at a purchase price of $4.78 per share and (ii) Pre-Funded Warrants to purchase up to an aggregate of 1,611,215 shares of Common Stock at a purchase price of $4.779 per Pre-Funded Warrant. We received aggregate gross proceeds from the private placement of approximately $50 million, before deducting placement agent fees and offering expenses.

We expect our expenses to increase substantially in connection with our ongoing activities, particularly as we advance the clinical trials for our product candidates in development. The timing and amount of our funding requirements will depend on many factors, including:

•the cost associated with Phase 1 clinical trials for PYX-201, PYX-106 and clinical trials for PYX-107;

•the manufacture of drug products and drug substance for our product candidates for PYX-201, PYX-106 and PYX-107;

•the timing and progress of our other preclinical and clinical development activities;

•the number and scope of other preclinical and clinical programs we decide to pursue;

•the progress of the development efforts of parties with whom we have entered or may in the future enter into in-licensing, collaborations and research and development agreements;

•the costs and timing of future commercialization activities, including product manufacturing, marketing, sales and distribution, for any of our product candidates for which we receive marketing licensure;

•our ability to maintain our current licenses and research and development programs and to establish new collaboration arrangements;

•the costs involved in prosecuting, maintaining and enforcing patent and other intellectual property rights;

•the costs of maintaining, expanding and protecting our intellectual property portfolio;

•the cost and timing of regulatory licenses;

•our efforts to hire additional clinical, regulatory, scientific, operational, financial and management personnel; and

•insurance, legal and other regulatory compliance expenses to operate as a public company.

Until such time, if ever, we can generate substantial product revenue, we expect to finance our operations through a combination of equity offerings, debt financings, collaborations, strategic alliances and marketing, distribution or 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 of these securities may include liquidation or other preferences that adversely affect your rights as a common stockholder. Debt financing and preferred 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 acquisitions, engaging in acquisition, merger or collaboration transactions, selling or licensing our assets, making capital expenditures, redeeming our stock, making certain investments or declaring dividends.

If we raise additional funds through collaborations, strategic alliances or marketing, distribution or licensing arrangements with third parties, we may have to relinquish valuable rights to our technologies, future revenue streams, research programs or product candidates, or grant licenses on terms that may not be favorable to us. If we are 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 product candidates that we would otherwise prefer to develop and market ourselves.

Cash Flows

The following table provides information regarding our cash flows for the years ended December 31, 2023 and 2022 (in thousands):

	Year Ended December 31,	
	2023	**2022**
Net cash used in operating activities	$ (70,709)	$ (89,335)
Net cash used in investing activities	(104,849)	(6,399)
Net cash provided by financing activities	5,929	183
Net decrease in cash, cash equivalents and restricted cash	**$ (169,629)**	**$ (95,551)**

Operating Activities

Net cash used in operating activities for the year ended December 31, 2023 was $70.7 million, which consisted of our net loss of $73.8 million and a net change in our operating assets and liabilities of $11.7 million, offset by non-cash charges of $14.7 million. The non-cash charges of $14.7 million was primarily due to $16.9 million in stock-based compensation and $4.8 million of accretion of discounts on marketable debt securities as well as $1.9 million of depreciation and amortization expense. The net change in our operating assets and liabilities was primarily due to a decrease of $14.1 million in accrued expenses and other current liabilities, which primarily relates to a one-time payment of $8.0 million made to Pfizer in January 2023 pursuant to the Pfizer A&R License Agreement, and reduction in accounts payable by $3.5 million resulting from the timing of payments to our service providers. This decrease is partially offset by a $2.5 million increase to prepaid expenses and other current assets and a $2.4 million increase to operating lease liabilities driven by tenant improvement allowance deposits.

Net cash used in operating activities for the year ended December 31, 2022 was $89.3 million, which consisted of our net loss of $120.7 million, partially offset by non-cash charges of $26.9 million and a net change in our operating assets and liabilities of $4.6 million. The non-cash charges primarily consisted of $9.3 million related to license fees for Pfizer FACT Platform settled and payable in common stock, stock-based compensation expenses of $15.8 million, and amortization of operating lease right-of-use assets of $1.1 million. The change in our operating assets and liabilities was primarily due an increase in operating lease liabilities of $4.3 million as a result of the operating lease for our headquarters and an increase in prepaid expenses and other current assets of $3.4 million primarily related to prepayment of clinical and contract manufacturing costs and directors and officers insurance policy costs, offset by an increase in accrued expenses and other current liabilities of $12.0 million and a decrease in accounts payable of $8.3 million related to timing of routine vendor payments.

Investing Activities

Net cash used in investing activities for the year ended December 31, 2023 was $104.9 million, which consisted primarily of purchases of marketable debt securities of $196.8 million and leasehold improvements and purchases of property and equipment for our headquarters of $7.0 million, partially offset by redemption of marketable debt securities of $92.0 million and cash acquired as part of the acquisition of Apexigen of $6.7 million.

Net cash used in investing activities for the year ended December 31, 2022 was $6.4 million, which consisted primarily of purchases of property and equipment. The purchases of property and equipment consists of laboratory equipment, furniture and fixtures and leasehold improvements for our headquarters.

Financing Activities

Net cash provided by financing activities for the year ended December 31, 2023 was $5.9 million, which consisted primarily of net proceeds from our ATM program.

Net cash provided by financing activities for the year ended December 31, 2022 was $0.2 million, which consisted primarily of proceeds from exercise of stock options.

Outlook

As of December 31, 2023, we had approximately $119.3 million in cash, cash equivalents, and short-term investments. Additionally, on January 30, 2024, we issued additional shares under the ATM offering program that resulted in gross proceeds of $10.8 million, before deducting placement agent commissions. On February 29, 2024, we completed the private placement which resulted in gross proceeds of $50 million, before deducting placement agent commissions and other offering expenses. We believe that our cash and cash equivalents as of December 31, 2023, along with proceeds from the ATM offering and the proceeds from the private placement will be sufficient to fund our operations into the second half of 2026. However, we have based this estimate on assumptions that may prove to be wrong, and our operating plan may change as a result of many factors currently unknown to us. In addition, we could utilize our available capital resources sooner than we expect.

Contractual Obligations and Commitments

Operating lease obligation

We lease an office and laboratory space in Boston, Massachusetts with lease payments that continue through December 31, 2032, and have scheduled rent increases each year of 3%. Additionally, we sublease 17,729 square feet of office and laboratory space in the building located at 321 Harrison Avenue, Boston, Massachusetts. The remaining contractual fixed lease payments, net of sublease payments and tenant improvement allowance, over the term of the lease aggregate to $28.1 million. The operating lease obligation is discussed in Note 12, *Leases*, in our Notes to Financial Statements included in Part II, Item 8 of this Annual Report on Form 10-K.

Other obligations

We enter into licensing and related agreements in the normal course of business. In accordance with these agreements, we are obligated to pay, among other items, future contingent payments, royalties, and sublicensing revenue in the future, as applicable. We have not included potential future payments due under these licensing and collaboration agreements in contractual obligations because the payment obligations under the agreements are contingent upon future events. Refer to Note 4, *Licensing Agreements*, in our Notes to Financial Statements included in Part II, Item 8 of this Annual Report on Form 10-K for further information.

In addition, we enter into contracts in the normal course of business with CDMOs, CROs, and other third parties for preclinical work and clinical development related work. These contracts do not contain minimum purchase commitments and are cancelable by us upon prior written notice. Payments due upon cancellation consist only of payments for services provided or expenses incurred, including non-cancelable obligations of our service providers, up to the date of cancellation. These payments are not included in the contractual obligations above as the amount and timing of such payments are not known.

Off-Balance Sheet Arrangements

We did not have during the years presented, and we do not currently have, any off-balance sheet arrangements, as defined in the rules and regulations of the Securities and Exchange Commission.

Critical Accounting Policies and Significant Judgments and Estimates

Our consolidated financial statements are prepared in accordance with generally accepted accounting principles in the United States. The preparation of our consolidated financial statements and related disclosures requires us to make estimates and judgments that affect the reported amounts of assets, liabilities, costs and expenses, and the disclosure of contingent assets and liabilities in our consolidated financial statements. We base our estimates on historical experience, known trends and events, and various other factors that we believe are 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. We evaluate our estimates and assumptions on an ongoing basis. Our actual results may differ from these estimates under different assumptions or conditions.

While our significant accounting policies are described in more detail in Note 2 to our audited consolidated financial statements appearing elsewhere in this Annual Report on Form 10-K, we believe that the following accounting policies are the critical accounting policies used in the preparation of our consolidated financial statements that require significant estimates and judgments.

Research and Development Expenses

As part of the process of preparing our consolidated financial statements, we are required to estimate our accrued research and development expenses. This process involves 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 actual costs. The majority of our service providers invoice us in arrears for services performed, on a pre-determined schedule or when contractual milestones are met; however, some require advance payments. We make estimates of our accrued expenses as of each balance sheet date in the consolidated financial statements based on facts and circumstances known to us at that time. At each period end, we corroborate the accuracy of these estimates with the service providers and make adjustments, if necessary. Examples of estimated accrued research and development expenses include those related to fees paid to:

•CROs in connection with performing research and development services on our behalf;

•CDMOs in connection with manufacturing of drug substance and drug products to be used in clinical trials on our behalf;

•other providers in connection with clinical trials;

•vendors in connection with non-clinical development activities; and

•vendors related to product manufacturing, development and distribution of clinical supplies.

We record the expense and accrual related to contract research and manufacturing based on our estimates of the services received and efforts expended considering a number of factors, including our knowledge of the progress towards completion of the research, development and manufacturing activities; invoicing to date under contracts; communication from the CROs, CDMOs and other companies of any actual costs incurred during the period that have not yet been invoiced; and the costs included in the contracts and purchase orders. In accruing service fees, we estimate the 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 the estimate, we adjust the accrual or the amount of prepaid expense accordingly. There have not been any material adjustments to our prior estimates of accrued research and development expenses.

Stock-Based Compensation

We maintain equity incentive plans as a long-term incentive for employees, consultants, and directors. We account for all stock-based awards granted to employees and non-employees based on their fair value on the date of the grant and recognize compensation expense for those awards over the requisite service period, which is generally the vesting period of the respective award. The grant date fair value of the stock-based awards with graded vesting is recognized on a straight-line basis over the requisite service period. We recognize forfeitures related to stock-based compensation awards as they occur and reverse any previously recognized compensation cost associated with forfeited awards in the period the forfeiture occurs.

We value stock options with service conditions using the Black-Scholes option-pricing model. The Black-Scholes option-pricing model uses various inputs and we make certain assumptions regarding the fair value of our common stock, the expected volatility of our common stock, the expected term of stock options, the risk-free interest rate for a period that approximates the expected term of our common stock options and our expected dividend yield. The following summarizes the inputs used and assumptions made:

Expected Volatility—We lack company-specific historical and implied volatility information. Therefore, we estimate the expected stock volatility based on the historical volatility of a publicly traded set of peer companies and expect to continue to do so until we have adequate historical data regarding the volatility of our traded stock price.

Expected Term—We use the simplified method described in the SEC's Staff Accounting Bulletin No. 107, *Share-Based Payment* ("SAB 107"), to determine the expected life of the option grants.

Risk-Free Interest Rate—The risk-free interest rate is determined by reference to the U.S. Treasury yield curve in effect at the time of grant of the award for time periods approximately equal to the expected term of the award.

Dividends—Expected dividend yield is zero because we have not paid cash dividends on shares of common stock and do not expect to pay any cash dividends in the foreseeable future.

Income Taxes

We account for income taxes in accordance with FASB ASC 740, *Income Taxes* ("ASC 740"), which requires the use of the asset and liability method of accounting for income taxes. Under this method, deferred tax assets and liabilities are determined on the basis of the differences between amounts in the consolidated financial statements and the tax bases 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 tax (benefit) expense in the consolidated statements of operations and comprehensive loss in the period that includes the enactment date.

We recognize deferred tax assets to the extent that we believe these assets are more likely than not to be realized. In making such a determination, we consider 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 we determine that it would be able to realize our deferred tax assets in the future in excess of our net recorded amount, we would make an adjustment to the deferred tax asset valuation allowance, which would reduce the provision for income taxes. Changes in recognition or measurement are reflected in the period in which the change in judgment occurs.

When uncertain tax positions exist, we recognize the tax benefit of tax positions to the extent that the benefit will more likely than not be realized. The determination as to whether the tax benefit will more likely than not be realized is based upon the technical merits of the tax position as well as consideration of the available facts and circumstances.

Business Combinations

We determine whether a transaction or other event is a business combination by determining whether the assets acquired and liabilities assumed constitutes a business. Business combinations are accounted for by applying the acquisition method as set out by ASC 805, *Business Combinations* ("ASC 805"). The acquisition method of accounting requires the acquirer to recognize and measure all identifiable assets acquired, liabilities assumed and any noncontrolling interest in the acquiree at their acquisition-date fair values, with certain exceptions for specific items.

Goodwill is measured as the excess of the consideration transferred in the business combination over the net acquisition date amounts of the identifiable assets acquired and the liabilities assumed. Alternatively, if the acquisition date amounts of the identifiable assets acquired and the liabilities assumed exceeds the consideration transferred, a gain on bargain purchase is recognized in the consolidated statements of operations and comprehensive loss. The consideration transferred in a business combination is measured as the sum of the fair values of the assets transferred, the liabilities incurred to former owners of the target and the equity interests issued.

The results of operations of businesses acquired by us are included in our consolidated statements of operations and comprehensive loss as of the respective acquisition date.

Where the acquirer exchanges its share-based payment awards for awards held by grantees of the acquiree, such exchanges are treated as a modification of share-based payment awards and are referred to as replacement awards. The replacement awards are measured as of the acquisition date and the portion of the fair-value-based measure of the replacement award that is attributable to pre-combination service is considered part of the consideration transferred. For awards with service-based vesting conditions only, the amount attributable to pre-combination service is the fair-value-based measure of the acquiree award multiplied by the ratio of the employee's pre-combination service period to the greater of the total service period or the original service period of the acquiree award.

Acquisition-related costs, including advisory, legal and other professional fees and administrative fees are expensed as incurred except for the costs of issuing equity securities, which are recognized as a reduction to the amounts recognized in the consolidated statements of stockholders' equity for the respective equity issuance.

Intangible Assets, Net

Acquired In-Process Research & Development

Our indefinite-lived intangible assets consist of in-process research and development ("IPR&D"), which were acquired in connection with the acquisition of Apexigen. IPR&D represents the fair value assigned to research and development projects acquired which are in-process, but not yet completed at the time of acquisition. The primary basis for determining the completion of these projects is obtaining regulatory approval to market the underlying products in an applicable geographic region.

The Company classifies IPR&D acquired in a business combination as an indefinite-lived intangible asset until the associated research and development efforts are either completed or abandoned. IPR&D becomes definite-lived upon the completion or abandonment of the associated research and development efforts. Indefinite-lived intangible assets are not amortized, but evaluated for impairment on an annual basis or more frequently if an indicator of impairment is identified. All research and development costs incurred subsequent to the acquisition of IPR&D are expensed as incurred.

Definite-Lived Intangible Assets

Definite-lived intangible assets are recorded at cost, net of accumulated amortization, and, if applicable, impairment charges. Amortization of defined-lived intangible assets is recorded over the assets' estimated useful lives on a straight-line basis or based on the pattern in which economic benefits are consumed, if reliably determinable.

Impairment of Intangible Assets

We evaluate our intangible assets, including both acquired IPR&D and definite-lived intangible assets, for impairment at least annually and whenever events or changes in circumstances indicate that the carrying value of an asset may not be recoverable. Factors that we consider in deciding when to perform an impairment review include significant underperformance of the business in relation to expectations, significant negative industry or economic trends, and significant changes or planned changes in the use of the assets. If the projected undiscounted cash flows of the intangible asset are less than the carrying amount, the intangible asset is written down to its fair value in the period in which the impairment occurs.

Recent Accounting Pronouncements

For information with respect to recently issued accounting standards and the impact of these standards on our consolidated financial statements, refer to "Note 2 — Summary of Significant Accounting Policies" in our consolidated financial statements in Part II, Item 8 of this Annual Report on Form 10-K.

Jumpstart Our Business Startups Act

The Jumpstart Our Business Startups Act of 2012, or the JOBS Act, permits an "emerging growth company" to take advantage of an extended transition period to comply with new or revised accounting standards. We are an "emerging growth company," as defined in the JOBS Act. Thus, an emerging growth company can delay the adoption of certain accounting standards until those standards would otherwise apply to private companies. We have irrevocably elected not to avail ourselves of this extended transition period, and, as a result, we will adopt new or revised accounting standards on the relevant dates on which adoption of such standards is required for other public companies.

We are also a "smaller reporting company," meaning that the market value of our shares held by non-affiliates is less than $700 million and our annual revenue was less than $100 million during the most recently completed fiscal year. We may rely on exemptions from certain disclosure requirements that are available to smaller reporting companies. Specifically, as a smaller reporting company, we may choose to present only the two most recent fiscal years of audited financial statements in our Annual Report on Form 10-K and have reduced disclosure obligations regarding executive compensation, and, similar to emerging growth companies, if we are a smaller reporting company with less than $100 million in annual revenue, we would not be required to obtain an attestation report on internal control over financial reporting issued by our independent registered public accounting firm.

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

Under SEC rules and regulations, because we are considered to be a "smaller reporting company", we are not required to provide the information required by this item in this report.

Item 8. Financial Statements and Supplementary Data.

The financial information required by Item 8 is located beginning on page F-1 of this report.

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

None.

Item 9A. Controls and Procedures.

Evaluation of Disclosure Controls and Procedures.

We maintain "disclosure controls and procedures" (as defined in Rules 13a-15(e) and 15d-15(e) under the Securities Exchange Act of 1934, as amended, or the Exchange Act), that are designed to provide reasonable assurance that information required to be disclosed by us in the reports that we file or submit under the Exchange Act is recorded, processed, summarized and reported within the time periods specified in the SEC's rules and forms.

Disclosure controls and procedures include, without limitation, controls and procedures designed to provide reasonable assurance that information required to be disclosed by us in the reports that we file or submit under the Exchange Act is accumulated and communicated to our management, including our Chief Executive Officer and Chief Financial Officer, as appropriate, to allow for timely decisions regarding required disclosure.

Our management, with the participation of our Chief Executive Officer and our Chief Financial Officer, evaluated the effectiveness of our disclosure controls and procedures as of December 31, 2023, the end of the period covered by this Annual Report. Based on this evaluation, our Chief Executive Officer and Chief Financial Officer concluded that our disclosure controls and procedures were effective as of December 31, 2023, at the reasonable assurance level.

Management's Report on Internal Control over Financial Reporting.

Our management is responsible for establishing and maintaining adequate internal control over our financial reporting. Internal control over financial reporting is defined in Rules 13a-15(f) and 15d-15(f) promulgated under the Exchange Act as a process designed by, or under the supervision of, our principal executive and principal financial officers and effected by our board of directors, management, and other personnel to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with United States GAAP. Our internal control over financial reporting includes those policies and procedures that:

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

Because of its inherent limitations, internal control over financial reporting may not prevent or detect misstatements. 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.

Our management assessed the effectiveness of our internal control over financial reporting as of December 31, 2023. In making this assessment, management used the criteria set forth by the Committee of Sponsoring Organizations of the Treadway Commission, or COSO, in its 2013 Internal Control - Integrated Framework. Based on our assessment, our management has concluded that, as of December 31, 2023, our internal control over financial reporting is effective based on those criteria.

Changes in Internal Control Over Financial Reporting.

There was no change in our internal control over financial reporting (as defined in Rules 13a-15(f) and 15d-15(f) under the Exchange Act) that occurred during the fiscal quarter ended December 31, 2023, that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

Inherent Limitation on the Effectiveness of Internal Control.

Our management, including our Chief Executive Officer and Chief Financial Officer, does not expect that our disclosure controls and procedures, or our internal controls, will prevent all error and all fraud. A control system, no matter how well conceived and operated, can provide only reasonable, not absolute, assurance that the objectives of the control system are met. Further, the design of a control system must reflect the fact that there are resource constraints, and the benefits of controls must be considered relative to their costs. Because of the inherent limitations in all control systems, no evaluation of controls can provide absolute assurance that all control issues and instances of fraud, if any, within our Company have been detected.

Attestation Report of the Registered Public Accounting Firm.

This Annual Report does not include an attestation report of our independent registered public accounting firm regarding internal control over financial reporting due to an exemption established by the JOBS Act for "emerging growth companies."

Item 9B. Other Information.

None.

Item 9C. Disclosure Regarding Foreign Jurisdictions that Prevent Inspections

Not applicable.

PART III

Item 10. Directors, Executive Officers and Corporate Governance.

Board of Directors

Our business and affairs are managed under the direction of the Board of Directors, or the Board. The Board presently consists of eight directors and is divided into three classes for purposes of elections, with staggered, three-year terms. Each of our current directors will continue to serve as a director until the election and qualification of his or her successor, or until his or her earlier death, resignation or removal. There are no family relationships among any of our directors or executive officers.

The following table sets forth the name and age of each director as of March 20, 2024.

Name	Age	Position Held	Director Since	Class and Year in Which Term Will Expire
John Flavin	55	Director and Chairman of the Board	May 2019	Class III - 2024
Lara Sullivan, M.D.	51	Director, President and Chief Executive Officer	December 2019	Class III - 2024
Thomas Civik	55	Director	September 2021	Class II - 2026
Darren Cline	59	Director	September 2021	Class I - 2025
Jakob Dupont, M.D.	58	Director	August 2023	Class III - 2024
Freda Lewis-Hall, M.D.	69	Director	September 2021	Class II - 2026
Rachel Humphrey, M.D.	62	Director	August 2022	Class I - 2025
Santhosh Palani, Ph.D., CFA	41	Director	March 2024	Class I - 2024

The following is a biographical summary of the experience of our directors:

John Flavin. Mr. Flavin is co-founder, founding Chairman and an independent director. Mr. Flavin has served as Chairman of the Board since our IPO. He is also the Founder and Chief Executive Officer of Portal Innovations, a life sciences venture development engine. Prior to joining us, between April 2018 and February 2020, Mr. Flavin was the Chief Financial Officer at Endotronix, Inc., a medical equipment manufacturer. Between September 2013 and April 2018, Mr. Flavin was the Head of the Polsky Center for Entrepreneurship and Innovation at the University of Chicago. Mr. Flavin has over 20 years of experience in finance, operations, and innovation. Mr. Flavin has co-founded and scaled several life sciences companies as President and Chief Financial Officer such as Advanced Life Sciences and MediChem Life Sciences. Mr. Flavin has also co-founded and led transformative life sciences incubators including MATTER and the Polsky Center for Entrepreneurship and Innovation at the University of Chicago. He received his B.S. in Business Administration from Marquette University and his M.B.A. in Finance from Lewis University. Mr. Flavin is qualified to serve on our Board because of his extensive expertise and experience in the life sciences industry, knowledge of our operations and his leadership experience in other companies in our industry.

Lara Sullivan, M.D. Dr. Sullivan has served as our President and Chief Executive Officer since December 2019. Prior to joining us, Dr. Sullivan was a senior advisor from July 2018 to September 2019 at Lara Sullivan BioAdvisory Services, consulting for biotechnology companies. From September 2017 to June 2018, Dr. Sullivan was Founder and President of SpringWorks Therapeutics, a clinical stage biopharmaceutical company spun-out from Pfizer Inc., or Pfizer. Between February 2011 and September 2017, Dr. Sullivan was at Pfizer, a pharmaceutical and biotechnology corporation, where she led strategy, competitive intelligence and portfolio operations for the company's early-stage R&D pipeline. Prior to joining Pfizer, Dr. Sullivan was an associate partner at McKinsey & Company, where she specialized in biopharmaceutical R&D productivity and efficiency. Dr. Sullivan also served as a principal at Paul Capital Partners, where she led due diligence for healthcare investments, and earlier in her career worked in healthcare equity research and healthcare municipal finance at Credit Suisse First Boston. Dr. Sullivan holds an M.D. from the University of Pennsylvania School of Medicine, an M.B.A. from The Wharton School at the University of Pennsylvania, and a B.A. in Comparative Literature from Cornell University. Dr. Sullivan is qualified to serve on our Board because of her extensive expertise and experience in the life sciences industry, her leadership and management experience and her educational background.

Thomas Civik. Mr. Civik currently serves a member and Chairman of the board of directors of Repare Therapeutics, a biotechnology company. From April 2020 to May 2021, Mr. Civik served as President, Chief Executive Officer and a member of the board of directors at Five Prime Therapeutics, Inc., a biotechnology company. From November 2017 until September 2019, Mr. Civik served as Chief Commercial Officer of Foundation Medicine, Inc., a genomic profiling and molecular information company. From December 2000 to November 2017, Mr. Civik served in positions of increasing responsibility at Genentech, Inc. ("Genentech"), a biotechnology company, most recently serving as Vice President and Franchise Head leading the commercialization efforts for the Avastin®, Tarceva®, Tecentriq®, and Alecensa®, products. From July 1992 to December 2000, Mr. Civik served at Sanofi S.A. in sales and marketing roles of increasing responsibility. Mr. Civik received an M.B.A. in business strategy and marketing from the Kellogg School of Management at Northwestern University and a B.A. in political science from Saint Norbert College. Mr. Civik is qualified to serve on our Board because of his extensive commercial expertise and leadership experience at other biotechnology companies.

Darren Cline. Mr. Cline currently serves on the board of directors of Pliant Therapeutics, a biotechnology company, and Impel Pharmaceuticals, a biopharmaceutical company. Mr. Cline served as President and Chief Executive Officer of Epygenix Therapeutics, Inc., a biopharmaceutical company, from March 2022 to March 2023. From April 2019 to December 2021, Mr. Cline served as the U.S. Chief Commercial Officer and member of the Executive Committee for Greenwich Bioscience, the U.S. subsidiary of GW Pharmaceuticals, a British pharmaceutical company, prior to the acquisition by Jazz Pharmaceuticals. From October 2010 to March 2019, Mr. Cline served as Executive Vice President, Commercial at Seattle Genetics, Inc., a biotechnology company, where he oversaw all marketing, sales, and managed markets. He was directly involved in the commercial build out for the launch of Adcetris, an antibody-based biologic the FDA approved for treatment of certain hematologic cancers and played an integral role driving Adcetris's continued growth. Prior to Seattle Genetics, between October 2006 and October 2009, Mr. Cline was at Alexion Pharmaceuticals, where he was part of the initial commercial leadership team for the Soliris launch, helping to build out key sales functions. Mr. Cline received his undergraduate degree from San Diego State University and his M.B.A. from Pepperdine University. Mr. Cline is qualified to serve on the Board because of his management experience and background in the biotechnology sector.

Jakob Dupont, M.D. Dr. Dupont served as a member of the board of directors at Apexigen from August 2020 until we completed the acquisition of Apexigen in August 2023. Dr. Dupont currently serves as an Executive Partner at Sofinnova Investments, a healthcare investment firm. Dr. Dupont also serves on the board of directors of Imugene, a biotechnology company. Prior to joining Sofinnova, Dr. Dupont served as the Global Head of Research and Development and Executive Vice President at Atara Biotherapeutics, a biotechnology company, from May 2020 to December 2023. From December 2018 to May 2020, he served as Chief Medical Officer and from May 2020 to July 2021 as a consultant oncologist at Gossamer Bio Inc. From January 2017 to December 2018 he served as Vice President, Global Head Breast and Gynecologic Cancer Development at Genentech, a biotechnology company. Dr. Dupont served as Chief Medical Officer and Senior Vice President at OncoMed Pharmaceuticals, a biotechnology company, from October 2011 to December 2016. Dr. Dupont holds an A.B. in Philosophy from Vassar College, an M.A. in Philosophy from New York University and an M.D. from Cornell University. Dr. Dupont is qualified to serve on our Board because of his extensive experience in the biotechnology field and his knowledge and expertise in oncology drug development.

Freda Lewis-Hall, M.D. Dr. Lewis-Hall served as Senior Medical Advisor to the Chief Executive Officer at Pfizer, a pharmaceutical and biotechnology corporation, until her retirement in March 2020. Prior to this role, Dr. Lewis-Hall was the Chief Patient Officer and Executive Vice President at Pfizer from January 2019 to January 2020. In this role, Freda worked to extend the reach of Pfizer's patient-facing health information and education and amplify the patient's voice inside and outside Pfizer. From 2009-2018 Freda served as Pfizer's Chief Medical Officer, responsible for the safe, effective and appropriate use of Pfizer medicines and vaccines. Prior to joining Pfizer in 2009, Dr. Lewis-Hall held various senior leadership positions including Chief Medical Officer and Executive Vice President, Medicines Development at Vertex Pharmaceuticals, Inc., from June 2008 to May 2009, and Senior Vice President, U.S. Pharmaceuticals, Medical Affairs for Bristol-Myers Squibb Co. from 2003 to May 2008. Dr. Lewis-Hall has served on the board of directors of SpringWorks Therapeutics, Inc. since August 2017, Exact Sciences Corporation since November 2020 and Conduit Pharmaceuticals since September 2023. From December 2014 to May 2017, she served on the board of directors of Tenet Healthcare Corporation, and from November 2019 to 2023 on the board of 1Life Healthcare, Inc. Dr. Lewis-Hall earned a B.A. in Natural Sciences from Johns Hopkins University and an M.D. from Howard University College of Medicine. Dr. Lewis-Hall is qualified to serve on our Board based on her expertise and experience in the life sciences industry and her leadership experience as a senior executive at various biopharmaceutical companies as well as her educational background.

Rachel Humphrey, M.D. Dr. Humphrey is a medical oncologist with over 25 years of experience in the pharmaceutical industry. Currently she serves as President and Founding CEO of Normunity, a biotechnology company focused on immuno-oncology mechanisms, a position she has held since October 2021. Previously, she served as Chief Medical Officer at Black Diamond Therapeutics, a novel precision oncology therapy company, from September 2021 to September 2022, and as Chief Medical Officer at Treadwell Therapeutics, Inc., a clinical stage, multi-modality oncology company, from January 2020 to May 2020 and Head of Research and Development at TIO Bioventures, a venture capital firm, over the same time period. Dr. Humphrey served as Senior Vice President, Chief Medical Officer at CytomX Therapeutics, a clinical-stage biopharmaceutical company, from August 2015 to September 2019. Over the course of her career, Dr. Humphrey also held numerous senior leadership roles in large pharmaceutical companies including Senior Vice President and Head of Immuno-Oncology at AstraZeneca, and Vice President, Clinical Development and Immuno-oncology at Bristol-Myers Squibb where she supervised the development of ipilimumab (Yervoy) from early development to post-launch and founded and chaired the first immuno-oncology working group. She currently serves on the board of directors of Sporos Biosciences, and previously served on the board of directors of Xilio and CytomX Therapeutics, respectively. Dr. Humphrey holds an M.D. from Case Western Reserve University and a B.A. from Harvard University. She received her training in internal medicine at the Johns Hopkins Hospital and started her career as an oncology fellow and staff physician at the National Cancer Institute in Bethesda, Maryland. Dr. Humphrey is qualified to serve on our Board based on her expertise and experience in the life sciences industry and her leadership experience as a senior executive at various biopharmaceutical companies as well as her educational background.

Santhosh Palani, Ph.D., CFA. Dr. Palani is a former investment partner and a current advisory partner at PFM Health Sciences, a healthcare investment advisory firm. At PFM, Dr. Palani led public and private biotechnology investments and served on the board of companies in the cell therapy and gene editing fields. Prior to joining PFM in 2020, Dr. Palani was a Principal at New Enterprise Associates, where he invested in early-stage private biotechnology companies and served on the boards of companies in the radiopharmaceuticals, cell therapy, targeted oncology, and gene editing fields. From 2016 to 2018, Dr. Palani was a Vice President of Biotechnology Equity Research at Cowen and Company, where he covered small- to mid-cap biotechnology stocks across numerous therapeutic areas. Prior to Cowen, Dr. Palani was in oncology drug development at Pfizer and Takeda Pharmaceuticals. Dr. Palani has a Ph.D. in bioengineering from the University of Pennsylvania and completed his postdoctoral work in biochemistry and molecular biophysics at Columbia University. He also holds an M.S. in chemical engineering from Texas A&M University and a B.S. in chemical engineering from the University of Madras. Dr. Palani is a CFA® Charterholder. Dr. Palani is qualified to serve on the Board based his strong financial and investing background, significant experience in the biotech industry and experience in the fields of internal medicine, endocrinology and oncology.

Executive Officers

Our executive officers serve at the discretion of our Board. There are no arrangements or understandings between any of our executive officers and any other person pursuant to which he or she is or was to be selected as an officer. The following table sets forth the name and age of each executive officer as of March 20, 2024.

Name	Age	Title
Lara Sullivan, M.D.	51	Director, President and Chief Executive Officer
Pamela Connealy	62	Chief Financial Officer and Chief Operating Officer
Ken Kobayashi, M.D.	63	Chief Medical Officer

The following is a biographical summary of the experience of our executive officers:

Lara Sullivan, M.D. As Dr. Sullivan also serves on the Board, please see “Board of Directors” above for the biographical information about Dr. Sullivan, our President and Chief Executive Officer.

Pamela Connealy. Ms. Connealy has served as our Chief Financial Officer since July 2021 and as our Chief Financial Officer and Chief Operating Officer since March 2023. Ms. Connealy currently serves as a member of the board of directors and Chair of the audit committee of Orchestra BioMed, Inc., a biotechnology company. From November 2019 to July 2021, Ms. Connealy served as Chief Financial Officer and Chief Human Resources Officer at Immunovant, Inc., a biotechnology company. From August 2018 to November 2019, Ms. Connealy served as the Chief Financial Officer, Chief Operating Officer and Chief Human Resources Officer of Kiva, a San Francisco based nonprofit organization. From April 2014 to June 2018, Ms. Connealy served as Global Head of Talent at the Bill & Melinda Gates Foundation, focusing on talent management, compensation, benefits, and global mobility. From March 2012 to November 2013, she served as Vice President of Business Operations at Salesforce, a software company, and from March 2002 to April 2010, Ms. Connealy served as a Vice President and Corporate Officer at Genentech, a biotechnology company, with roles including Chief Financial Officer of Research and Development, Global Head of Procurement and other Commercial and Technology roles.

Ms. Connealy earned a B.S. in Chemistry from Gannon University and an M.B.A. in Finance from the University of St. Thomas in Houston, Texas.

Ken Kobayashi, M.D. Dr. Kobayashi is an experienced medical oncologist, clinical pharmacologist, and senior global life sciences executive with a deep background as a clinician-scientist, regulator, scientific diplomat, and drug developer across the US, Europe, Latin America, and Japan/Asia. From September 2022 to November 2023, Dr. Kobayashi served as President at Small Woods Biopharma Consulting, LLC. From June 2021 to September 2022, Dr. Kobayashi served as Senior Vice President, Clinical Development, at Kinnate Biopharma, a precision oncology company focused on the discovery, design and development of small molecule kinase inhibitors for difficult-to-treat, genomically defined cancers. From March 2019 to June 2021, Dr. Kobayashi served as Vice President, Early Oncology Development and Clinical Research, at Pfizer, a pharmaceutical and biotechnology corporation. From October 2016 to March 2019, Dr. Kobayashi served as Executive Director, Global Oncology Research and Development, at Daiichi Sankyo, Inc., a pharmaceutical company. His experience also includes roles at the National Cancer Institute and the FDA.

Dr. Kobayashi holds an AB from Washington University in St. Louis, Missouri and an M.D. from Northwestern University Medical School in Chicago, Illinois.

Director Independence

As our common stock is listed on the Nasdaq, our determination of the independence of directors is made using the definition of “independent director” contained in Nasdaq Rule 5605(a)(2). In addition, the rules of Nasdaq require that, subject to specified exceptions, each member of a listed company’s audit, compensation and nominating and governance committees be independent. A director will only qualify as an “independent director” if, in the opinion of that company’s board of directors, that person does not have a relationship that would interfere with the exercise of independent judgment in carrying out the responsibilities of a director. Additionally, compensation committee members and audit committee members must satisfy additional independence criteria under Nasdaq and SEC rules.

Our Board has undertaken a review of the independence of each director and considered whether each director has a material relationship with us that could compromise his or her ability to exercise independent judgment in carrying out his or her responsibilities. As a result of this review, our Board determined that, with the exception of our President and Chief Executive Officer, Dr. Sullivan, each member of our board of directors is an "independent director" as defined under the applicable rules and regulations of the SEC and the listing requirements and rules of Nasdaq. In making these determinations, our Board reviewed and discussed information provided by the directors and by us with regard to each director's business and personal activities and relationships as they may relate to us and our management, including the beneficial ownership of our common stock by each non-employee director and the transactions involving them described in the section titled "Certain Relationships and Related Party Transactions".

Leadership Structure of the Board of Directors

Our bylaws and corporate governance guidelines provide our Board with flexibility to combine or separate the positions of Chairperson of the Board and Chief Executive Officer and/or the implementation of a lead director in accordance with its determination that utilizing one or the other structure would be in the best interests of our company. Mr. Flavin currently serves as our Chairman of the Board.

As a general policy, our Board believes that separation of the positions of Chairman of the Board and Chief Executive Officer reinforces the independence of the board of directors from management, creates an environment that encourages objective oversight of management's performance and enhances the effectiveness of the Board as a whole. As such, Dr. Sullivan serves as our President and Chief Executive Officer while Mr. Flavin serves as our Chairman of the Board but is not an officer of our company. The Board has concluded that our current leadership structure is appropriate at this time. However, our Board continues to periodically review our leadership structure and may make such changes in the future as it deems appropriate.

Board of Directors' Role in Risk Oversight

One of the key functions of the Board is informed oversight of our risk management process. Our Board does not have a standing risk management committee, but rather administers this oversight function directly through the board of directors as a whole, as well as through its standing committees that address risks inherent in their respective areas of oversight. In particular, the Board is responsible for monitoring and assessing strategic risk exposure. Our Audit Committee has the responsibility to consider and discuss our major financial risk exposures and the steps our management has taken to monitor and control these exposures, including guidelines and policies to govern the process by which risk assessment and management is undertaken. Our Audit committee also oversees and continuously monitors our cybersecurity risk profile and assesses potential risk exposure. Our Audit Committee also monitors compliance with legal and regulatory requirements, in addition to oversight of the performance of our external audit function. Our Nominating and Corporate Governance Committee monitors the effectiveness of our corporate governance guidelines and risks associated with our governance practices, including those related to emerging topics such as human capital analysis and disclosures and our environmental, sustainability and governance efforts, progress and disclosures. Our Compensation Committee assesses and monitors whether any of our compensation policies and programs has the potential to encourage excessive risk-taking. Our Research & Development Committee provides guidance to management and the Board on matters relating to our research and development efforts and product pipeline.

Evaluation of the Board of Directors

The Board evaluates its performance and the performance of its committees and individual directors on an annual basis through an evaluation process administered by the Nominating and Corporate Governance Committee. The Board discusses each evaluation to determine what, if any, actions should be taken to improve the effectiveness of the Board or any committee thereof or of the directors.

Board Diversity Matrix

The table below provides information regarding certain diversity attributes of our directors as of March 20, 2024, with categories as set forth by Nasdaq Listing Rule 5605(f).

Board Diversity Matrix
Total Number of Directors: 8

	Female	Male	Non Binary	Did Not Disclose Gender
Part I: Gender Identity				
Directors	3	5	—	—
Part II: Demographic Background				
African American or Black	1	—	—	—
Alaskan Native or Native American	—	—	—	—
Asian	—	1	—	—
Hispanic or Latinx	—	—	—	—
Native Hawaiian or Pacific Islander	—	—	—	—
White	2	4	—	—
Two or More Races or Ethnicities	—	—	—	—
LGBTQ+	—	—	—	—
Did Not Disclose Demographic Background	—	—	—	—

Attendance of Directors at Board Meetings and Stockholder Meetings

Our Board held ten meetings during the year ended December 31, 2023. During 2023, each person currently serving as a director attended 75% or more of the total number of meetings of the Board and each committee of which he or she was a member. Each director is also encouraged and expected to attend our annual meetings of shareholders.

Committees of the Board of Directors

The Board has established four standing committees: Audit Committee, Compensation Committee, Nominating and Corporate Governance Committee and Research and Development Committee. Each committee operates pursuant to a written charter that has been approved by the Board. A copy of the current charter for each committee is available on our website at www.pyxisoncology.com by selecting the “Investors” link and then the “Corporate Governance” link.

The Audit Committee met six times in 2023, the Compensation Committee met eight times in 2023, the Nominating and Corporate Governance Committee met three times in 2023 and the Research & Development Committee met four times in 2023.

Committee Composition

Name	Audit Committee	Compensation Committee	Nominating and Corporate Governance Committee	Research and Development Committee
John Flavin	♟	♙		
Thomas Civik	♙	♟		
Darren Cline	♙		♟	
Jakob Dupont, M.D.		♙		♙
Freda Lewis-Hall, M.D.			♙	
Rachel Humphrey, M.D.		♙	♙	♟
Santhosh Palani, Ph.D., CFA				

♟ = Chairperson
♙ = Member

Dr. Palani is not yet appointed to any of the Board committees and may join any of the above committees in future, as deemed appropriate by the Board based on the recommendation of our Nominating and Corporate Governance Committee.

Audit Committee

Our Audit Committee oversees our corporate accounting and financial reporting processes. The Audit Committee charter defines the responsibilities of the Audit Committee, including:

- overseeing our corporate accounting and financial reporting processes and our internal controls over financial reporting;
- evaluating the independent public accounting firm's qualifications, independence and performance;
- engaging and providing for the compensation of the independent public accounting firm;
- pre-approving audit and permitted non-audit and tax services to be provided to us by the independent public accounting firm;
- reviewing and discussing with management and the independent auditor the results of the annual audit and the independent auditor's review of our quarterly financial statements
- reviewing our financial statements;
- reviewing our critical accounting policies and estimates;
- establishing procedures for complaints received by us regarding accounting, internal accounting controls or auditing matters, including for the confidential anonymous submission of concerns by our employees, and periodically reviewing such procedures, as well as any significant complaints received, with management;
- review and approve any transaction between us and any related person (as defined by the Securities Exchange Act of 1934, as amended, or the Exchange Act) in accordance with our related party transaction approval policy;
- overseeing our risk assessment and risk management policies and programs, including our code of business conduct and ethics and our compliance activities;
- overseeing cybersecurity, including measures to protect and improve our informational technology systems, and monitoring cybersecurity and data privacy risks associated with our activities and those of third parties we work with; and
- such other matters that are specifically designated to the Audit Committee by the Board from time to time.

The Audit Committee has been established in accordance with Section 3(a)(58(A) of the Exchange Act. Mr. Flavin has served as Chairman of the Audit Committee since May 2019. The other members of our Audit Committee are Mr. Civik and Mr. Cline. The Board has determined that each member of our Audit Committee is independent within the meaning of Rule 10A-3 under the Exchange Act. Our Board has also determined that Mr. Flavin is an "Audit Committee financial expert" as defined by the applicable SEC rules and has the requisite accounting or related financial management expertise and financial sophistication under the applicable rules and regulations of Nasdaq.

Compensation Committee

Our Compensation Committee oversees our compensation policies, plans and benefits program. The Compensation Committee charter defines the responsibilities of the Compensation Committee, including:

- reviewing and recommending policies relating to compensation and benefits of our officers and employees, including reviewing and approving corporate goals and objectives relevant to compensation of the Chief Executive Officer and other senior officers;
- evaluating the performance of the Chief Executive Officer and other senior officers in light of those goals and objectives;
- setting compensation of the Chief Executive Officer and other senior officers based on such evaluations;
- administering the issuance of equity awards under our equity-based incentive plans;
- reviewing and approving, for the Chief Executive Officer and other senior officers, employment agreements, severance agreements, consulting agreements and change in control or termination agreements; and
- such other matters that are specifically designated to the Compensation Committee by the Board from time to time.

Our Board has determined that each member of the Compensation Committee is independent under the Nasdaq listing standards and a "non-employee director" as defined in Rule 16b-3 promulgated under the Exchange Act.

Research and Development Committee

Our Research and Development Committee provides guidance to management and the Board on matters relating to our research and development efforts and product pipeline. The Research and Development Committee charter defines the responsibilities of the Research and Development Committee, including:

- evaluate risks associated with our preclinical studies, clinical trials and clinical development;
- reviewing our overall scientific, research and development strategy;
- assessing each of our program's and product candidates' progress;
- summarizing significant findings of our research and development efforts and product pipeline to the Board; and
- review and advise the Board on the scientific, medical, research and development aspects of any proposed material transactions.

Nominating and Corporate Governance Committee

Our Nominating and Corporate Governance Committee oversees and assists the Board in evaluating and recommending nominees for election as directors. The Nominating and Corporate Governance Committee charter defines the responsibilities of the Nominating and Corporate Governance Committee, including:

- identifying and evaluating candidates, including the nomination of incumbent directors for re-election and nominees recommended by stockholders, to serve on the Board;
- considering and making recommendations to the Board regarding changes to the size and composition of the Board;
- instituting plans or programs for the continuing education of the Board and orientation of new directors;
- establishing procedures to exercise oversight of, and oversee the performance evaluation process of, the Board and management;
- developing and making recommendations to the Board regarding corporate governance guidelines and matters, including emerging topics such as human capital analysis and disclosures and our environmental, sustainability and governance efforts, progress and disclosures; and
- overseeing periodic evaluations of the Board's performance, including committees of the Board.

Our Board has determined that each member of our Nominating and Corporate Governance Committee is independent under the applicable Nasdaq listing standards.

Our Nominating and Corporate Governance Committee also oversees compliance by the Company with certain legal and regulatory obligations applicable to the company and periodically reviews our policies and procedures, including:

- Corporate Disclosure Policy;
- Code of Business Conduct and Ethics;
- Insider Trading Policy;
- Clawback Policy;
- Related Persons Transaction Policy;
- independence of our directors;
- amended and restated certificate of incorporation; and
- amended and restated bylaws.

Board Membership Criteria and Nomination Process

The Board and the Nominating and Corporate Governance Committee will determine the appropriate characteristics, skills and experience for the board of directors as a whole and for its individual members. The Board and the Nominating and Corporate Governance Committee will consider the minimum general criteria set forth below, and may add any specific additional criteria with respect to specific searches, in selecting candidates and existing directors for service on the Board. An acceptable candidate may not fully satisfy all of the criteria, but is expected to satisfy nearly all of them. Our Board and our Nominating and Corporate Governance Committee believe that candidates for director should have certain minimum qualifications, including being able to read and understand basic financial statements, being over 21 years of age and having the highest personal integrity and ethics.

In considering candidates, our Board and Nominating and Corporate Governance Committee intend to consider such factors as possessing relevant expertise upon which to be able to offer advice and guidance to management, having sufficient time to devote to the affairs of Pyxis Oncology, demonstrated excellence in his or her field, having the ability to exercise sound business judgment and having the commitment to rigorously represent the long-term interests of our stockholders. Our Board and Nominating and Corporate Governance Committee review candidates for director nomination in the context of the current composition of the Board, the operating requirements of Pyxis Oncology and the long-term interests of our stockholders. In conducting this assessment, our Board and Nominating and Corporate Governance Committee consider diversity (including race/ethnicity and gender), age, skills, and such other factors as it deems appropriate given the current needs of the Board and Pyxis Oncology to maintain a balance of knowledge, experience and capability.

In the case of incumbent directors whose terms of office are set to expire, our Board and Nominating and Corporate Governance Committee review such directors' overall service to Pyxis Oncology during their term, including the number of meetings attended, level of participation, quality of performance, and any other relationships and transactions that might impair such directors' independence. In the case of new director candidates, our Board and Nominating and Corporate Governance Committee also determine whether the nominee must be independent for purposes of any stock exchange on which Pyxis Oncology's common stock is listed.

Our Nominating and Corporate Governance Committee will consider director candidates recommended by our stockholders and will apply the same standards in considering director candidates recommended by stockholders as it applies to other candidates. Once the Nominating and Corporate Governance Committee receives a recommendation from a stockholder, it may request additional information from the candidate about the candidate's independence, qualifications and other information that would assist the committee in evaluating the candidate, as well as certain information that must be disclosed about the candidate in our proxy statement, if nominated. Stockholders may also directly nominate a candidate for director by submitting the candidate's name, resume and biographical information to c/o Corporate Secretary, Pyxis Oncology, Inc., 321 Harrison Avenue, Boston, Massachusetts 02118, pursuant to the advance notice provisions of our bylaws.

Changes in Board of Directors Member Criteria

The Board and Pyxis Oncology wish to maintain a board of directors composed of members who can productively contribute to the success of Pyxis Oncology. From time to time, the Board and/or the Nominating and Corporate Governance Committee may change the criteria for board of director membership to maximize the opportunity to achieve this success. When this occurs, the Board and the Nominating and Corporate Governance Committee will evaluate existing members according to the new criteria. The Board may ask a director who no longer meets the complete criteria for board membership to adjust his or her committee assignments or resign from the Board.

Term Limits and Retirement Age

The Board does not believe it should limit the number of terms for which an individual may serve as a director or set a fixed retirement age. Directors who have served on the Board for an extended period of time are able to provide continuity and valuable insight into Pyxis Oncology, our operations and prospects based on their experience with, and understanding of, our history, policies and objectives. The Board believes that, as an alternative to term limits and retirement policies, it can ensure that the Board continues to evolve and adopt new ideas and viewpoints through the director nomination process described above.

Succession Planning

The Nominating and Corporate Governance Committee develops and periodically reviews with the Chief Executive Officer our plan for succession to the offices of our executive officers and makes recommendations to the Board with respect to the selection of appropriate individuals to succeed to these positions.

Compensation Committee Interlocks and Insider Participation

During the year ended December 31, 2023, none of the members of our Compensation Committee were or had been an officer or employee of us or any of our subsidiaries. In addition, none of our executive officers serves or has served as a member of the board of directors, compensation committee or other board committee performing equivalent functions of any entity that has one or more executive officers serving as one of our directors or on our Compensation Committee.

Corporate Governance Guidelines

The Board has adopted our Corporate Governance Guidelines which provide the framework for our corporate governance along with our amended and restated certificate of incorporation, bylaws, committee charters and other key governance practices and policies. Our Corporate Governance Guidelines cover a wide range of subjects, including the conduct of board meetings, independence and selection of directors, board membership criteria and board committee composition. The Corporate Governance Guidelines are available on our website at www.pyxisoncology.com by selecting the "Investors" link and then the "Corporate Governance" link.

Code of Business Conduct and Ethics

We have adopted a Code of Business Conduct and Ethics that applies to our directors and employees. The policy document is available on our website at www.pyxisoncology.com by selecting the "Investors" link and then the "Corporate Governance" link.

Prohibition on Hedging and Pledging of Company Securities

We have a policy that prohibits officers, directors and employees from engaging in hedging transactions, such as the purchase or sale of puts or calls, or the use of any other derivative instruments. Our officers, directors and employees are also prohibited from holding our securities in a margin account or pledging our securities as collateral for a loan.

Item 11. Executive Compensation.

Director Compensation

The Board engaged Pearl Meyer & Partners, LLC ("Pearl Meyer"), an independent compensation consultant, to provide advice on non-employee director compensation. Based on such review, the Board approved the non-employee director compensation program set forth below for 2023. This program did not change as compared to the 2022 program except with respect to the introduction of cash retainers for the Research and Development Committee.

Board Position	Annual Compensation
Board of Directors	
Board Cash Retainer - Non-Employee Directors	$ 30,000
Additional Chairman of the Board Cash Retainer	$ 30,000
Committee Member Cash Retainers	
Audit Committee	$ 7,500
Compensation Committee	$ 5,000
Nominating and Governance Committee	$ 4,000
Research and Development Committee	$ 5,000
Additional Committee Chair Cash Retainers	
Audit Committee	$ 15,000
Compensation Committee	$ 10,000
Nominating and Governance Committee	$ 8,000
Research and Development Committee	$ 5,000

In addition, our non-employee directors are eligible to receive an annual equity award and an equity award at the time the director joins the Board. The annual equity award for 2023 had a grant date fair value equal to $307,975, while the sign-on equity award had a grant date fair value equal to $505,650.

The vesting schedules for the non-employee director equity awards are as follows;

- The annual equity award will vest in full on the first anniversary of the grant date, subject to the director's continued service through the applicable vesting date; and
- The sign-on equity award vest in three equal installments beginning on the first anniversary of the vest commencement date, subject to the director's continued service through the applicable vesting date.

We also reimburse our directors for reasonable travel and other related expenses incurred in connection with their service on the Board.

2023 Summary Director Compensation Table

The following table sets forth information for the fiscal year ended December 31, 2023 regarding the compensation awarded to, earned by or paid to each of our non-employee directors serving during 2023. Dr. Sullivan also serves as a member of the Board, but does not receive any additional compensation for her service on the Board. Please see the "2023 Summary Compensation Table" within "Executive Compensation" for a summary of the compensation Dr. Sullivan received for her service as our President and Chief Executive Officer during 2023. As Dr. Palani was appointed to the Board in March 2024, he has been excluded from the compensation table below.

Name	Fees Earned or Paid in Cash ($)	Stock Awards ($) (2)(4)	Option Awards ($)(2)(3)	Total
John Flavin	$ 87,500	$ 307,975	—	$ 395,475
Thomas Civik	$ 52,500	$ 307,975	—	$ 360,475
Darren Cline	$ 49,500	$ 307,975	—	$ 357,475
Jakob Dupont, M.D. (1)	$ 32,617	$ —	$ 505,650 (1)	$ 538,267
Freda Lewis-Hall, M.D.	$ 34,000	$ 307,975	—	$ 341,975
Rachel Humphrey, M.D.	$ 58,938	$ 228,772 (5)	—	$ 287,710

(1) Dr. Dupont joined the Board on August 23, 2023 upon completion of the acquisition of Apexigen. The total stock options herein include Dr. Dupont's initial equity award granted upon his appointment to the Board.

(2) The following table summarizes the equity awards granted to our non-employee directors for their service on the Board during 2023 and the grant date fair values of such equity awards:

Name	Grant Date	Number of Shares Underlying Option Award Grants (#)	Number of Stock Award Grants (#)	Grant Date Fair Value of Option Award Grants ($)(3)	Grant Date Fair Value of Stock Award Grants ($)(4)
John Flavin	3/24/2023	—	139,355	—	$ 307,975
Thomas Civik	3/24/2023	—	139,355	—	$ 307,975
Darren Cline	3/24/2023	—	139,355	—	$ 307,975
Jakob Dupont, M.D.	9/22/2023	392,461	—	$ 505,650	$ —
Freda Lewis-Hall, M.D.	3/24/2023	—	139,355	—	$ 307,975
Rachel Humphrey, M.D.	3/24/2023	—	58,064	—	$ 228,772 (5)

(3) The amount reported in this column reflects the aggregate grant date fair value of the stock options granted for the fiscal year ended December 31, 2023, computed in accordance with FASB ASC Topic 718, *Compensation — Stock Compensation.* The assumptions used in calculating the grant date fair value of the stock options reported in this column are set forth in Note 14 – "Stock-Based Compensation" within our Notes to Financial Statements included in Part II, Item 8 of this Annual Report on Form 10-K. Whether, and to what extent, a non-employee director realizes value will depend on our actual operating performance, stock price fluctuations and the non-employee director's continued service on the Board.

(4) The amounts reported in this column reflect the aggregate grant date fair values of the restricted stock units ("RSUs") granted for the fiscal year ended December 31, 2023, computed in accordance with FASB ASC Topic 718, *Compensation — Stock Compensation,* calculated based on the number of shares of RSUs granted multiplied by the quoted closing market price of our common stock on the date of grant. These amounts do not reflect the actual economic value that may be realized by the non-employee director. Whether, and to what extent, a non-employee director realizes value will depend on our actual operating performance, stock price fluctuations and the non-employee director's continued service on the Board.

(5) During 2023, the Compensation Committee and the Board approved acceleration of the unvested RSUs previously granted to Dr. Humphrey and the amount reported includes $100,451 representing the fair value associated with the accelerated vesting of her 2023 RSU grant.

Director Outstanding Equity Awards at Fiscal Year-End 2023

The following table summarizes the equity awards that were outstanding as of December 31, 2023 for each of our non-employee directors serving during 2023:

Name	Options Awards (a) Number of Shares Underlying Unexercised Options (#)		Stock Awards Number of Unearned Shares, Units, or Other Rights That Have Not Vested (#)
John Flavin	57,916		139,355
Thomas Civik	57,916		139,355
Darren Cline	57,916		139,355
Jakob Dupont, M.D.	419,124	(b)	—
Freda Lewis-Hall, M.D.	57,916		139,355
Rachel Humphrey, M.D.	236,220		—

(a) Unexercised option awards represent both exercisable and unexercisable awards.

(b) Dr. Dupont joined the Board on August 23, 2023 upon completion of the acquisition of Apexigen. Pursuant to the Merger Agreement, each outstanding stock option issued by Apexigen to Dr. Dupont was assumed and converted into stock options to acquire Pyxis Oncology common stock, on substantially similar terms and conditions as were applicable under such Apexigen equity plan, or the Replacement Stock Options. Unexercised options for Dr. Dupont also includes 26,663 Replacement Stock Options in accordance with the Merger Agreement.

Executive Compensation

The following is a discussion and analysis of compensation arrangements of our named executive officers. As an "emerging growth company" as defined in the JOBS Act, we are not required to include a Compensation Discussion and Analysis section and have elected to comply with the scaled disclosure requirements applicable to emerging growth companies.

Overview

Our current executive compensation program is intended to align executive compensation with our business objectives and to enable us to attract, retain and reward executive officers who contribute to our long-term success. The compensation paid or awarded to our executive officers is generally based on the assessment of each individual's performance compared against the business objectives established for the fiscal year as well as our historical compensation practices. In the case of newly hired executive officers, their compensation is primarily determined based on the negotiations of the parties as well as our historical compensation practices. For 2023, the material elements of our executive compensation program were base salary, annual cash bonuses and equity-based compensation. Our board of directors engaged Pearl Meyer to assist with the evaluation of our executive compensation program.

This section provides a discussion of the compensation paid or awarded to our President and Chief Executive Officer and our two other most highly compensated executive officers as of December 31, 2023 and one former executive officer of the Company. We refer to these individuals as our "named executive officers". For 2023, our named executive officers were:

- Lara Sullivan, M.D., President and Chief Executive Officer;
- Pamela Connealy, Chief Financial Officer and Chief Operating Officer;
- Ken Kobayashi, M.D., Chief Medical Officer; and
- Jay Feingold, M.D., Ph.D., Former Chief Medical Officer.

Compensation of Named Executive Officers

Base Salary. Base salaries are intended to provide a level of compensation sufficient to attract and retain an effective management team, when considered in combination with the other components of our executive compensation program. The relative levels of base salary for our named executive officers are designed to reflect each executive officer's functional specialty and scope of responsibility and accountability with us. The Compensation Committee periodically reviews the base salaries of our executive officers, including our named executive officers, and adjusts (or, in the case of our Chief Executive Officer, may recommend adjustments for approval by the Board) as necessary to reflect changes in the scope of the executive officer's performance, contributions, responsibilities, prior salary level, position and market conditions. The annual base salary for each of Dr. Sullivan, Ms. Connealy, Dr. Kobayashi and Dr. Feingold for the fiscal year ended December 31, 2023 was $625,000, $473,000, $500,000 and $500,000 respectively. Please see the "Salary" column in the "2023 Summary Compensation Table" for the base salary amounts earned by the named executive officers in 2023.

Annual Cash Bonuses. Historically, we have provided our senior leadership team with short-term incentive compensation through our annual cash bonus plan. Annual bonus compensation holds executives accountable, rewards the executives based on actual business results and motivates our executive officers to achieve annual corporate and individual performance objectives. Our annual cash bonus plan provides cash incentive award opportunities for the achievement of annual performance goals established by the Board at the beginning of each fiscal year. Dr. Sullivan does not have individual performance objectives as she is viewed as more directly responsible for the achievement of our corporate objectives.

Each of our named executive officers are eligible to receive an annual performance cash bonus based on the achievement of pre-established corporate and, in the case of Ms. Connealy and Dr. Kobayashi, individual objectives as determined by the Board and our Compensation Committee, in consultation with the Pearl Myer and upon review of the recommendations of Dr. Sullivan for our other named executive officers. The payment of awards under the 2023 annual cash bonus plan applicable to the named executive officers was subject to the attainment of corporate goals for our President and Chief Executive Officer and a combination of corporate and individual goals, weighted 80% and 20%, respectively, for our other named executive officers. The corporate component of the annual cash bonus plan was determined based on a number of goals relating to (i) clinical development of our product pipeline, weighted 80%, (ii) preclinical support for our lead product candidates, weighted 10% and (iii) investor and business operations, weighted 10%. The individual goals for Ms. Connealy and Dr. Kobayashi were pre-established goals determined based on their functional areas of responsibility.

At the beginning of the performance year, each officer is assigned a target bonus opportunity expressed as a percentage of his or her base salary. Actual bonus payments may be higher or lower than the target bonus amount, as determined by the Board and the Compensation Committee, based on the achievement of the pre-established corporate and, if applicable, individual objectives. The target bonus opportunities, as a percentage of base salary, in 2023 for Dr. Sullivan, Ms. Connealy, Dr. Kobayashi and Dr. Feingold were 60%, 45%, 40% and 40%, respectively. Based on our 2023 performance, the Compensation Committee awarded payouts under our annual cash bonus program in a total payout of 100% of the target bonus opportunity.

In determining the amount of the annual cash bonuses, the Compensation Committee determines the level of achievement of the corporate goals and, if applicable, individual goals for the year. In determining the level of achievement for our named executive officers other than Dr. Sullivan, the Compensation Committee also reviews and considers the recommendations of Dr. Sullivan. These achievement levels are used to determine each named executive officer's bonus. Based on our 2023 performance, our Compensation Committee awarded payouts under our annual cash bonus program in a total payout of 100% of the target bonus opportunity for each of the continuing named executive officers. Dr. Feingold terminated employment with us prior to December 31, 2023 and, as such, did not receive an annual bonus for 2023.

Actual bonus amounts paid are reflected in the “Non-Equity Incentive Plan Compensation” column of the "2023 Summary Compensation Table" below.

Other Bonuses. From time to time the board of directors or the compensation committee or board may approve discretionary cash bonuses for our named executive officers based on individual performance, company performance or as otherwise determined appropriate. In April 2022, the Compensation Committee and the Board awarded Dr. Sullivan a one-time cash bonus of $200,000 subject to her continued employment for one year, which was paid in April 2023.

Equity Awards. To further align the interests of our executive officers with the interests of our stockholders and to further focus our executive officers on our long-term performance, we grant equity compensation to our named executive officers. In 2023, our named executive officers received equity grants in the form of RSUs with a combination of one-year and four-year vesting schedules. In connection with his appointment to Chief Medical Officer in November 2023, we also granted Dr. Kobayashi stock options that will vest upon the achievement of certain clinical milestones related to data disclosure for PYX-201. In addition, during 2023, the Compensation Committee granted RSUs to Dr. Sullivan and Ms. Connealy on September 7, 2023, with the RSUs vested as of the grant date.

Please see the “Outstanding Equity Awards at Fiscal 2023 Year-End” table for further information regarding the outstanding equity awards held by each of the named executive officers.

On March 24, 2023 and in accordance with the terms of the Pyxis Oncology, Inc. 2019 Equity and Incentive Plan (the “2019 Plan”), the Board approved a stock option repricing (the “Repricing”) where the exercise price of each outstanding stock option issued to our current employees prior to our IPO was reduced to $2.21 per share, the closing stock price on the date of approval by the Board. The Board believes that the Repricing was in the best interests of the Company, as the amended stock options provide added incentives to retain and motivate key contributors to the Company without incurring the stock dilution resulting from significant additional equity grants or significant additional cash expenditures resulting from additional cash compensation. The Board also believed that the Repricing better aligned the interests of the key contributors with our goals.

As a result of the Repricing, the exercise prices for the following options held by each of the named executive officers were adjusted to $2.21 per share: Dr. Sullivan, 1,052,286 stock options; Ms. Connealy, 332,569 stock options; and Dr. Feingold, 174,774 stock options (of which 126,765 were forfeited upon Dr. Feingold’s resignation). Except for the reduction in the exercise prices, all outstanding stock options will continue to remain outstanding in accordance with their current terms and conditions as set forth in the 2019 Plan and the applicable award agreements.

Upon Dr. Feingold's registration, all unvested options and RSUs granted to Dr. Feingold were canceled on his termination date. Additionally, all vested and unexercised options were subsequently forfeited 90 days after his termination date, in accordance with our equity incentive plans.

Clawback Policy

To comply with the Dodd-Frank Act and Nasdaq listing standards, we have adopted an incentive compensation recoupment policy, or "clawback" policy, which applies to our current and former executive officers, within the meaning of Section 10D of the Exchange Act and Rule 10D-1 promulgated thereunder, who were employed by us or a subsidiary of us during the applicable recovery period. Under the policy, in the event that the financial results upon which a cash or equity-based incentive award was predicated become the subject of a financial restatement that is required because of material non-compliance with financial reporting requirements, the Compensation Committee will conduct a review of awards covered by the policy and recoup any erroneously awarded incentive-based compensation to ensure that the ultimate payout gives retroactive effect to the financial results as restated. The policy covers any cash or equity-based incentive compensation award that was paid, earned or granted to a covered officer during the last completed three fiscal years immediately preceding the date on which we are required to prepare the accounting restatement.

2023 Summary Compensation Table

The following table shows information regarding the compensation of our named executive officers for services performed in the year ended December 31, 2023:

Name and Principal Position	Year	Salary	Bonus (2)	Stock Awards (3)	Option Awards (4)	Non-Equity Incentive Plan Compensation (5)	All Other Compensation (6)(7)(8)	Total
Lara Sullivan, M.D.	**2023**	$ 625,000	$ 200,000	$ 2,686,510	$ 546,091	$ 375,000	$ 9,900	$ 4,442,501
President and Chief Executive Officer	**2022**	$ 565,000	—	$ 4,150,745	—	$ 301,428	$ 9,900	$ 5,027,073
Pamela Connealy	**2023**	$ 473,000	—	$ 923,684	$ 187,975	$ 226,800	$ 9,900	$ 1,821,359
Chief Financial Officer and Chief Operating Officer	**2022**	$ 430,000	—	$ 1,341,246	—	$ 245,466	$ 9,900	$ 2,026,612
Ken Kobayashi, M.D.	**2023**	$ 49,242	—	—	812,140	$ 18,630	$ —	$ 880,013
Chief Medical Officer	**2022**	—	—	—	—	—	—	—
Jay Feingold, M.D., Ph.D. [(1)]	**2023**	$ 229,167	—	$ 538,089	$ 97,081	—	$ 286,188	$ 1,053,444
Former Chief Medical Officer	**2022**	$ 500,000	—	$ 1,663,145	—	$ 220,400	$ 9,900	$ 2,393,445

(1) Dr. Feingold resigned as Chief Medical Officer effective June 15, 2023. As he terminated employment with us prior to December 31, 2023, he did not receive an annual bonus for 2023. Additionally, all stock awards granted to Dr. Feingold in 2023 were forfeited upon his termination date.

(2) In April 2022, the Compensation Committee and the Board awarded Dr. Sullivan a one-time cash bonus of $200,000 subject to her continued employment for one year, which was paid in April 2023.

(3) The amounts reported in this column reflect the aggregate grant date fair values of the RSUs granted for the fiscal year ended December 31, 2023, computed in accordance with FASB ASC Topic 718, *Compensation — Stock Compensation,* calculated based on the number of shares of RSUs granted multiplied by the quoted closing market price of our common stock on the date of grant. These amounts do not reflect the actual economic value that may be realized by the named executive officers.

(4) The amounts reported in this column represent the incremental fair value associated with the repricing of outstanding stock options granted to our named executive officers prior to our IPO, computed as of the repricing date in accordance with FASB ASC Topic 718, and do not represent a new option award granted to the named executive officer. The assumptions used in calculating the fair value of the stock options due to repricing reported in this column are set forth in Note 14 – "Stock-Based Compensation" within our Notes to Financial Statements included in Part II, Item 8 of this Annual Report on Form 10-K.

(5) The amounts reported in this column for 2023 represent annual incentive bonuses that were paid based on the achievement of corporate and, in the case of Ms. Connealy and Dr. Kobayashi, individual performance goals in 2023. Please see the description above under "Annual Cash Bonuses" for further information regarding the 2023 bonuses.

(6) All Other Compensation for Dr. Feingold consists of $270,833 and $5,455 paid as severance and continuation of health coverage under the Consolidated Omnibus Budget Reconciliation Act of 1985 ("COBRA"), respectively, pursuant to his employment agreement, as detailed below in "Employment Agreements."

(7) The amounts reported in this column for Dr. Sullivan, Ms. Connealy, and Dr. Feingold reflect the matching 401(k) contribution paid by us on their behalf in the amount of $9,900 for 2023.

(8) In accordance with SEC rules, the compensation described in this table does not include various health and welfare or other benefits received by our named executive officers that were generally available to all of our regular, full-time employees, as well as certain perquisites and other benefits received by our named executive officers that, in the aggregate, were less than $10,000 for any officer.

Outstanding Equity Awards at 2023 Fiscal Year-End

The following table presents information regarding the outstanding equity awards held by each of the named executive officers as of December 31, 2023. As Dr. Feingold had no awards outstanding as of December 31, 2023, he is excluded from the "Outstanding Equity Awards at 2023 Fiscal Year-End" table below.

			Option Awards (1)				Stock Awards	
Name	Grant Date	Footnote	Number of Securities Underlying Unexercised Options Exercisable (#)	Number of Securities Underlying Unexercised Options Unexercisable (#)	Option Exercise Price ($/Share)	Option Expiration Date	Number of Shares or Units of Stock That Have Not Vested (#)	Market Value of Shares or Units of Stock That Have Not Vested ($) (2)
Lara Sullivan, M.D.	3/31/2021	(3), (4)	990,461	—	$ 2.21	3/31/2031	—	—
	9/14/2021	(3), (5)	33,488	28,337	$ 2.21	9/14/2031	—	—
	10/7/2021	(6)	347,493	614,796	$ 16.00	10/7/2031	—	—
	3/31/2022	(7)	—	—	—	—	417,698	$ 751,856
	3/24/2023	(8)	—	—	—	—	703,379	$ 1,266,082
Pamela Connealy	7/31/2021	(3), (9)	194,701	127,564	$ 2.21	7/31/2031	—	—
	9/15/2021	(3), (5)	5,581	4,723	$ 2.21	9/15/2031	—	—
	12/6/2021	(10)	31,987	20,957	$ 9.64	12/6/2023	—	—
	3/31/2022	(7)	—	—	—	—	139,233	$ 250,619
	3/24/2023	(8)	—	—	—	—	209,803	$ 377,645
Ken Kobayashi, M.D.	12/29/2023	(11)	—	443,514	$ 1.80	12/29/2033	—	—
	12/29/2023	(12)	—	110,878	$ 1.80	12/29/2033	—	—

(1) Unexercised option awards represent both vested and unvested option awards.

(2) The market value of shares that have not vested reflects a stock price of $1.80, our closing stock price on December 29, 2023, the last trading day of fiscal year 2023.

(3) In accordance with the terms of the 2019 Plan, the Board approved a stock option repricing pursuant to which option awards granted prior to our IPO under the 2019 Plan were amended to reduce the exercise price to $2.21 per share, the closing stock price on the date of Board approval. Except for the modified exercise price, all other terms and conditions of each of the option awards will continue as set forth in the 2019 Plan and the applicable award agreements.

(4) These stock options vest in 48 substantially-equal monthly installments beginning January 2, 2020, subject to the named executive officer's continued employment through the applicable vesting date.

(5) These stock options vested 25% on the first anniversary of the closing of the initial public offering, and then vest in 36 substantially-equal monthly installments thereafter, subject to the named executive officer's continued employment through the applicable vesting date.

(6) Two-thirds of these stock options vested 25% on the first anniversary of the grant date, and then vest in 36 substantially-equal monthly installments thereafter, and one-third of these stock options vest in full on the fourth anniversary of the grant date, in each case, subject to the named executive officer's continued employment through the applicable vesting date.

(7) These RSUs vested 25% on the first anniversary of March 31, 2022, and then vest in 12 substantially-equal quarterly installments thereafter, subject to the named executive officer's continued employment through the applicable vesting date.

(8) These RSUs vested 25% on the first anniversary of March 24, 2023, and then vest in 12 substantially-equal quarterly installments thereafter, subject to the named executive officer's continued employment through the applicable vesting date.

(9) These stock options vested 25% on the first anniversary of July 31, 2021, and then vest in 36 substantially-equal monthly installments thereafter, subject to the named executive officer's continued employment through the applicable vesting date.

(10) These stock options vested 25% on July 19, 2022, and then vest in 36 substantially-equal monthly installments thereafter, subject to the named executive officer's continued employment through the applicable vesting date.

(11) The shares subject to this option will vest over four years, with 25% vesting on November 27, 2024 and the remainder vesting in 36 equal monthly installments thereafter, subject to the named executive officer's continued employment through the applicable vesting date.

(12) The shares subject to this option will vest upon the achievement of certain clinical milestones related to data disclosure for PYX-201.

Employment Agreements, Severance and Change in Control Agreements

Lara Sullivan, M.D.

We entered into an employment letter agreement with Dr. Sullivan in October 2019, which was subsequently amended in connection with our IPO and again in October 2022. Under the terms of the amended letter agreement, in the event that Dr. Sullivan is terminated by us for any reason other than for "cause" or she terminates her employment for "good reason", she will be entitled to receive, upon execution and effectiveness of a release of claims, base salary for a period of twelve (12) months and up to twelve (12) months of continued health insurance coverage at the Company's expense. In addition, in the event of termination by us for any reason other than for "cause" or due to "good reason" within three (3) months before or twelve (12) months following a change of control of Pyxis Oncology, subject to the execution and non-revocation of a release of claims, (i) Dr. Sullivan will receive a cash payment in an amount equal to the sum of eighteen (18) months' base salary and Dr. Sullivan's target annual bonus, payable in a lump sum on the 60th day following such termination of employment, unless required to be paid in installments to comply with Section 409A of the Code, (ii) up to twelve (12) months of continued health insurance coverage at our expense and (iii) any unvested portions of the option awards granted to Dr. Sullivan will immediately vest in full on the date of termination. Dr. Sullivan's amended letter agreement also provides for any unvested portion of stock options and stock awards granted to fully vest in the event of a change in control in which neither Pyxis Oncology nor its successor entity (if applicable) assumes, substitutes or continues the unvested portion of such award. In the event that we terminate Dr. Sullivan with "cause" or she resigns without "good reason", then she will not be entitled to receive severance benefits. Dr. Sullivan's letter agreement also contains IP assignment obligations.

Pamela Connealy

We entered into an employment letter agreement with Ms. Connealy in June 2021, which was subsequently amended in connection with our IPO and again in November 2022. Under the terms of the amended letter agreement, in the event that Ms. Connealy is terminated by us without "cause" or due to disability or she terminates her employment for "good reason", she will be entitled to receive, upon execution and effectiveness of a release of claims, base salary for a period of nine (9) months and up to nine (9) months of COBRA premiums. In addition, in the event of termination by us for any reason other than for "cause" or Ms. Connealy's resignation due to "good reason" within three (3) months before or twelve (12) months following a change of control of Pyxis Oncology, Ms. Connealy will receive a lump sum payment equal to twelve (12) months of base salary plus Ms. Connealy's target annual bonus, payable in a single lump sum on the 60th day following such termination of employment, and up to twelve (12) months of COBRA premiums. Ms. Connealy's amended letter agreement also provides for any unvested portion of stock options and stock awards granted to fully vest in the event of a change in control in which neither Pyxis Oncology nor its successor entity (if applicable) assumes, substitutes or continues the unvested portion of such award. Under the terms of the amended letter agreement, if the payments and benefits to Ms. Connealy under the amended letter agreement or another plan, arrangement or agreement would subject her to the excise tax imposed by Section 4999 of the Internal Revenue Code, then such payments will be reduced by the minimum amount necessary to avoid such excise tax, but only if such reduction will result in Ms. Connealy receiving a higher net after-tax amount.

Ken Kobayashi, M.D.

We entered into an employment letter agreement with Dr. Kobayashi in November 2023, in connection with his appointment to the position of Chief Medical Officer. Under the terms of the employment letter agreement, in the event that Dr. Kobayashi is terminated by us without "cause" or due to disability or he terminates his employment for "good reason", he will be entitled to receive, upon execution and effectiveness of a release of claims, base salary for a period of nine (9) months and up to nine (9) months of continued health insurance coverage at our expense. In addition, in the event of termination by us for any reason other than for "cause" or Dr. Kobayashi's resignation due to "good reason" within three (3) months before or twelve (12) months following a change of control of Pyxis Oncology, Dr. Kobayashi will receive a lump sum payment equal to twelve (12) months of base salary plus Dr. Kobayashi's target annual bonus, payable in a single lump sum on the 60th day following such termination of employment, and up to twelve (12) months of continued health insurance coverage at our expense. Dr. Kobayashi's employment letter agreement also provides for any unvested portion of stock options and stock awards granted to fully vest in the event of a change in control in which neither Pyxis Oncology nor its successor entity (if applicable) assumes, substitutes or continues the unvested portion of such award. Under the terms of the amended letter agreement, if the payments and benefits to Dr. Kobayashi under the employment letter agreement or another plan, arrangement or agreement would subject him to the excise tax imposed by Section 4999 of the Code, then such payments will be reduced by the minimum amount necessary to avoid such excise tax, but only if such reduction will result in Dr. Kobayashi receiving a higher net after-tax amount.

Jay Feingold, M.D., Ph.D.

Dr. Feingold resigned as Chief Medical Officer in June 2023. In connection with Dr. Feingold's termination, pursuant to his employment letter agreement with us, Dr. Feingold received a separation payment of $270,833 and COBRA premiums with a value of $5,455.

Retirement Plan

We maintain the Pyxis Oncology 401(k) Plan (the “401(k) Plan”), a qualified 401(k) savings plan that provides participants with an opportunity to save for retirement on a tax advantaged basis. Eligible employees, including our named executive officers, are able to contribute 100% of his or her eligible compensation up to the maximum amount allowed under Internal Revenue Service guidelines. Currently, we match 50% of each eligible employee's contributions up to 6% of total eligible compensation. Contributions are allocated to each participant’s individual account and are then invested in selected investment alternatives according to the participants’ directions. The 401(k) Plan currently does not offer the ability to invest in our securities. Employees are immediately and fully vested in their contributions.

Employee Stock Purchase Plan

We maintain an employee stock purchase plan (the “ESPP”), which is designed to allow our eligible employees to purchase shares of our common stock at designated intervals at a discounted price of 15% through payroll deductions or other contributions. Employees who are United States tax residents may benefit from favorable tax treatment as the ESPP is intended to quality as an employee stock purchase plan under Section 432 of the Code.

Compensation Risk Assessment

We conducted an assessment of the risks associated with our compensation practices and policies, and determined that risks arising from such policies and practices are not reasonably likely to have a material adverse effect on us. In conducting the assessment, we undertook a review of our compensation philosophies, our compensation governance structure and the design and oversight of our compensation programs. Overall, we believe that our programs include an appropriate mix of fixed and variable features, and short- and long-term incentives with compensation-based goals aligning with corporate goals.

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

The following table sets forth certain information with respect to the beneficial ownership of our common stock as of March 20, 2024:

- each person, or group of affiliated persons, known by us to beneficially own more than 5% of our common stock;
- each of our directors;
- each of our named executive officers; and
- all directors and executive officers as a group.

Beneficial ownership is determined in accordance with the rules of the SEC. Under such rules, beneficial ownership includes any shares over which the individual has sole or shared voting power or investment power as well as any shares that the individual has the right to acquire within 60 days of March 20, 2024, through the exercise of any option, warrant or other right. In computing the percentage beneficial ownership of a person, common stock not outstanding and subject to options, warrants or other rights held by that person that are currently exercisable or exercisable within 60 days of March 20, 2024 are deemed outstanding for purposes of calculating the percentage ownership of that person, but are not deemed outstanding for computing the percentage ownership of any other person. Subject to the foregoing, percentage of beneficial ownership is based on 58,133,375 shares of common stock outstanding as of March 20, 2024.

To our knowledge, except as set forth in the footnotes to this table and subject to applicable community property laws, each person named in the table has sole voting and investment power with respect to the shares set forth opposite such person's name. Except as otherwise indicated, the address of each of the persons in this table is c/o Pyxis Oncology, Inc., 321 Harrison Avenue, Boston, Massachusetts 02118.

Name of Beneficial Owner	Number of Shares of Common Stock Beneficially Owned	Percentage of Shares of Common Stock Beneficially Owned
5% Stockholders:		
Entities affiliated with Pfizer Inc. (1)	7,032,770	12.1%
Ridgeback Capital Investments L.P. (2)	5,956,443	9.97%
Deep Track Biotechnology Master Fund, Ltd. (3)	4,184,100	7.2%
Laurion Capital Management LP (4)	3,861,179	6.6%
Directors and Executive Officers:		
Lara Sullivan, M.D. (5)	3,074,713	5.2%
Pamela Connealy (6)	801,477	1.4%
John Flavin (7)	416,407	*
Thomas Civik (8)	260,497	*
Darren Cline (9)	254,797	*
Freda Lewis-Hall, M.D. (10)	244,797	*
Rachel Humphrey, M.D. (11)	136,804	*
Jakob Dupont, M.D. (12)	26,663	*
All executive officers and directors as a group (8 persons) (13)	5,216,155	8.8%

* Indicates beneficial ownership of less than 1% of the outstanding shares of our common stock.

(1) Based on a Schedule 13G/A filed on February 13, 2023 by Pfizer Inc. ("Pfizer") and Pfizer Ventures (US) LLC ("PVUS"), with Pfizer reporting sole voting and dispositive power over 4,140,669 shares and each of Pfizer and PVUS reporting shared voting and dispositive power over 1,080,507 shares and the Form 4 and Form 4/A filed on March 21, 2023 and March 23, 2023, respectively, with Pfizer reporting additional securities acquired of 1,811,594. The address for Pfizer and PVUS is 66 Hudson Boulevard East, New York NY 10001.

(2) Based on (i) a Schedule 13G filed on January 26, 2024 by Ridgeback Capital Investments L.P. ("RCILP"), with RCILP, Ridgeback Capital Investments LLC ("RCI"), and Ridgeback Capital Management LLC ("RCM") reporting shared voting and dispositive power over 4,345,228 shares and (ii) the purchase of Pre-Funded Warrants in the Private Placement transaction, pursuant to the terms of a securities purchase agreement dated February 26, 2024 between us and certain purchasers named therein, which closed on February 29, 2024. The address for RCILP, RCI, and RCM is 30 Star Island Drive, Miami, Florida, 33139.

(3) Based on the Schedule 13G filed on March 8, 2024, reflecting the purchase of common stock in the Private Placement transaction, pursuant to the terms of a securities purchase agreement dated February 26, 2024 between us and certain purchasers named therein, which closed on February 29, 2024. The address for Deep Track Biotechnology Master Fund, Ltd. ("Deep Track Master Fund") is 200 Greenwich Avenue, 3rd Floor Greenwich, Connecticut 06830

(4) Based on (i) a Schedule 13G filed on February 8, 2023 by Laurion Capital Management LP ("Laurion"), with Benjamin Alexander Smith ("Mr. Smith"), and Janaka Sheehan Maduraperuma ("Mr. Maduraperuma") each reporting shared voting and dispositive power over 3,170,803 shares and (ii) the purchase of common stock in the Private Placement transaction, in the Private Placement transaction, pursuant to the terms of a securities purchase agreement dated February 26, 2024 between us and certain purchasers named therein, which closed on February 29, 2024. The address for Laurion, Mr. Smith, and Mr. Maduraperuma is 360 Madison Avenue, Suite 1900, New York NY 10017.

(5) Consists of 1,630,006 shares of common stock held directly by Dr. Sullivan and 1,444,707 shares of common stock issuable upon the exercise of stock options and restricted stock exercisable or vesting within 60 days of March 20, 2024.

(6) Consists of 529,050 shares of common stock held directly by Ms. Connealy and 272,427 shares of common stock issuable upon the exercise of stock options and restricted stock exercisable or vesting within 60 days of March 20, 2024.

(7) Consists of 238,441 shares of common stock held directly by Mr. Flavin and 177,966 shares of common stock issuable upon the exercise of stock options and restricted stock exercisable or vesting within 60 days of March 20, 2024.

(8) Consists of 82,531 shares of common stock held directly by Mr. Civik and 177,966 shares of common stock issuable upon the exercise of stock options and restricted stock exercisable or vesting within 60 days of March 20, 2024.

(9) Consists of 76,831 shares of common stock held directly by Mr. Cline and 177,966 shares of common stock issuable upon the exercise of stock options and restricted stock exercisable or vesting within 60 days of March 20, 2024.

(10) Consists of 66,831 shares of common stock held directly by Dr. Lewis-Hall and 177,966 shares of common stock issuable upon the exercise of stock options and restricted stock exercisable or vesting within 60 days of March 20, 2024.

(11) Consists of 58,064 shares of common stock held directly by Dr. Humphrey and 78,740 shares of common stock issuable upon the exercise of stock options and restricted stock exercisable or vesting within 60 days of March 20, 2024.

(12) Consists of 26,663 shares of common stock issuable upon the exercise of stock options and restricted stock exercisable or vesting within 60 days of March 20, 2024.

(13) Consists of 2,681,754 shares of common stock held and 2,534,401 shares of common stock issuable upon the exercise of stock options and restricted stock exercisable or vesting within 60 days of March 20, 2024.

Equity Compensation Plan Information

Securities authorized for issuance under equity incentive plans

The following table summarizes information about our equity incentive plans as of December 31, 2023. All outstanding awards relate to our common stock.

	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 (1)(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:			
2019 Equity Incentive Plan	3,235,223	$ 2.45	52,299
2021 Equity Incentive Plan (2)	4,489,893	$ 14.15	537,772
2022 Equity Incentive Plan (3)	921,476	$ 9.17	77,326
2021 Employee Stock Purchase Plan (4)	—	—	565,405
Equity compensation plans not approved by security holders:			
2022 Inducement Plan	967,303	$ 1.94	346,443
Total	**9,613,895**	**$ 7.31**	**1,579,246**

(1) RSUs issued under the 2022 Inducement Plan, 2022 Equity Incentive Plan, 2021 Equity Incentive Plan and 2019 Equity Incentive Plan, which do not have an exercise price, are excluded in the calculation of weighted-average exercise price.

(2) The number of shares of common stock reserved for issuance under the 2021 Equity Incentive Plan will automatically increase annually on the first day of each fiscal year, beginning with the fiscal year ending December 31, 2022, and continuing until (and including) the fiscal year ending December 31, 2031 by the lesser of (i) 5% of the total number of shares of common stock outstanding on December 31st of the immediately preceding fiscal year and (ii) the number of shares as may be determined by the board of directors. On January 1, 2023, the number of shares of common stock available for issuance under the 2021 Equity Incentive Plan increased by 1,755,501 shares as a result of the evergreen provision.

(3) The number of shares of common stock reserved for issuance under the 2022 Equity Incentive Plan will automatically increase on January 1 of each calendar year, starting on January 1, 2023 through January 1, 2032, in an amount equal to the lesser of (i) 0.8625% of the total number of shares of common stock outstanding on the last day of the calendar month before the date of each automatic increase, (ii) 554,890 shares, or (iii) such number of shares determined by the administrator of the 2022 Plan. On January 1, 2023, the number of shares of common stock available for issuance under the 2022 Equity Incentive Plan increased by 554,890 shares as a result of the evergreen provision.

(4) The number of shares of common stock reserved for issuance under the 2021 Employee Stock Purchase Plan will automatically increase annually on the first day of each fiscal year, beginning with the fiscal year ending December 31, 2022, and continuing until (and including) the fiscal year ending December 31, 2031 by the lesser of (i) 110,080 shares, (ii) 1% of the total number of shares of common stock outstanding on December 31st of the immediately preceding fiscal year and (iii) the number of shares as may be determined by the board of directors. On January 1, 2023, the number of shares of common stock available for issuance under the 2021 Employee Stock Purchase Plan increased by 110,080 shares as a result of the evergreen provision.

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

The Audit Committee has the primary responsibility for the review and approval of any "related person transaction," which is any transaction, arrangement or relationship (or series of similar transactions, arrangements or relationships) in which we are, were or will be a participant and the amount involved exceeds $120,000, and in which the related person has, had or will have a direct or indirect material interest. We have adopted a formal, written policy which sets forth the policies and procedures for the review and approval or ratification of related person transaction by the Audit Committee. The Audit Committee will consider all relevant facts and circumstances, including but not limited to whether the transaction is on terms comparable to those that could be obtained in an arm's length transaction with an unrelated third party and the extent of the related person's interest in the transaction.

A related person transaction does not include the compensation arrangements with our directors and executive officers that are described elsewhere in this proxy statement. The related party transactions described below reflect all such transactions since January 1, 2022, and have all been approved pursuant to our existing related party transaction policy.

Pfizer, Inc. License Agreement

In December 2020, we entered into the Pfizer License Agreement, which was amended and became effective in March 2021. Pursuant to this agreement, we incurred a combined $25.0 million, consisting of an upfront cash payment of $5.0 million and the issuance of 12,152,145 shares of Series B convertible preferred stock, which was converted into 1,911,015 shares of its common stock upon our IPO in October 2021, with a value of $20.0 million to Pfizer. We are also obligated to pay future contingent payments and royalties under the Pfizer License Agreement.

On October 6, 2022, we entered into the A&R License Agreement, with Pfizer, which amends and restates the Pfizer License Agreement. In accordance with the terms of the A&R License Agreement, the Company issued 2,229,654 shares of its common stock in October 2022, paid $8.0 million to Pfizer in January 2023 and issued 1,811,594 shares of its common stock in March 2023.

Pfizer owns more than 10% of Pyxis Oncology and is considered the principal owner of our company. During the years ended December 31, 2023 and 2022, we incurred $0 and $17.2 million, respectively, of research and development expenses towards licensing fees.

The University of Chicago Agreement

In April 2020, we entered into the University License Agreement, as well as a sponsored research agreement, with the University. Under the terms of the license, we have the global right to develop and commercialize products that are covered by a valid claim of a licensed patent, incorporate or use the licensed know-how and materials or are known to assess, modulate or utilize the activity of certain specified biological targets. In partial consideration for the license from the University, we issued to the University 48,919 shares of its common stock in 2020.

Pursuant to the University License Agreement, we are obligated to pay potential development and commercial milestones of up to $7.7 million as well as running royalties on net sales of licensed products at varying rates ranging from less than a percent to the low single digits, subject to a minimum annual royalty of up to $3.0 million during certain years following the effective date. We are also obligated to pay the University a percentage of certain sublicensing revenue ranging from low- to mid-teens based on the date of entering into the applicable sublicense.

We incurred $0.2 million and $0.3 million for the years ended December 31, 2023 and 2022, respectively, with regards to the University License Agreement.

Voxall Joint Venture

In March 2021, we formed a joint venture company, Voxall, with Alloy to leverage our technology and Alloy's ATX-Gx™ platform and antibody discovery services. Both Allow and Pyxis Oncology contributed $50,000 each to Voxall along with certain license in 2021. We did not incur expenses during the years ended December 31, 2023 and 2022 with regards to Voxall. The board of directors of Voxall decided to dissolve the joint venture in February 2024.

See Note 20, Subsequent Events, within our Notes to Financial Statements included in Part II, Item 8 of this Annual Report on Form 10-K for further discussion of developments regarding Voxall subsequent to the balance sheet date and prior to the filing of this Annual Report on Form 10-K for the year ended December 31, 2023.

Item 14. Principal Accounting Fees and Services.

The following table presents fees for professional services rendered by Ernst & Young LLP ("EY"), our independent public accounting firm, for the years ended December 31, 2023 and 2022. EY has audited our financial statements since 2021.

	Fiscal Year 2023 ($)	Fiscal Year 2022 ($)
Audit fees	$ 864,377	$ 609,453
Audit-related fees	—	—
Tax fees	—	—
All other fees	—	—
Total fees	**$ 864,377**	**$ 609,453**

Audit fees consist of fees for professional services rendered for the annual audit of our consolidated financial statements included in our Annual Report on Form 10-K, reviews of the interim consolidated financial statements included in our Form 10-Q Quarterly Reports, consents and procedures related to our registration statements filed with the SEC, comfort letters for equity offerings, and services that are normally provided in connection with the consolidated financial statement audit.

There were no tax fees billed by EY for the years ended December 31, 2023 and 2022.

Determination of Independence

In considering the nature of the services provided by our independent registered public accounting firm, the Audit Committee determined that such services are compatible with the provision of independent audit services. The Audit Committee discussed these services with our independent registered public accounting firm and our management to determine that they are permitted under the rules and regulations concerning auditor independence.

Pre-Approval Policy

According to policies adopted by the Audit Committee and ratified by our board of directors, to ensure compliance with the SEC's rules regarding auditor independence, all audit and non-audit services to be provided by our independent registered public accounting firm must be pre-approved by the Audit Committee. 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 each service. The pre-approval of services may be delegated to one or more of the audit committee's members, but the decision must be reported to the full audit committee at its next scheduled meeting.

Our Audit Committee pre-approved all services provided by EY during the years ended December 31, 2023 and 2022 in accordance with this policy.

PART IV

Item 15. Exhibits, Financial Statement Schedules.

(1)For a list of the financial statements included herein and report of independent registered public accounting firm (PCAOB ID: 42), see *Index to the Consolidated Financial Statements* on page F-1 of this Annual Report on Form 10-K, incorporated into this Item by reference.

(2)Financial statement schedules have been omitted because they are either not required or not applicable or the information is included in the consolidated financial statements or the notes thereto.

(3)Exhibits:

Exhibit Number	Description	Form	File No.	Exhibit	Filing Date	Filed Herewith
2.1	Agreement and Plan of Merger, dated May 23, 2023, by and among Pyxis Oncology, Inc., Ascent Merger Sub Corp., and Apexigen Inc.	8-K	001-40881	2.1	May 24, 2023	
3.1	Amended and Restated Certificate of Incorporation of Pyxis Oncology, Inc.	10-Q	001-40881	3.1	November 15, 2021	
3.2	Amended and Restated Bylaws of Pyxis Oncology, Inc.	10-Q	001-40881	3.1	November 15, 2021	
4.1	Description of registrant's securities	10-K	001-40881	4.1	March 22, 2023	
4.2	Form of Pyxis Oncology Warrant #1 (common stock purchase warrant of Apexigen assumed by Pyxis Oncology in connection with the Merger on August 23, 2023)	POS AM	333-272510	4.2	August 23, 2023	
4.3	Form of Pyxis Oncology Warrant #2 (placement agent common stock purchase warrant of Apexigen assumed by Pyxis Oncology in connection with the Merger on August 23, 2023)	POS AM	333-272510	4.3	August 23, 2023	
4.4	Warrant Assumption Agreement, dated August 23, 2023, by and among Apexigen and Pyxis Oncology	POS AM	333-272510	4.4	August 23, 2023	
4.5	Amended and Restated Warrant Agreement, dated July 29, 2022, by and between Brookline Capital Acquisition Corp. ("BCAC") and Continental Stock Transfer and Trust Company ("Continental") which includes a form of warrant certificate for the Pyxis Oncology Warrant #3 (warrant of BCAC assumed by Apexigen in connection with its business combination with BCAC, assumed by Pyxis Oncology in connection with the Merger on August 23, 2023	POS AM	333-272510	4.5	August 23, 2023	
4.6	Warrant Assignment, Assumption and Amendment Agreement, dated August 23, 2023, by and among Apexigen (as successor to BCAC), Pyxis Oncology and Broadridge Corporate Issuer Solutions, LLC (as successor to Continental).	POS AM	333-272510	4.6	August 23, 2023	
4.7	Form of Pyxis Oncology Warrant #4 (warrant of Epitomics, Inc. ("Epitomics") assumed by Apexigen in connection with its spin-out from Epitomics, assumed by Pyxis Oncology in connection with the Merger on August 23, 2023	POS AM	333-272510	4.7	August 23, 2023	
4.8	Form of Pre-Funded Warrant	8-K	001-40881	4.1	February 28, 2024	
10.1	Amended and Restated Investor Rights Agreement, dated March 5, 2021	S-1/A	333-259627	10.1	October 1, 2021	
10.2+	Form of Indemnification Agreement	S-1/A	333-259627	10.2	October 4, 2021	
10.3+	Employment Agreement between Pyxis Oncology, Inc. and Lara Sullivan, M.D.	S-1/A	333-259627	10.3	October 4, 2021	
10.4+	Pyxis Oncology, Inc. 2019 Equity Incentive Plan	S-8	333-260441	4.3	October 22, 2021	
10.5+	Pyxis Oncology, Inc. 2021 Equity Incentive Plan	S-8	333-260441	4.4	October 22, 2021	
10.6+	Pyxis Oncology, Inc. Employee Stock Purchase Plan	S-8	333-260441	4.5	October 22, 2021	
10.7†	License Agreement by and between Pyxis Oncology, Inc. and Pfizer Inc., dated December 8, 2020	S-1	333-259627	10.7	September 17, 2021	
10.8†	Amendment No. 1 to License Agreement by and between Pyxis Oncology, Inc. and Pfizer Inc., dated March 22, 2021	S-1	333-259627	10.8	September 17, 2021	
10.9†	Exclusive License Agreement between the University of Chicago and Pyxis Oncology for Cancer Immunotherapy Technology, dated April 16, 2020	S-1	333-259627	10.9	September 17, 2021	
10.10†	License Agreement between Pyxis Oncology, Inc. and LegoChem Biosciences Inc., dated December 1, 2020	S-1	333-259627	10.10	September 17, 2021	
10.11†	First Amendment to License Agreement between Pyxis Oncology, Inc. and LegoChem Biosciences Inc., dated February 25, 2021	S-1	333-259627	10.11	September 17, 2021	
10.12†	Opt-In, Investment and Additional Consideration Agreement between Pyxis Oncology, Inc. and LegoChem Biosciences, Inc., dated December 1, 2020	S-1	333-259627	10.12	September 17, 2021	
10.13	Amendment to Opt-In, Investment and Additional Consideration Agreement between Pyxis Oncology, Inc. and LegoChem Biosciences, Inc., dated August 2, 2021	S-1/A	333-259627	10.13	October 1, 2021	

10.14†	Collaboration Agreement by and among Pyxis Oncology, Inc., Alloy Therapeutics, Inc. and Voxall Therapeutics, LLC., dated March 30, 2021	S-1/A	333-259627	10.14	October 1, 2021	
10.15	Lease by and between B9 LS Harrison & Washington LLC and Pyxis Oncology, Inc., dated September 29, 2021.	S-1/A	333-259627	10.15	October 1, 2021	
10.16+	Employment Agreement between Pyxis Oncology, Inc. and Pamela Connealy.	S-1/A	333-259627	10.16	October 4, 2021	
10.17+	Employment Agreement between Pyxis Oncology, Inc. and Jay Feingold, M.D.	S-1/A	333-259627	10.17	October 4, 2021	
10.18†	License Agreement, dated March 28, 2022 between the registrant and Biosion USA, Inc.	10-Q	001-40881	10.1	May 13, 2022	
10.19†	Amended and Restated License Agreement by and between Pyxis Oncology, Inc. and Pfizer Inc., dated October 6, 2022	10-Q	001-40881	10.1	November 1, 2022	
10.20†	Letter Agreement by and between Pyxis Oncology, Inc. and Pfizer Inc., dated October 14, 2022	10-Q	001-40881	10.2	November 1, 2022	
10.21+	Amended Employment Agreement between Pyxis Oncology, Inc. and Lara Sullivan, M.D.	10-K	001-40881	10.21	March 22, 2023	
10.22+	Amended Employment Agreement between Pyxis Oncology, Inc. and Pamela Connealy	10-K	001-40881	10.22	March 22, 2023	
10.23+	Amended Employment Agreement between Pyxis Oncology, Inc. and Jitu Wadhane	10-K	001-40881	10.23	March 22, 2023	
10.24	Amendment No. 1 dated March 16, 2023 to Amended and Restated License Agreement by and between Pyxis Oncology, Inc. and Pfizer Inc., dated October 14, 2022	10-K	001-40881	10.24	March 22, 2023	
10.25†	Amendment No. 1 to License Agreement, dated March 28, 2022 between the registrant and Biosion USA, Inc.	10-K	001-40881	10.25	March 22, 2023	
10.26†	Amendment No. 2 to License Agreement, dated March 28, 2022 between the registrant and Biosion USA, Inc.	10-K	001-40881	10.26	March 22, 2023	
10.27†	Amendment No. 3 to License Agreement, dated March 28, 2022 between the registrant and Biosion USA, Inc.	10-K	001-40881	10.27	March 22, 2023	
10.28†	Amendment No. 4 to License Agreement by and between Pyxis Oncology, Inc. and Biosion USA, Inc. Dated May 17, 2023	10-Q	001-40881	10.1	August 11, 2023	
10.29+	Apexigen, Inc. 2010 Equity Incentive Plan.	S-8 POS	333-272510	4.3	August 23, 2023	
10.30+	Apexigen, Inc. 2020 Equity Incentive Plan.	S-8 POS	333-272510	4.4	August 23, 2023	
10.31+	Apexigen, Inc. 2022 Equity Incentive Plan.	S-8 POS	333-272510	4.5	August 23, 2023	
10.32†	Securities Purchase Agreement, dated February 26, 2024, by and among Pyxis Oncology, Inc. and each of the purchasers as party thereto	8-K	001-40881	10.1	February 28, 2024	
10.33	Form of Registration Rights Agreement	8-K	001-40881	10.2	February 28, 2024	
10.34+†	Amended Employment Agreement between Pyxis Oncology, Inc. and Ken Kobayashi, M.D.					X
10.35	Dissolution Agreement by and among Pyxis Oncology, Inc., Alloy Therapeutics, Inc. and Voxall Therapeutics, LLC., dated February 6, 2024					X
21.1	List of Subsidiaries					X
23.1	Consent of Ernst & Young LLP, independent registered public accounting firm.					X
24.1	Power of Attorney (included on signature page to this Annual Report on Form 10-K)					X
31.1*	Certification of Principal Executive Officer Pursuant to Rules 13a-14(a) and 15d-14(a) under the Securities Exchange Act of 1934, as Adopted Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.					X
31.2*	Certification of Principal Financial Officer Pursuant to Rules 13a-14(a) and 15d-14(a) under the Securities Exchange Act of 1934, as Adopted Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.					X
32.1*	Certification of Principal Executive Officer Pursuant to 18 U.S.C. Section 1350, as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.					X
32.2*	Certification of Principal Financial Officer Pursuant to 18 U.S.C. Section 1350, as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.					X
97	Pyxis Oncology, Inc. Clawback Policy					X
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.					X
101.SCH	Inline XBRL Taxonomy Extension Schema with Embedded Linkbase Document					X
104	Cover Page Interactive Data File (embedded within the Inline XBRL document)					X

* The certifications furnished in Exhibits 32.1 and 32.2 hereto are deemed to accompany this Annual Report on Form 10-K and are not deemed “filed” for purposes of Section 18 of the Exchange Act, or otherwise subject to the liability of that section, nor shall they be deemed

incorporated by reference into any filing under the Securities Act or the Exchange Act, irrespective of any general incorporation language contained in such filing.

+ Indicates management contract or compensatory plan.

† Certain confidential information contained in this exhibit, marked by [***], has been omitted pursuant to Item 601(b)(10)(iv) of Regulation S-K.

Item 16. Form 10-K Summary

None.

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**.**

Pyxis Oncology, Inc.

Date: March 21, 2024

By: /s/ Lara Sullivan
Lara Sullivan, M.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 Lara Sullivan, M.D. and Pamela Connealy and each of them, as such person's true and lawful attorneys-in-fact and agents, with full power of substitution and resubstitution, for such person and in such person's name, place and stead, in any and all capacities, to sign any and all amendments (including post-effective amendments) to this Annual Report on Form 10-K and to file the same, with all exhibits thereto, and other documents in connection therewith, with the Securities and Exchange Commission, granting unto said attorneys-in-fact and agents, and each of them, full power and authority to do and perform each and every act and thing requisite and necessary to be done in connection therewith and about the premises, as fully to all intents and purposes as such person might or could do in person, hereby ratifying and confirming all that said attorneys-in-fact and agents, or any of them, or their or such person's substitute or substitutes, may lawfully 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/ Lara Sullivan **Lara Sullivan, M.D.**	President, Chief Executive Officer and Director *(Principal Executive Officer)*	March 21, 2024
/s/ Pamela Connealy **Pamela Connealy**	Chief Financial Officer and Chief Operating Officer *(Principal Financial Officer)*	March 21, 2024
/s/ Jitendra Wadhane **Jitendra Wadhane**	Chief Accounting Officer *(Principal Accounting Officer)*	March 21, 2024
/s/ John Flavin **John Flavin**	Chairman of the Board of Directors	March 21, 2024
/s/ Thomas Civik **Thomas Civik**	Director	March 21, 2024
/s/ Darren Cline **Darren Cline**	Director	March 21, 2024
/s/ Freda Lewis-Hall, M.D. **Freda Lewis-Hall, M.D.**	Director	March 21, 2024
/s/ Rachel Humphrey, M.D. **Rachel Humphrey, M.D.**	Director	March 21, 2024
/s/ Jakob Dupont, M.D. **Jakob Dupont, M.D.**	Director	March 21, 2024
/s/ Santhosh Palani, Ph.D., CFA **Santhosh Palani, Ph.D., CFA**	Director	March 21, 2024

PYXIS ONCOLOGY, INC.
INDEX TO CONSOLIDATED FINANCIAL STATEMENTS

Report of Independent Registered Public Accounting Firm

To the Stockholders and the Board of Directors of Pyxis Oncology, Inc.

Opinion on the Financial Statements

We have audited the accompanying consolidated balance sheets of Pyxis Oncology, Inc. (the Company) as of December 31, 2023 and 2022, the related consolidated statements of operations and comprehensive loss, stockholders' equity and cash flows for each of the two years in the period ended December 31, 2023, and the related notes (collectively referred to as the “consolidated financial statements”). In our opinion, the consolidated financial statements present fairly, in all material respects, the financial position of the Company at December 31, 2023 and 2022, and the results of its operations and its cash flows for each of the two years in the period ended December 31, 2023, in conformity with U.S. generally accepted accounting principles.

Basis for Opinion

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

We conducted our audits in accordance with the standards of the PCAOB. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement, whether due to error or fraud. The Company is not required to have, nor were we engaged to perform, an audit of its internal control over financial reporting. As part of our audits we are required to obtain an understanding of internal control over financial reporting but not for the purpose of expressing an opinion on the effectiveness of the Company's internal control over financial reporting. Accordingly, we express no such opinion.

Our audits included performing procedures to assess the risks of material misstatement of the financial statements, whether due to error or fraud, and performing procedures that respond to those risks. Such procedures included examining, on a test basis, evidence regarding the amounts and disclosures in the financial statements. Our audits also included evaluating the accounting principles used and significant estimates made by management, as well as evaluating the overall presentation of the financial statements. We believe that our audits provide a reasonable basis for our opinion.

/s/ Ernst & Young LLP

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

Boston, Massachusetts

March 21, 2024

PYXIS ONCOLOGY, INC.

Consolidated Balance Sheets
(In thousands, except share and per share amounts)

	December 31, 2023	December 31, 2022
Assets		
Current assets:		
Cash and cash equivalents	$ 9,664	$ 179,293
Marketable debt securities, short-term	109,634	—
Restricted cash	1,472	1,472
Prepaid expenses and other current assets	3,834	5,847
Total current assets	124,604	186,612
Property and equipment, net	11,872	11,165
Intangible assets, net	24,308	—
Operating lease right-of-use assets	12,942	13,602
Total assets	**$ 173,726**	**$ 211,379**
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable	$ 3,896	$ 7,097
Accrued expenses and other current liabilities	12,971	24,537
Operating lease liabilities, current portion	1,232	—
Deferred revenue	7,660	—
Total current liabilities	25,759	31,634
Operating lease liabilities, net of current portion	20,099	18,921
Deferred tax liability, net	2,164	—
Total liabilities	48,022	50,555
Commitments and contingencies (Note 19)		
Stockholders' equity:		
Preferred stock, par value $0.001 per share, 10,000,000 shares authorized; zero shares issued and outstanding	—	—
Common stock, $0.001 par value per share; 190,000,000 shares authorized; 44,754,853 and 35,110,016 shares issued as of December 31, 2023 and 2022, respectively, 44,754,853 and 34,958,730 shares outstanding as of December 31, 2023 and 2022, respectively	45	34
Additional paid-in capital	411,821	373,225
Accumulated other comprehensive income	63	—
Accumulated deficit	(286,225)	(212,435)
Total stockholders' equity	125,704	160,824
Total liabilities and stockholders' equity	**$ 173,726**	**$ 211,379**

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

PYXIS ONCOLOGY, INC.

Consolidated Statements of Operations and Comprehensive Loss
(In thousands, except share and per share amounts)

	Year Ended December 31,	
	2023	**2022**
Operating expenses:		
Research and development	$ 49,586	$ 86,129
General and administrative	32,610	37,352
Total operating expenses	82,196	123,481
Loss from operations	(82,196)	(123,481)
Other income, net:		
Interest and investment income	6,630	2,764
Sublease income	1,776	—
Total other income, net	8,406	2,764
Net loss	**$ (73,790)**	**$ (120,717)**
Net loss per common share - basic and diluted	$ (1.85)	$ (3.65)
Weighted average shares of common stock outstanding - basic and diluted	39,904,603	33,033,081
Other comprehensive income:		
Net unrealized gain on marketable debt securities	63	—
Other comprehensive income	63	—
Comprehensive loss	**$ (73,727)**	**$ (120,717)**

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

PYXIS ONCOLOGY, INC.

Consolidated Statements of Stockholders' Equity
(In thousands, except share amounts)

	Common Stock		Additional Paid-In Capital	Accumulated Other Comprehensive Income	Accumulated Deficit	Total Stockholders' Equity
	Shares	Amount				
Balance at December 31, 2022	**34,958,730**	**$ 34**	**$ 373,225**	**$ —**	**$ (212,435)**	**$ 160,824**
Issuance of common stock to Pfizer Inc. (Refer to Note 4)	1,811,594	2	4,998	—	—	5,000
Shares issued pursuant to at-the-market ("ATM") program, net of commission	1,001,208	1	6,121	—	—	6,122
Issuance of shares upon acquisition of Apexigen, Inc. ("Apexigen") (Refer to Note 3)	4,344,435	4	10,728	—	—	10,732
Stock options exercised	83,235	—	120	—	—	120
Issuance of restricted common stock, net of tax withholdings	2,476,301	4	(449)	—	—	(445)
Issuance of common stock under employee stock purchase plan ("ESPP")	79,350	—	132	—	—	132
Stock-based compensation	—	—	16,946	—	—	16,946
Net unrealized gain on marketable debt securities	—	—	—	63	—	63
Net loss	—	—	—	—	(73,790)	(73,790)
Balance at December 31, 2023	**44,754,853**	**$ 45**	**$ 411,821**	**$ 63**	**$ (286,225)**	**$ 125,704**

	Common Stock		Additional Paid-In Capital	Accumulated Other Comprehensive Income	Accumulated Deficit	Total Stockholders' Equity
	Shares	Amount				
Balance at December 31, 2021	**32,222,881**	**$ 32**	**$ 352,999**	**$ —**	**$ (91,718)**	**$ 261,313**
Issuance of common stock to Pfizer Inc. (Refer to Note 4)	2,229,654	2	4,279	—	—	4,281
Stock options exercised	73,841	—	183	—	—	183
Issuance of restricted common stock	432,354	—	—	—	—	—
Stock-based compensation	—	—	15,764	—	—	15,764
Net loss	—	—	—	—	(120,717)	(120,717)
Balance at December 31, 2022	**34,958,730**	**$ 34**	**$ 373,225**	**$ —**	**$ (212,435)**	**$ 160,824**

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

PYXIS ONCOLOGY, INC.

Consolidated Statements of Cash Flows
(In thousands)

	Year Ended December 31, 2023	2022
Operating activities		
Net loss	$ (73,790)	$ (120,717)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	1,927	709
Stock-based compensation	16,946	15,764
Non-cash research and development expenses	—	9,281
Non-cash lease expense	660	1,127
Accretion of discount on marketable debt securities	(4,788)	—
Changes in operating assets and liabilities:		
Prepaid expenses and other assets	2,532	(3,381)
Accounts payable	(3,507)	(8,328)
Accrued expenses and other current liabilities	(14,097)	11,951
Operating lease liabilities	2,410	4,259
Deferred revenue	998	—
Net cash used in operating activities	**(70,709)**	**(89,335)**
Investing activities		
Cash acquired in acquisition of Apexigen, Inc.	6,660	—
Redemption of marketable debt securities	92,048	—
Purchase of marketable debt securities	(196,831)	—
Purchase of property and equipment	(6,726)	(6,399)
Net cash used in investing activities	**(104,849)**	**(6,399)**
Financing activities		
Proceeds from shares issued under ATM, net of commission	6,122	—
Tax withholding payments related to net settlement of restricted common stock	(445)	—
Proceeds from the exercise of stock options	120	183
Proceeds from the sale of stock under employee stock purchase plan	132	—
Net cash provided by financing activities	**5,929**	**183**
Net decrease in cash, cash equivalents, and restricted cash	(169,629)	(95,551)
Cash, cash equivalents and restricted cash at beginning of year	180,765	276,316
Cash, cash equivalents and restricted cash at end of period	**$ 11,136**	**$ 180,765**
Supplemental cash flow information:		
Cash received for interest	$ 2,419	$ 2,166
Cash paid for taxes	$ 48	$ 17
Noncash operating, investing and financing activities:		
Shares, warrants, and replacement stock options and restricted stock units issued for acquisition of Apexigen, Inc.	$ 10,732	$ —
Property and equipment in accounts payable and accrued expenses	$ 237	$ 4,479
Operating lease right-of-use assets obtained in exchange for operating lease liabilities	$ —	$ 14,497
Issuance of common stock to Pfizer Inc. (Refer to Note 4)	$ 5,000	$ —
Reconciliation of cash, cash equivalents and restricted cash:		
Cash and cash equivalents	$ 9,664	$ 179,293
Restricted cash	1,472	1,472
Total cash, cash equivalents and restricted cash shown in the statement of cash flows	**$ 11,136**	**$ 180,765**

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

1. Description of Business

Nature of Business

Pyxis Oncology, Inc. (the "Company"), a Delaware corporation, was founded in June 2018 and launched its operations in July 2019. The Company is a clinical stage company focused on defeating difficult-to-treat cancers. The Company is efficiently building next-generation therapeutics that hold the potential for mono and combination therapies. The Company's therapeutic candidates are designed to kill tumor cells and to address the underlying pathologies created by cancer that enable its uncontrollable proliferation and immune evasion. The Company's antibody-drug conjugates ("ADCs") and immuno-oncology ("IO") programs employ novel and emerging strategies to target a broad range of solid tumors resistant to current standards of care.

The Company has one operating segment. The Company's chief operating decision maker, its Chief Executive Officer, manages the Company's operations on a consolidated basis for the purposes of assessing performance and allocating resources.

2. Basis of Presentation and Summary of Significant Accounting Policies

Basis of Presentation

The Company's fiscal year ends on December 31 and its first three quarters end on March 31, June 30 and September 30. The accompanying consolidated financial statements are prepared in conformity with accounting principles generally accepted in the United States of America ("GAAP"). Any reference in these notes to applicable guidance is meant to refer to the authoritative GAAP as found in the Accounting Standards Codification ("ASC") and Accounting Standards Updates ("ASU") of the Financial Accounting Standards Board ("FASB"). The consolidated financial statements include the Company and its wholly-owned subsidiaries. All intercompany balances and transactions have been eliminated upon consolidation.

The Company is an "emerging growth company," as defined in the Jumpstart Our Business Startups Act of 2012 (the "JOBS Act"). Section 107(b) of the JOBS Act provides that an emerging growth company can take advantage of an extended transition period for complying with new or revised accounting standards. Thus, an emerging growth company can delay the adoption of certain accounting standards until those standards would otherwise apply to private companies. The Company has irrevocably elected not to avail itself of this extended transition period, and, as a result, the Company will adopt new or revised accounting standards on the relevant dates on which adoption of such standards is required for other public companies.

Liquidity

As of December 31, 2023, the Company had an accumulated deficit of $286.2 million. The Company has incurred losses and negative cash flows from operations since inception, including net losses of $73.8 million and $120.7 million for the years ended December 31, 2023 and 2022, respectively.

The Company has not generated any revenues from product sales to date and does not anticipate generating any revenues from product sales unless and until it successfully completes development and obtains regulatory approval for its current or any future product candidates. The Company expects that its operating losses and negative cash flows will continue for the foreseeable future as the Company continues to expand its research and development programs and develop its product candidates.

The Company currently expects that its existing cash, cash equivalents and short-term investments of $119.3 million as of December 31, 2023 will fund its operating expenses and capital requirements at least twelve months from the date these audited consolidated financial statements are issued. Additional funding may be necessary to fund future clinical and preclinical activities.

The Company plans to continue to fund its losses from operations and capital funding needs through public or private equity, convertible or debt financing 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.

Use of Estimates

The preparation of consolidated financial statements in conformity with GAAP requires management to make estimates and assumptions that affect the reported amounts of assets, liabilities, expense, and related disclosures. The Company regularly evaluates estimates and assumptions related to assets, liabilities, stock-based compensation, operating leases, assessment of the useful lives of property and equipment, marketable debt securities, fair value of intangible assets and research and development costs, including clinical trial accruals. The Company bases its estimates and assumptions on historical experience and on various other factors that it believes 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 could differ from those estimates and there may be changes to management's estimates in future periods.

Risks and Uncertainties

The Company is subject to risks common to early-stage companies in the biopharmaceutical industry including, but not limited to, uncertainties related to commercialization of products, regulatory approvals, dependence on key suppliers for active ingredients and third-party service providers such as contract development and manufacturing organizations ("CDMOs"), protection of intellectual property rights and the ability to make milestone, royalty or other payments due under any license, collaboration or supply agreements.

Concentration of Credit Risks

Financial instruments which potentially subject the Company to significant concentration of credit risk consist of cash and cash equivalents, restricted cash and short-term investments.

The Company invests its excess cash primarily in money market funds and highly liquid U.S. Treasury securities. The Company has adopted an investment policy that includes guidelines relative to credit quality, diversification and maturities to preserve principal and liquidity.

Cash and Cash Equivalents

The Company considers all short term, highly liquid investments with original maturities of 90 days or less to be cash equivalents. Cash equivalents consist primarily of money market funds as of December 31, 2023 and 2022.

Investments

Short-term investments consist of U.S. Treasury securities with original maturities greater than three months. The Company may sell investments at any time for use in current operations even if the investments have not yet reached maturity. As a result, the Company classifies its investments as current assets. All investments have been classified as available-for-sale marketable debt securities. Marketable debt securities are recorded at fair value, with unrealized gains and losses, net of tax, included as a component of accumulated other comprehensive income (loss) in stockholders' equity and a component of total comprehensive loss in the consolidated statements of operations and comprehensive loss, until realized. The fair value of these securities is determined based upon quoted market prices at period end. Premiums paid or discounts received at the time of purchase of marketable securities, are amortized to interest and investment income over the terms of the related securities. Realized gains and losses are included in earnings and are derived using the specific identification method for determining the cost of securities sold.

At each reporting date the Company will evaluate available-for-sale marketable debt securities in an unrealized loss position, using the discounted cash flow model, to determine whether the unrealized loss or any potential credit losses should be recognized in net loss. For available-for-sale marketable debt securities in an unrealized loss position, the Company will assess (i) whether it intends to sell, or (ii) it is more likely than not that it will be required to sell the security before recovery of its amortized cost basis. If the aforementioned criteria is met, such marketable debt security's amortized cost basis will be written down to its fair value through earnings along with any existing allowance for credit losses. For available-for-sale marketable debt securities that do not meet this criteria, the Company will evaluate whether the decline in fair value has resulted from credit losses or other factors. In making this assessment, the Company considers the severity of the impairment, any changes in interest rates, underlying credit ratings, and forecasted recovery, among other factors. The credit-related portion of unrealized losses, and any subsequent improvements, are recorded as an allowance in interest income.

There have been no impairment or credit losses recognized during the periods presented in the accompanying consolidated statements of operations and comprehensive loss.

Fair Value Measurements

Certain assets and liabilities are carried at fair value under GAAP. Fair value is defined as the exchange price that would be received for an asset or paid to transfer a liability (an exit price) in the principle or most advantageous market for the asset or liability in an orderly transaction between market participants on the measurement date. Valuation techniques used to measure fair value must maximize the use of observable inputs and minimize the use of unobservable inputs. Financial assets and liabilities carried at fair value are to be classified and disclosed in one of the following three levels of the fair value hierarchy, the first two are considered observable and the last is considered unobservable:

***Level* 1**—Unadjusted quoted prices in active markets that are accessible at the measurement date for identical, unrestricted assets or liabilities;

***Level* 2**—Quoted prices in markets that are not considered to be active or financial instrument valuations for which all significant inputs are observable, either directly or indirectly; and

***Level* 3**—Prices or valuations that require inputs that are both significant to the fair value measurement and unobservable.

To the extent that the valuation is based on models or inputs that are less observable or unobservable in the market, the determination of fair value requires more judgment. Accordingly, the degree of judgment exercised by the Company in determining fair value is greatest for instruments categorized in Level 3.

Property and Equipment, net

Property and equipment are recorded at cost less accumulated depreciation and amortization. Depreciation and amortization expense is recognized using the straight-line method over the estimated useful lives of the related assets as follows:

	Estimated Useful Life (Years)
Laboratory equipment	3
Furniture and office equipment	3
Leasehold improvements	Shorter of remaining life of lease or useful life
Construction in process	N/A

Depreciation and amortization expense is included in research and development and general and administrative expenses. Major additions and upgrades are capitalized; maintenance and repairs, which do not improve or extend the life of the respective assets, are expensed as incurred. Upon retirement or sale, the cost of assets disposed of, and the related accumulated depreciation and amortization are removed from the respective accounts and any resulting gain or loss is included in income (loss) from operations.

Impairment of Long-Lived Assets

The Company evaluates its long-lived assets, which consist of property and equipment and operating lease right-of-use assets, whenever events or changes in circumstances indicate that the carrying value of an asset may not be recoverable. Factors that the Company considers in deciding when to perform an impairment review include significant underperformance of the business in relation to expectations, significant negative industry or economic trends, and significant changes or planned changes in the use of the assets. Management then determines whether the remaining useful life continues to be appropriate, or whether there has been an impairment of long-lived assets based primarily upon whether expected future undiscounted cash flows are sufficient to support the assets' recovery. Recoverability of these assets is measured by comparison of the carrying amount of the asset to the future undiscounted cash flows the asset is expected to generate. If the asset is considered to be impaired, the amount of any impairment is measured as the difference between the carrying value and the fair value of the impaired asset. The Company recognized no impairment losses for the years ended December 31, 2023 and 2022.

Business Combinations

The Company determines whether a transaction or other event is a business combination by determining whether the assets acquired and liabilities assumed constitutes a business. Business combinations are accounted for by applying the acquisition method as set out by ASC 805, *Business Combinations* ("ASC 805"). The acquisition method of accounting requires the acquirer to recognize and measure all identifiable assets acquired, liabilities assumed and any noncontrolling interest in the acquiree at their acquisition-date fair values, with certain exceptions for specific items.

Goodwill is measured as the excess of the consideration transferred in the business combination over the net acquisition date amounts of the identifiable assets acquired and the liabilities assumed. Alternatively, if the acquisition date amounts of the identifiable assets acquired and the liabilities assumed exceeds the consideration transferred, a gain on bargain purchase is recognized in the consolidated statements of operations and comprehensive loss. The consideration transferred in a business combination is measured as the sum of the fair values of the assets transferred, the liabilities incurred to former owners of the target and the equity interests issued.

The results of operations of businesses acquired by the Company are included in the Company's consolidated statements of operations and comprehensive loss from the respective acquisition date.

Where the acquirer exchanges its share-based payment awards for awards held by grantees of the acquiree, such exchanges are treated as a modification of share-based payment awards and are referred to as replacement awards. The replacement awards are measured as of the acquisition date and the portion of the fair-value-based measure of the replacement award that is attributable to pre-combination service is considered part of the consideration transferred. For awards with service-based vesting conditions only, the amount attributable to pre-combination service is the fair-value-based measure of the acquiree award multiplied by the ratio of the employee's pre-combination service period to the greater of the total service period or the original service period of the acquiree award.

Acquisition-related costs, including advisory, legal and other professional fees and administrative fees are expensed as incurred except for the costs of issuing equity securities, which are recognized as a reduction to the amounts recognized in the consolidated statements of stockholders' equity for the respective equity issuance.

Intangible Assets, Net

Acquired In-Process Research & Development

The Company's indefinite-lived intangible assets consist of in-process research and development ("IPR&D"), which were acquired in connection with the acquisition of Apexigen. IPR&D represents the fair value assigned to research and development projects acquired which are in-process, but not yet completed at the time of acquisition. The primary basis for determining the completion of these projects is obtaining regulatory approval to market the underlying products in an applicable geographic region.

The Company classifies IPR&D acquired in a business combination as an indefinite-lived intangible asset until the associated research and development efforts are either completed or abandoned. IPR&D becomes definite-lived upon the completion or abandonment of the associated research and development efforts. Indefinite-lived intangible assets are not amortized, but evaluated for impairment on an annual basis or more frequently if an indicator of impairment is identified. All research and development costs incurred subsequent to the acquisition of IPR&D are expensed as incurred.

Definite-Lived Intangible Assets

Definite-lived intangible assets are recorded at cost, net of accumulated amortization, and, if applicable, impairment charges. Definite-lived intangible assets consist of retained royalty rights under certain Apexigen agreements. The useful lives of these royalty rights are 3- and 13-years, which were determined based on the terms and conditions underlying the licensing agreements and the expected uses of the assets by the Company. Amortization of defined-lived intangible assets is recorded over the assets' estimated useful lives on a straight-line basis and is included as part of "Research and development" within the accompanying consolidated statements of operations and comprehensive loss.

Impairment of Intangible Assets

The Company evaluates its intangible assets, including both acquired IPR&D and definite-lived intangible assets, for impairment at least annually and whenever events or changes in circumstances indicate that the carrying value of an asset may not be recoverable. Factors that the Company considers in deciding when to perform an impairment review include significant underperformance of the business in relation to expectations, significant negative industry or economic trends, and significant changes or planned changes in the use of the assets. If the projected undiscounted cash flows of the intangible asset are less than the carrying amount, the intangible asset is written down to its fair value in the period in which the impairment occurs. The Company recognized no impairment losses for the year ended December 31, 2023. The Company had no intangible assets during the year ended December 31, 2022.

Leases

Operating lease right-of-use ("ROU") assets represent the Company's right to use an underlying asset during the lease term, and operating lease liabilities represent the Company's obligation to make lease payments arising from the lease. Operating lease ROU assets and lease liabilities are initially recognized and measured based on the present value of the future fixed lease payments over the expected lease term at the commencement date calculated using the Company's incremental borrowing rate applicable to the lease asset, unless the implicit rate is readily determinable. The Company determines the lease term as the non-cancelable period of the lease and may include options to extend or terminate the lease when it is reasonably certain that the Company will exercise that option. Operating lease ROU assets also include any initial direct costs incurred and any lease payments made on or before the lease commencement date, less lease incentives received. Operating lease ROU assets are subsequently measured throughout the lease term at the carrying amount of the lease liability, plus initial direct costs, plus (minus) any prepaid (accrued) lease payments, less the unamortized balance of lease incentives received. Leases with a term of 12 months or less are not recognized on the consolidated balance sheets. Lease expense for minimum lease payments is recognized on a straight-line basis over the lease term. Variable lease costs such as common area costs and other operating costs are expensed as incurred. The Company accounts for lease and non-lease components as a single lease component for all its facilities leases.

Investment in Joint Venture

Investment in the Company's joint venture is accounted for using the equity method of accounting. The Company applies the equity method of accounting to investments when the Company has significant influence, but not controlling interest in the investee. Judgment regarding the level of influence over equity method investment includes considering key factors such as ownership interest, representation on the board of directors, participation in policy-making decisions and material intercompany transactions. Under the equity method, investments are initially recorded at cost and are adjusted for dividends, distributed and undistributed earnings and losses, and additional investments. In the event the Company's share of a joint venture's cumulative losses exceeds the Company's investment balance, the balance is reported at zero value until proportionate income exceeds the losses. The Company assesses investments for impairment whenever events or changes in circumstances indicate that the carrying value of an investment may not be recoverable.

Warrants

The Company accounts for warrants to purchase shares of its common stock in accordance with the guidance in ASC 480, *Distinguishing Liabilities from Equity* ("ASC 480") and ASC 815, *Derivatives and Hedging* ("ASC 815"). The Company classifies warrants issued for the purchase of shares of its common stock as either equity or liability instruments based on an assessment of the specific terms and conditions of each respective contract. The assessment considers whether the warrants are freestanding financial instruments or embedded in a host instrument, whether the warrants meet the definition of a liability pursuant to ASC 480, whether the warrants meet the definition of a derivative under ASC 815, and whether the warrants meet all of the requirements for equity classification under ASC 815. This assessment, which requires the use of professional judgment, is conducted at the time of warrant issuance and as of each subsequent quarterly period end date while the warrants are outstanding.

For issued or modified warrants that meet all of the criteria for equity classification, the warrants are required to be recorded as a component of equity at the time of issuance. For issued or modified warrants that do not meet all the criteria for equity classification, the warrants are required to be recorded as liabilities at their initial fair value on the date of issuance, and each balance sheet date thereafter. Changes in the estimated fair value of the warrants classified as liabilities are recognized as a non-cash gain or loss in the consolidated statements of operations and comprehensive loss.

Contingencies

The Company, from time to time, may be a party to various disputes and claims arising from normal business activities. The Company continually assesses disputes and claims including resulting litigation to determine if an unfavorable outcome would lead to a probable loss or reasonably possible loss which could be estimated. The Company accrues for all contingencies at the earliest date at which the Company deems it probable that a liability has been incurred and the amount of such liability can be reasonably estimated. If the estimate of a probable loss is a range and no amount within the range is more likely than another, the Company accrues the minimum of the range. In the cases where the Company believes that a reasonably possible loss exists, the Company discloses the facts and circumstances of the contingencies, including an estimable range, if possible.

Revenue Recognition

The Company recognizes revenue based on guidance under ASC 606, *Revenue from Contracts with Customers* ("ASC 606"). Under ASC 606, revenue is recognized when the customer obtains control of the promised goods or services, at an amount that reflects the consideration the Company expects to receive in exchange for those goods or services. The Company has not commenced sales of its drug candidates and does not have any products approved for marketing as of December 31, 2023.

The Company may also earn contingent fees, including milestone payments, based on counterparty performance and royalties on sales, from collaborations and other out-license arrangements. The Company recognizes milestone payments as revenue once the underlying events are probable of being met and there is not a significant risk of reversal. The Company recognizes sales-based royalties as revenue when the underlying sales occur and there are no constrains to recognize the revenue for such sales-based royalties.

Research and Development Expenses

The Company expenses research and development costs as incurred. The Company's research and development expenses consist primarily of license fees to acquire intellectual property which does not meet the definition of intangible assets and costs incurred in performing research and development activities, including personnel-related expenses such as salaries, stock-based compensation and benefits, facilities costs, depreciation as well as external costs from third parties who conduct research and development activities (including manufacturing) on behalf of the Company. The Company accrues expenses related to development activities performed by third parties based on an evaluation of services received and efforts expended pursuant to the terms of the contractual arrangements. Payments under some of these contracts depend on preclinical and/or clinical trial milestones. There may be instances in which payments made to the Company's vendors will exceed the level of services provided and result in a prepayment of expenses. In accruing service fees, the Company estimates 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 the estimate, the Company adjusts the accrual or prepaid expense accordingly.

Stock-Based Compensation

The Company maintains an equity incentive plan as a long-term incentive for employees, consultants and directors. The Company accounts for all stock-based awards granted to employees and non-employees based on their fair value on the date of the grant and recognizes compensation expense for those awards over the requisite service period, which is generally the vesting period of the respective award. The grant date fair value of the stock-based awards with graded vesting is recognized on a straight-line basis over the requisite service period. The Company recognizes forfeitures related to stock-based compensation awards as they occur and reverses any previously recognized compensation cost associated with forfeited awards in the period the forfeiture occurs. The Company classifies stock-based compensation expense in the consolidated statements of operations and comprehensive loss in the same manner in which the award recipients' payroll costs are classified or in which the award recipients' service payments are classified.

The Company values its stock options with service conditions using the Black-Scholes option-pricing model. The Company uses certain assumptions to determine fair value of the stock options pursuant to the Black-Scholes option-pricing model, including the expected life of the award, volatility of the underlying shares, the risk-free interest rate, expected dividend yield and the fair value of the Company's common stock. Since the Company lacks sufficient historical option exercise data to provide a reasonable basis upon which to estimate the expected term, the Company uses the simplified method described in the U.S. Securities and Exchange Commission's ("SEC") Staff Accounting Bulletin No. 107, *Share-Based Payment* ("SAB 107"), to determine the expected life of the option grants. The Company lacks sufficient company-specific historical and implied volatility information. Therefore, the Company estimates the expected stock volatility based on the historical volatility of a publicly traded set of peer companies. The risk-free interest rate is based on the rates paid on securities issued by the U.S. Treasury with a term approximating the expected life of the equity award. As the Company has never paid and does not anticipate paying cash dividends on its common stock, the expected dividend yield is considered as zero.

Income Taxes

The Company accounts for income taxes in accordance with FASB ASC 740, *Income Taxes* ("ASC 740"), which requires the use of the asset and liability method of accounting for income taxes. Under this method, deferred tax assets and liabilities are determined on the basis of the differences between amounts in the consolidated financial statements and the tax bases 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 tax (benefit) expense in the consolidated statements of operations and comprehensive loss in the period that includes the enactment date.

The Company recognizes deferred tax assets to the extent that it believes these assets are more likely than not to be realized. In making such a determination, the Company 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 the Company determines that it would be able to realize its deferred tax assets in the future in excess of its net recorded amount, the Company would make an adjustment to the deferred tax asset valuation allowance, which would reduce the provision for income taxes. Changes in recognition or measurement are reflected in the period in which the change in judgment occurs.

When uncertain tax positions exist, the Company recognizes the tax benefit of tax positions to the extent that the benefit will more likely than not be realized. The determination as to whether the tax benefit will more likely than not be realized is based upon the technical merits of the tax position as well as consideration of the available facts and circumstances.

Net Loss per Share

Basic net income (loss) per share attributable to common stockholders is computed by dividing net income (loss) attributable to common stockholders by the weighted average number of common shares outstanding for the period. Diluted net income (loss) per share attributable to common stockholders is computed by dividing the diluted net income (loss) attributable to common stockholders by the diluted weighted average number of common shares outstanding for the period, including potential dilutive common shares.

In periods in which the Company reports a net loss, all common stock equivalents are deemed anti-dilutive such that basic net loss per common share and diluted net loss per common share are equivalent. Potentially dilutive common stock has been excluded from the diluted net loss per common share computations in all periods presented because such securities have an anti-dilutive effect on net loss per common share due to the Company's net loss. There are no reconciling items used to calculate the weighted-average number of total common stock outstanding for basic and diluted net loss per common share data.

Recently Adopted Accounting Pronouncements

In June 2016, the FASB issued ASU 2016-13, *Financial Instruments-Credit Losses (Topic 326): Measurement of Credit Losses on Financial Instruments* ("ASU 2016-13"), which requires the measurement and recognition of expected credit losses for financial assets held at amortized cost. ASU 2016-13 replaces the existing incurred loss impairment model with an expected loss model that requires the use of forward-looking information to calculate credit loss estimates. It also eliminates the concept of other-than-temporary impairment and requires credit losses on available-for-sale debt securities to be recorded through an allowance for credit losses instead of as a reduction in the amortized cost basis of the securities. For "emerging growth companies", ASU 2016-13 is effective for fiscal years beginning after December 15, 2022, and interim periods within those fiscal years. On January 1, 2023, the Company adopted ASU 2021-08, which did not have a material effect on the Company's financial position, results of operations, or cash flows.

In October 2021, the FASB issued ASU 2021-08, *Business Combinations (Topic 805): Accounting for Contract Assets and Contract Liabilities from Contracts with Customers* ("ASU 2021-08"), which amends the accounting related to contract assets and liabilities acquired in business combinations. ASU 2021-08 requires that entities recognize and measure contract assets and contract liabilities acquired in a business combination in accordance with ASC Topic 606, *Revenue from Contracts with Customers.* ASU 2021-08 is effective for fiscal years beginning after December 15, 2022, including interim periods within those fiscal years, and should be applied prospectively to businesses combinations occurring on or after the effective date of the amendment. Early adoption is permitted, including adoption in an interim period. On January 1, 2023, the Company adopted ASU 2021-08, which did not have a material effect on the Company's financial position, results of operations, or cash flows.

Recently Issued Accounting Pronouncements

In August 2020, the FASB issued ASU 2020-06, *Debt – Debt with Conversion and Other Options (Subtopic 470-20) and Derivatives and Hedging – Contracts in Entity's Own Equity (Subtopic 815-40)* ("ASU 2020-06"). ASU 2020-06 revises the guidance on calculating earnings per share, requiring use of the if-converted method for all convertible instruments and rescinding an entity's ability to rebut the presumption of share settlement for instruments that may be settled in cash or other assets. As an "emerging growth company", ASU 2020-06 will become effective for the Company for fiscal years beginning after December 15, 2023, and early adoption is permitted. The Company is currently evaluating the new standard and expects it to have no material impact on the Company's consolidated financial statements and related disclosures.

In November 2023, the FASB issued Accounting Standards Update No. 2023-07, *Segment Reporting - Improvements to Reportable Segment Disclosures*. The amendments require disclosure of incremental segment information on an annual and interim basis. The amendments also require companies with a single reportable segment to provide all disclosures required by this amendment and all existing segment disclosures in Accounting Standards Codification 280, *Segment Reporting*. The amendments are effective for fiscal years beginning after December 15, 2023, and interim periods beginning after December 15, 2024. The Company is currently evaluating the new standard and expects it to have no material impact on the Company's consolidated financial statements and related disclosures.

In December 2023, the FASB issued Accounting Standards Update No. 2023-09, *Income Taxes - Improvements to Income Tax Disclosures*. The amendments require (i) enhanced disclosures in connection with an entity's effective tax rate reconciliation and (ii) income taxes paid disaggregated by jurisdiction. The amendments are effective for annual periods beginning after December 15, 2024. The Company is currently evaluating the new standard and expects it to have no material impact on the Company's consolidated financial statements and related disclosures.

3. Acquisition of Apexigen

On May 23, 2023, the Company entered into an Agreement and Plan of Merger (the "Merger Agreement"), by and among the Company, Ascent Merger Sub Corp., a Delaware corporation and wholly-owned subsidiary of the Company ("Merger Sub"), and Apexigen, a Delaware corporation and a clinical-stage biopharmaceutical company focused on discovering and developing innovative antibody therapeutics for oncology.

On August 23, 2023 (the "Closing Date"), the Company completed the acquisition of Apexigen contemplated by the Merger Agreement, pursuant to which, Merger Sub merged with and into Apexigen, with Apexigen surviving as a wholly owned subsidiary of the Company (the "Merger"). The Company issued 4,344,435 shares of its common stock to Apexigen stockholders. The Merger expanded the Company's pipeline with the addition of sotigalimab (now PYX-107), a CD40 agonist with demonstrated anti-cancer activity in patients who previously progressed on PD-(L)1 inhibitors, and enhanced the Company's ADC capabilities with an addition of the commercially and clinically validated APXiMAB platform to generate novel antibodies that can be optimized for targeted payload delivery.

Under the Merger Agreement, each share of Apexigen common stock outstanding as of the Closing Date was automatically converted into the right to receive 0.1725 shares of the Company's common stock ("Exchange Ratio"). Additionally, each outstanding stock option, restricted stock unit ("RSU") and warrant issued by Apexigen was assumed and converted into stock options, RSUs and warrants to acquire the Company's common stock, on substantially similar terms and conditions as were applicable under such Apexigen equity plans (collectively, the "Replacement Awards") and warrant agreements. The number of stock options, RSUs and warrants and their respective exercise prices were adjusted by the Exchange Ratio.

The Company accounted for the Merger as a business combination using the acquisition method in accordance with ASC 805. Under the acquisition method of accounting, the Company was identified as the acquirer, with Apexigen as the acquiree, and August 23, 2023 was determined as the acquisition date. Accordingly, the assets acquired and liabilities assumed are recorded at their estimated fair value on the date of acquisition. Apexigen's results of operations have been included in the consolidated statements of operations and comprehensive loss since the date of acquisition and were not material to the Company's results of operations for the year ended December 31, 2023.

The consideration transferred for Apexigen includes the shares issued by the Company to former Apexigen stockholders, the fair value of replacement awards (both stock options and RSUs) of the Company granted to Apexigen grantholders attributable to pre-combination service and the fair value of Apexigen warrants converted to the Company's warrants.

The following table summarizes the acquisition date fair value of the consideration transferred for Apexigen (in thousands, except share and per-share information):

Fair value of Pyxis Oncology common stock issued to Apexigen stockholders (i)	$	9,970
Fair value of replacement options and RSUs attributable to pre-combination service (ii)		144
Fair value of replacement warrants (iii)		618
Provisional purchase price	$	10,732

(i) The fair value of the Company's common stock issued as consideration transferred was based on the closing price of Pyxis Oncology common stock as reported on The Nasdaq Global Select Market on the day prior to the Closing Date.

(ii) At the Closing Date, the Company replaced 4,128,809 Apexigen stock options and 200,000 Apexigen RSUs with approximately 712,181 Pyxis Oncology stock options ("Replacement Options") and 34,500 Pyxis Oncology RSUs ("Replacement RSU Awards"). The acquisition date fair value of the Replacement Options was determined by the Black-Scholes option-pricing model and the acquisition date fair value attributable to the pre-combination services of $0.1 million is included in the purchase price.

(iii) At the Closing Date, the Company replaced approximately 5,815,613 Apexigen warrants with approximately 1,003,191 Pyxis Oncology warrants ("Replacement Warrants"). The acquisition date fair value of the Replacement Warrants is $0.6 million, which was determined using the Black-Scholes option-pricing model and is included in the purchase price.

The following table summarizes the preliminary acquisition date fair value of the assets acquired and liabilities assumed (in thousands):

		Amount
Assets acquired:		
Cash and cash equivalents	$	6,660
Prepaid expenses and other current assets		519
Intangible assets, net		24,458
Total identifiable assets	$	31,637
Liabilities assumed:		
Accounts payable		(4,548)
Accrued liabilities		(7,531)
Deferred tax liability, net		(2,164)
Deferred revenue		(6,662)
Total identifiable liabilities		(20,905)
Net assets acquired	$	10,732

The assets acquired and liabilities assumed were measured based on management's estimates of the fair value as of the acquisition date. Intangible assets, net includes both IPR&D and definite-lived intangible assets acquired as part of the Merger. IPR&D represents Apexigen's research and development assets, which were in-process, but not yet completed, and which the Company has the opportunity to advance. The definite-lived intangible assets represent royalty rights under certain Apexigen out-licensing agreements that were assumed by the Company upon the Merger Agreement.

The fair value of the intangible assets, including both royalty rights and IPR&D acquired, was determined using the income approach. Under this method, an intangible asset's fair value is equal to the present value of the incremental after-tax cash flows attributable to the intangible asset. The fair value measurements were primarily based on significant inputs not observable in the market and thus represent a Level 3 measurement. The estimates the Company uses are consistent with the plans and estimates that it uses to manage its business. Significant assumptions utilized in the Company's income approach model include the discount rate, timing of clinical studies and regulatory approvals, the probability of success of its research and development programs, timing of commercialization of these programs, forecasted sales, selling, general and administrative expenses, capital expenditures, as well as anticipated growth rates.

Deferred tax liabilities, net of $2.2 million relates to the IPR&D acquired as part of the Merger.

The fair value estimates for the intangible assets are considered provisional and subject to adjustment during the measurement period, not to exceed one year after the date of acquisition, as additional information becomes available and as additional analyses are performed.

The Company incurred transaction related costs of $1.7 million for the year ended December 31, 2023. All transaction related costs were recognized in general and administrative expenses on the consolidated statements of operations and comprehensive loss. No issuance costs were incurred relating to the issuance of shares to Apexigen stockholders.

Supplemental Pro Forma Information (Unaudited)

On a pro forma basis to give effect to the Merger as if it occurred on January 1, 2022, net loss for the years ended December 31, 2023 and 2022, respectively, would have been as follows:

	Year Ended December 31,	
	2023	**2022**
Net loss	$ (97,791)	$ (153,207)

The supplemental pro forma net loss includes a pro forma adjustment related to amortization expense for the acquired royalty rights as if the Merger occurred on January 1, 2022.

4. Licensing Agreements

The University of Chicago Agreement

In April 2020, the Company entered into a license agreement (the "University License Agreement"), as well as a sponsored research agreement, with the University of Chicago (the "University"). Under the terms of the license, the Company has the global right to develop and commercialize products that are covered by a valid claim of a licensed patent, incorporate or use the licensed know-how and materials or are known to assess, modulate or utilize the activity of certain specified biological targets. In partial consideration for the license from the University, the Company issued to the University 48,919 shares of its common stock in 2020.

Pursuant to the University License Agreement, the Company is obligated to pay potential development and commercial milestones of up to $7.7 million as well as running royalties on net sales of licensed products at varying rates ranging from less than a percent to the low single digits, subject to a minimum annual royalty of up to $3.0 million during certain years following the effective date. The Company is also obligated to pay the University a percentage of certain sublicensing revenue ranging from low- to mid-teens based on the date of entering into the applicable sublicense.

The Company assessed the milestone and royalty events under the University License Agreement as of December 31, 2023 and 2022, and determined that no such amounts were required.

Pfizer Inc. Agreements

In December 2020, the Company entered into a license agreement (as amended, the "Pfizer License Agreement") with Pfizer Inc. ("Pfizer") for worldwide development and commercialization rights to ADC product candidates directed to certain licensed targets, including PYX-201 and PYX-203, and products containing the ADC product candidates. The Company's rights are exclusive with respect to certain patents owned or controlled by Pfizer covering the licensed ADCs. The initial licensed targets include CD123 and extra domain B (EDB+FN) and the Company has the option to expand the scope of its license to add additional licensed targets that have not been licensed to a third party or are not the subject of a Pfizer ADC development program. The Pfizer License Agreement became effective for the Company in March 2021. Pursuant to the Pfizer License Agreement, the Company paid a combined $25.0 million for the license fee, consisting of an upfront cash payment of $5.0 million and issued 12,152,145 shares of Series B convertible preferred stock, which was converted into 1,911,015 shares of its common stock upon the initial public offering ("IPO") in October 2021, with a value of $20.0 million to Pfizer.

On October 6, 2022, the Company entered into an amended and restated license agreement (the "A&R License Agreement") with Pfizer, which amends and restates the Pfizer License Agreement. Pursuant to the A&R License Agreement, Pfizer granted to the Company exclusive worldwide rights under Pfizer's Flexible Antibody Conjugation Technology ("FACT") Platform to develop and commercialize ADC product candidates directed to certain licensed targets, including PYX-201 and PYX-203, and products containing the ADC product candidates. Additional ADC targets may be licensed for a nominal upfront payment and milestones. In accordance with the terms of the A&R License Agreement, the Company issued 2,229,654 shares of its common stock to Pfizer in October 2022, paid $8.0 million to Pfizer in January 2023 and issued 1,811,594 shares of its common stock to Pfizer in March 2023.

The Company is also obligated to pay future contingent payments including development, regulatory and commercial milestones up to an aggregate of $665 million for the first four licensed ADCs. In addition, the Company is required to pay future contingent payments including development, regulatory and commercial milestones for ADCs to each additional licensed target beyond the first four licensed ADC targets developed and commercialized via the FACT Platform. Additionally, if ADC licensed products are launched, the Company will pay Pfizer tiered royalties on net sales of licensed products in varying royalty rates ranging from low single digits to mid-teens. The Company's royalty obligations apply on a licensed product-by-licensed product and country-by-country basis from first commercial sale until the latest to occur of: (1) 12 years from first commercial sale; (2) the expiration of all regulatory or data exclusivity; and (3) the expiration of the last valid claim of a licensed patent covering the licensed product in a country. The Company is also obligated to pay Pfizer a percentage of certain sublicensing revenue ranging from twenty percent to low-double digits based on the stage of development of the licensed product at the time of entering into the applicable sublicense.

The Company assessed the milestone and royalty events under A&R License Agreement as of December 31, 2023 and 2022, and determined that no such amounts were required.

License Agreement with Biosion USA, Inc.

On March 28, 2022, the Company entered into a license agreement (the "Biosion License Agreement") with Biosion USA, Inc. ("Biosion"), pursuant to which the Company obtained an exclusive, worldwide (other than Greater China (mainland China, Hong Kong, Macau and Taiwan)) license for development, manufacture and commercialization rights for BSI-060T, a Siglec-15 targeting antibody, an IO product candidate (now referred to as PYX-106), and products containing the licensed compound. Under the terms of the Biosion License Agreement, each party granted to the other party a right of first offer to obtain an exclusive license in the other party's territory (Greater China for Biosion, and the rest of the world for Pyxis) to develop, manufacture and commercialize any bi-specific or multi-specific antibody any antibody-drug conjugate controlled by a party or its affiliate that inhibits, modulates or binds to Siglec-15 as an intended mechanism of action.

Pursuant to the Biosion License Agreement, the Company paid an upfront license fee of $10.0 million, which was recorded as research and development expenses. The Company is also obligated to pay future contingent payments including development, regulatory and commercial milestones up to an aggregate of $217.5 million in case of normal approval and $222.5 million in case of accelerated approval. Additionally, if products are launched, the Company will pay Biosion tiered royalties on net sales of licensed products in varying royalty rates ranging from low single digits to low teens. The Company's royalty obligations apply on a licensed product-by-licensed product and country-by-country basis from first commercial sale until the latest to occur of: (1) 12 years from first commercial sale; (2) the expiration of all regulatory or data exclusivity; and (3) the expiration of the last valid claim of a licensed patent covering the licensed product in a country. The Company is also obligated to pay Biosion a percentage of certain sublicensing revenue ranging from mid-double to low-double digits based on the stage of development of the licensed product at the time of entering into the applicable sublicense.

The Company assessed the milestone and royalty events involving Biosion as of December 31, 2023 and 2022, and determined that no such amounts were required.

LegoChem Biosciences, Inc. Agreements

In December 2020, the Company entered into a license agreement (the “LegoChem License Agreement”) and an opt-in, investment and additional consideration agreement (the “Opt-In Agreement”) with LegoChem Biosciences, Inc. (“LegoChem”). Pursuant to the LegoChem License Agreement, the Company obtained worldwide (other than Korea) license for development and commercialization rights for LCB67, an ADC product candidate targeting DLK-1, and products containing the licensed compound. The Company paid $9.0 million in March 2021 to LegoChem, which was recorded as research and development expenses. Additionally, the Company may purchase certain initial quantities of licensed products from LegoChem for an estimated cost of $7.0 million. The Company is obligated to make future contingent payments including development, regulatory and commercial milestones as well as running royalties on net sales of licensed products at varying rates.

In addition, as part of the Opt-in Agreement, LegoChem exercised an option to pay $8.0 million to the Company, in exchange for the right to receive a milestone payment (the “Extra Milestone Payment”) of $9.6 million upon the earliest to occur of certain events, including the date of pricing or offer of the first public offering of its common stock or if the Company is the subject of a change in control transaction. Upon the Company's IPO in October 2021, the extra milestone payment event triggered, and the Company paid $9.6 million in January 2022 to LegoChem.

In 2022, the Company stopped the continued development of LCB67, based on review and analysis of data from the toxicity studies, and anticipated clinical use and commercial prospects of anti-DLK1 ADC. Due to stoppage of clinical development of LCB67, no amounts are due and payable related to the manufacturing of the initial quantities of licensed product and no milestone or royalty events are expected.

Acquired Out-Licensing Agreements

In August 2023, the Company completed the acquisition of Apexigen, as detailed in Note 3, *Acquisition of Apexigen*, and assumed all out-licensing agreements of Apexigen upon the Merger Agreement.

Described below are the out-license relationships and the related agreements under which the Company may receive milestone or royalty payments. The aggregate payments received from these relationships post-acquisition of Apexigen was $1.0 million and the Company has $7.7 million in deferred revenue relating to certain royalty payments as of December 31, 2023, as detailed below.

Beovu and Novartis Antibody Candidate Discovery and Development Agreement

In March 2007, Epitomics (Apexigen's predecessor), entered into an antibody candidate discovery and development agreement with ESBATech AG, or ESBA Tech, in March 2007 (the “ESBATech Agreement”). ESBATech was acquired by Alcon Research, Ltd. ("ARL") in 2009 and later merged with Novartis AG (“Novartis”) in 2011.

Novartis, the successor in interest to ESBATech, has successfully developed and commercialized one of those drug product candidates, brolucizumab-dbll, a single-chain antibody fragment (scFv) targeting all of the isoforms of VEGF-A, which was approved for commercial sale in 2019 and marketed under the brand name Beovu®.

Novartis and its predecessors have paid all upfront fees and milestone payments due under the ESBATech Agreement. Novartis is obligated to pay Apexigen a very low single-digit royalty on net sales of the Beovu® product. However, Novartis has disputed its obligation to pay these royalties on Beovu® sales under this agreement. As a result, the Company determined that any sales-based Beovu® product royalties received under this agreement through December 31, 2023 should be fully constrained. The Company assesses this position at each period end to determine if events or changes in circumstances indicate a change in position. As of December 31, 2023, deferred revenue totaled $7.7 million.

Simcere License and Collaboration Agreement

In December 2008, Epitomics (Apexigen's predecessor) and Jiangsu Simcere Pharmaceutical R&D Co., Ltd. ("Simcere") entered into a license and collaboration agreement (the “Simcere Agreement”) for the development and commercialization of suvemcitug (BD0801) for oncology in China. Suvemcitug is, a humanized anti-VEGF rabbit monoclonal antibody molecule. Under the Simcere Agreement, Simcere has an exclusive, royalty-bearing license (without the right to sublicense) to rights in certain intellectual property to develop and commercialize suvemcitug in the field of oncology therapeutics in China.

Simcere granted the Company a non-exclusive, royalty-free, worldwide license (without the right to sublicense) to improvements derived from suvemcitug using the intellectual property the Company licensed to Simcere. Simcere is obligated to pay the Company milestone payments for achievement of certain clinical development milestones and low to high single-digit percentage royalties on net sales of suvemcitug in China until 15 years after the first commercial sale of suvemcitug. The Company assessed the milestone and royalty events involving Simcere as of December 31, 2023 and determined that no such amounts were receivable.

T-Mab/Mabwell Agreement

In May 2008, Epitomics (Apexigen's predecessor) and Jiangsu T-Mab Biotechnology Ltd., Co. ("T-Mab") entered into a license, co-development and contract manufacture agreement (the "T-Mab Agreement") for the development and commercialization of therapeutic candidates, each directed to a specified target for specified fields, including VEGF for the treatment of ocular diseases, in China. Mabwell (Shanghai) Bioscience Co., Ltd. ("Mabwell") acquired T-Mab in 2015.

Under the agreement, Mabwell was granted an exclusive, royalty-bearing, perpetual license (without the right to sublicense) to rights in certain intellectual property to develop and commercialize such therapeutic candidates. Mabwell is obligated to pay the Company a mid-single-digit percentage royalty on net sales of such therapeutic candidates in China. The royalty term for 9MW0211, an anti-VEGF antibody licensed under the T-Mab Agreement, will begin on the first commercial sale in China. The Company assessed the milestone and royalty events involving Mabwell as of December 31, 2023 and determined that no such amounts were receivable.

Toray Sublicense Agreement

In May 2012, Epitomics (Apexigen's predecessor) and Toray Industries, Inc. ("Toray"), entered into a non-exclusive sublicense agreement (the "Toray Agreement") under which Epitomics granted Toray a non-exclusive, worldwide sublicense, with the right to grant further sublicenses, to develop and commercialize drug product candidates that Toray developed using antibodies created using the APXiMAB platform that target certain molecules to use in the development of its drug product candidates. Under the Toray Agreement, Toray paid an upfront fee, and agreed to pay certain development- and regulatory-related milestone payments and a low single-digit percentage royalty on net sales of licensed products by Toray or its affiliates. Toray is also obligated to pay the Company a mid-teens percentage of certain payments Toray receives from sublicensees under the Toray Agreement, which payments may limit Toray's obligations to pay the milestone payments described above. The Toray Agreement continues on a product-by-product and country-by-country basis until 10 years after the first commercial sale of such product in such country. The Company assessed the milestone and royalty events involving Toray as of December 31, 2023 and determined that no such amounts were receivable.

5. Joint Venture

In March 2021, the Company entered into definitive transaction agreements with Alloy Therapeutics, Inc. ("Alloy") and Voxall Therapeutics, LLC ("Voxall"), to finance and operate Voxall, a joint venture company formed in collaboration with Alloy to leverage the Company's technology and Alloy's ATX-Gx™ platform and antibody discovery services. Voxall granted to the Company and Alloy, 50% of the voting membership units of Voxall in exchange for certain contributions, including $50 thousand from both the Company and Alloy.

The Company accounted for the investment in Voxall under the equity method of accounting and recognizes its share of losses of Voxall only to the extent of the carrying value of its investment in Voxall.

See Note 20, *Subsequent Events*, for further discussion of developments regarding Voxall subsequent to the balance sheet date and prior to the filing of this Annual Report on Form 10-K for the year ended December 31, 2023.

6. Fair Value Measurements

The following tables present the financial instruments carried at fair value on a recurring basis as of December 31, 2023 and 2022, respectively, in accordance with the FASB ASC 820 hierarchy (in thousands):

	December 31, 2023			
	Level 1	**Level 2**	**Level 3**	**Total**
Cash equivalents				
Money market funds	$ 8,360	**$ —**	**$ —**	$ 8,360
Marketable debt securities				
U.S. Treasury securities	109,634	—	—	109,634
Total	$ 117,994	**$ —**	**$ —**	$ 117,994

	December 31, 2022			
	Level 1	**Level 2**	**Level 3**	**Total**
Cash Equivalents				
Money market funds	$ 177,279	**$ —**	**$ —**	$ 177,279
Restricted Cash				
Money market funds	1,472	—	—	1,472
Total	$ 178,751	**$ —**	**$ —**	$ 178,751

The Company's cash equivalents represent deposits in a short-term money market fund quoted in an active market and classified as Level 1 assets. Marketable debt securities include investments in United States Treasury securities and are classified as Level 1 assets as they are valued using quoted prices in active markets. There were no assets or liabilities measured at fair value on a nonrecurring basis at December 31, 2023 and 2022. There were no transfers between Level 1 and Level 2 of the fair value hierarchy during the years ended December 31, 2023 and 2022.

7. Marketable Debt Securities

Marketable debt securities, all of which were classified as available-for-sale, consist of the following (in thousands):

	December 31, 2023			
	Amortized Cost	Unrealized Gains	Unrealized Losses	Aggregate Fair Value
Marketable debt securities				
U.S. Treasury securities	$ 109,571	$ 71	$ (8)	$ 109,634

As of December 31, 2022, the Company did not have marketable debt securities.

As of December 31, 2023, the remaining contractual terms of the U.S. Treasury securities were less than 12 months. As of December 31, 2023, the Company held one security in an unrealized loss position of $8 thousand and had a fair value of $41.7 million. There were no securities in a continuous unrealized loss position for greater than twelve months at December 31, 2023.

To date, we have not recognized any allowances for credit losses or impairments in relation to our marketable securities as these securities are comprised of high credit quality, investment grade securities that we do not intend or expect to be required to sell prior to their anticipated recovery, and the decline in fair value of these securities is attributable to factors other than credit losses.

Interest and Investment Income

Interest and investment income consisted of the following (in thousands):

	Year Ended December 31,	
	2023	2022
Interest income	$ 1,842	$ 2,764
Accretion of discount, net	4,788	—
Total interest and investment income	$ 6,630	$ 2,764

8. Prepaid Expenses and Other Current Assets

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

	December 31,	
	2023	2022
Research and development	$ 2,496	$ 3,560
Insurance	1,012	1,308
Accrued interest receivable	21	598
Other	305	381
Total prepaid expenses and other current assets	**$ 3,834**	**$ 5,847**

9. Property and Equipment, Net

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

	December 31,	
	2023	2022
Leasehold improvements	$ 10,956	$ 530
Laboratory equipment	3,395	2,247
Furniture and office equipment	1,123	1,036
Construction in process	—	9,177
	15,474	12,990
Less: accumulated depreciation and amortization	(3,602)	(1,825)
Total property and equipment, net	**$ 11,872**	**$ 11,165**

Depreciation and amortization expense for the years ended December 31, 2023 and 2022 was $1.8 million and $0.7 million, respectively, of which $1.5 million and $0.7 million, respectively, was included within research and development expenses and $0.3 million and $15 thousand, respectively, was included in general and administrative expenses in the accompanying statements of operations and comprehensive loss.

10. Intangible Assets, Net

Intangible assets, net, consisted of the following (in thousands):

		As of December 31, 2023		
	Estimated Useful Life	**Gross Carrying Amount**	**Accumulated Amortization**	**Net Carrying Amount**
Royalty rights	3 - 13 years	$ 3,494	$ (150)	$ 3,344
IPR&D	Indefinite	20,964	—	20,964
Total		**$ 24,458**	**$ (150)**	**$ 24,308**

As described in Note 4, *Licensing Agreements*, the Company assumed all out-licensing agreements of Apexigen upon the completion of the Merger and retains royalty rights under certain Apexigen agreements. The Company recognized a definite-lived intangible asset related to these royalty rights, which was valued using the income approach and adjusted for any potential repayment provisions.

Royalty rights are amortized on a straight-line basis over its useful lives, which are 3- and 13-years, and was determined based on the terms and conditions underlying the licensing agreements and the expected use of the asset by the Company. Useful lives are periodically evaluated to determine whether events or circumstances have occurred which indicate the need for revision.

The weighted-average amortization period of the acquired royalty rights is approximately 8.3 years. Amortization expense was $0.2 million for the year ended December 31, 2023 and was recorded as part of “Research and development” within the accompanying consolidated statements of operations and comprehensive loss. Amortization of intangible assets for the next five years related to the intangible assets held as of December 31, 2023 is estimated to be as follows (in thousands):

Years Ending December 31,	**Estimated Amortization Expense**
2024	$ 421
2025	421
2026	322
2027	223
2028	223
Thereafter	1,734
Total	$ 3,344

IPR&D represents the research and development assets of Apexigen acquired by the Company, which were in-process, but not yet completed, and which the Company has the opportunity to advance. The primary basis for determining the completion of these projects is obtaining regulatory approval to market the underlying products in an applicable geographic region. IPR&D becomes definite-lived upon the completion or abandonment of the associated research and development efforts.

The Company had no intangible assets during the year ended December 31, 2022.

11. Accrued Expenses and Other Current Liabilities

Accrued expenses and other current liabilities consisted of the following (in thousands):

	December 31,	
	2023	**2022**
Research and development expenses	$ 6,594	$ 17,414
Employee compensation and benefits	5,219	4,238
Legal and professional fees	802	1,794
Other	356	1,091
Total accrued expenses and other current liabilities	**$ 12,971**	**$ 24,537**

12. Operating Leases

Leases classified as operating leases are included in operating lease right-of-use assets ("ROU"), operating lease liabilities, current portion and operating lease liabilities, net of current portion, in the Company's consolidated balance sheets.

The Company leases its office and facilities in Boston, Massachusetts under a non-cancellable operating lease agreement that continues through December 31, 2032. Under the terms of the lease agreement, the Company is responsible for certain insurance, property taxes and maintenance expenses, which represents the Company's proportionate share of the actual expenses incurred by the landlord. The operating lease agreement contains scheduled annual rent increases over the lease term.

On February 2, 2023, the Company entered into a sublease agreement for approximately 17,729 square feet of office and laboratory space in the building located at 321 Harrison Avenue, Boston, Massachusetts. The sublease included a rent-free period, with rent payments commencing on May 24, 2023. Under the terms of the sublease, the sublessee is to pay the Company approximately $1.5 million in year one and $1.9 million per year thereafter, which is subject to a 3.0% annual rent increase, plus certain other costs under the sublease, such as operating expenses, taxes, insurance, property management fee and utilities. The Company remains jointly and severally liable under the head lease and accounts for the sublease as an operating lease. The sub-lease term commenced on March 24, 2023 and is expected to end in March 2026. The sublessee has the option to extend the sublease for a one-year period on the same terms and conditions as the current sublease, subject to a change in base rent for the extended period equal to a 3% increase to the then current rent. Upon execution of the sublease agreement, the sublessee provided the Company a security deposit of $0.4 million which is held in the form of a letter of credit. The Company recognized sublease income of $1.8 million for the year ended December 31, 2023.

The Company was not party to any finance leases during the years ended December 31, 2023 and 2022.

The components of lease expense were as follows (in thousands):

	Year Ended December 31,	
	2023	2022
Lease cost		
Operating lease cost	$ 2,666	$ 1,978
Variable lease cost	753	121
Short-term lease cost	499	1,681
Total lease cost	**$ 3,918**	**$ 3,780**
Other information		
Operating lease right-of-use asset obtained in exchange for new operating lease liabilities	$ —	$ 14,497
Cash paid for amounts included in the measurement of lease liabilities, included in operating cash flows	$ 2,516	$ 663
Weighted-average remaining lease term (in years)	9.00	10.00
Weighted-average discount rate	9.40%	9.40%

Variable lease costs primarily relate to common area costs and other operating costs, which are assessed based on the Company's proportionate share of such costs for the leased premises. Total lease costs are included as operating expenses in the Company's consolidated statements of operations and comprehensive loss.

Maturities of lease liabilities as of December 31, 2023, were as follows (in thousands):

Years Ending December 31,	Operating Lease Payments	Sublease Receipts	Net Operating Lease Payments
2024	$ 3,185	$ 1,844	$ 1,341
2025	3,278	1,898	1,380
2026	3,375	437	2,938
2027	3,473	—	3,473
2028	3,575	—	3,575
Thereafter	15,383	—	15,383
Total undiscounted payments	$ 32,269	$ 4,179	$ 28,090
Less: present value adjustment	(10,938)		
Present value of future payments	21,331		
Less: current portion of operating lease liabilities	(1,232)		
Operating lease liabilities, net of current portion	$ 20,099		

13. Common Stock Warrants

As described in Note 3, *Acquisition of Apexigen*, pursuant to the Merger Agreement, each outstanding warrant issued by Apexigen as of the Closing Date was assumed and converted into a warrant to acquire the Company's common stock, on substantially similar terms and conditions as were applicable under such Apexigen warrant agreements. At the Closing Date, the Company replaced approximately 5,815,613 Apexigen warrants with approximately 1,003,191 Pyxis Oncology warrants. The acquisition date fair value of the Replacement Warrants was $0.6 million, which is included in the provisional purchase price.

The fair value of the Replacement Warrants was determined using the Black-Scholes option-pricing model and the following assumptions:

	As of August 23, 2023
Expected volatility	95.0%
Risk-free interest rate	4.36% - 4.50%
Expected dividend yield	0.00%
Expected term (in years)	3.93 - 4.94

As of December 31, 2023, there were 344,259 warrants outstanding with an exercise price of $8.12 per share, 17,212 warrants outstanding with an exercise price of $10.14 per share and 641,720 warrants with an exercise price of $66.67 per share. Each of the warrants with an exercise price of $66.67 per share will expire on the fifth anniversary of July 29, 2022, or earlier upon redemption or liquidation. Each of the warrants with an exercise price of $8.12 per share and $10.14 per share will expire on July 30, 2028, or earlier upon redemption or liquidation.

The Company may call the warrants outstanding with an exercise price of $10.14 per share for redemption:

•in whole or in part;

•at a price of $0.01 per warrant;

•upon a minimum of 30 days' prior written notice of redemption; and

•if, and only if, the last reported closing price of the ordinary shares equals or exceeds $104.35 per share for any 20 trading days within a 30-trading day period on the third trading day prior to the date on which the Company sends the notice of redemption to the warrant holders.

If the Company calls these warrants for redemption, management will have the option to require all holders that wish to exercise these warrants to do so on a "cashless basis," as described in the warrant agreement.

The Replacement Warrants are equity classified because they are freestanding financial instruments that are legally detachable and separately exercisable from the equity instruments, are immediately exercisable, do not embody an obligation for the Company to repurchase its shares, permit the holders to receive a fixed number of common shares upon exercise, are indexed to the Company's common stock and meet the equity classification criteria. In addition, such Warrants do not provide any guarantee of value or return. The Company valued the Replacement Warrants at the Acquisition Date using a relative fair value allocation method and recorded as a component of additional paid-in-capital.

14. Stockholders' Equity

Preferred Stock

As of December 31, 2023, the Company had 10,000,000 authorized shares of preferred stock, with a par value of $0.001 per share. The board of directors has the authority, without further action by the stockholders to issue such shares of preferred stock in one or more series, to establish from time to time the number of shares to be included in each such series, and to fix the dividend, dividend rights, conversion rights, voting, redemption terms, liquidation preference and other rights, preferences and privileges of the shares.

There were no issued and outstanding shares of preferred stock as of December 31, 2023 and 2022, respectively.

Common Stock

The Company was authorized to issue up to 190,000,000 shares of common stock as of December 31, 2023 and 2022, respectively, of which 44,754,853 and 35,110,016 shares were issued as of December 31, 2023 and 2022, respectively, and 44,754,853 and 34,958,730 shares were outstanding as of December 31, 2023 and 2022, respectively.

Voting, dividend and liquidation rights of the holders of the common stock are subject to and qualified by the rights, powers and preferences of the holders of the preferred stock.

Voting—Each holder of outstanding shares of common stock shall be entitled to one vote in respect of each share.

Reserved Shares— The Company reserved the following shares of common stock for issuance:

	December 31,	
	2023	**2022**
Stock options outstanding	5,982,464	5,720,415
Unvested restricted stock awards and units	3,631,431	3,015,387
Shares reserved for future issuance	1,013,840	1,697,166
Common stock warrants	1,003,191	—
Employee stock purchase plan	565,405	534,675
Total	**12,196,332**	**10,967,643**

Shelf Registration Statement and ATM Offering Program

On November 1, 2022, the Company filed a registration statement on Form S-3 with the SEC for the issuance of common stock, preferred stock, warrants, debt securities, rights and units up to an aggregate of $250.0 million. On November 14, 2022, the registration statement was declared effective by the SEC. The registration statement includes an ATM offering program for the sale of up to $125.0 million of shares of the Company's common stock.

Any shares offered and sold in the ATM offering will be issued pursuant to the Company's effective shelf registration statement on Form S-3 and the related prospectus supplement. Under the ATM, the sales agents may sell shares of common stock by any method permitted by law deemed to be an "at the market offering" as defined in Rule 415(a)(4) of the Securities Act of 1933, as amended. The Company will pay the sales agents a commission rate of up to 3% of the gross sales proceeds of any shares sold and has agreed to provide the sales agents with customary indemnification, contribution and reimbursement rights. The ATM contains customary representations and warranties and conditions to the placements of the shares pursuant thereto.

During the year ended December 31, 2023, the Company completed the sale of an aggregate of 1,001,208 shares of common stock under the ATM offering program with an average gross sale price of $6.30 per share, resulting in gross proceeds of $6.3 million. The Company paid commissions of $0.2 million to the placement agent under the ATM offering program.

See Note 20, *Subsequent Events*, for further discussion of sales of the Company's common stock under the ATM offering program subsequent to the balance sheet date and prior to the filing of this Annual Report on Form 10-K for the year ended December 31, 2023.

15. Stock-Based Compensation

2022 Equity Inducement Plan

On July 1, 2022, the Company's board of directors approved the 2022 Equity Inducement Plan (the "2022 Inducement Plan"), which became effective on that date. The 2022 Inducement Plan allows the Company to make equity-based incentive awards to its officers and employees without stockholder approval pursuant to Rule 5635(c)(4) of the NASDAQ Listing Rules, or any successor rule relating to inducement awards. Unless earlier terminated by the Board, 2022 Inducement Plan will terminate on the tenth anniversary of the effective date. The Company has initially reserved 1,400,000 shares of its common stock for the issuance of awards under the 2022 Inducement Plan. As of December 31, 2023, options to purchase 828,432 shares of common stock and 138,871 restricted stock units were outstanding under the 2022 Inducement Plan and 346,443 shares remained available for future issuance under the 2022 Inducement Plan.

2021 Equity Incentive Plan

On September 27, 2021, the Company's board of directors and stockholders approved the 2021 Equity Incentive Plan (the "2021 Plan"), which became effective on October 7, 2021, when the Company's registration statement was declared effective by the SEC. The 2021 Plan allows the Company to make equity-based and cash-based incentive awards to its officers, employees, directors and consultants. The Company has initially reserved 3,852,807 shares of its common stock for the issuance of awards under the 2021 Plan. The number of shares of common stock reserved for issuance under the 2021 Plan will automatically increase annually on the first day of each fiscal year, beginning with the fiscal year ending December 31, 2022, and continuing until (and including) the fiscal year ending December 31, 2031 by the lesser of (i) 5% of the total number of shares of common stock outstanding on December 31st of the immediately preceding fiscal year and (ii) the number of shares as may be determined by the board of directors. On January 1, 2023, the number of shares of common stock available for issuance under the 2021 Plan increased by 1,755,501 shares as a result of the evergreen provision. The maximum number of shares of common stock that may be issued pursuant to the exercise of incentive options under the 2021 Plan is 7,705,614. Unless earlier terminated by the Board, the 2021 Plan will terminate on the tenth anniversary of the effective date. As of December 31, 2023, options to purchase 2,037,393 shares of common stock and 2,452,500 restricted stock units were outstanding under the 2021 plan and 537,772 shares remained available for future issuance under the 2021 plan.

2019 Equity Incentive Plan

In 2019, the Company established the 2019 Equity Incentive Plan (the "2019 Plan"), under which the Company is allowed to grant options and restricted stock to its employees and non-employees. The maximum number of shares of common stock reserved for issuance under the 2019 Plan is 4,042,408 shares. Options granted under the 2019 Plan include incentive stock options that can be granted only to the Company's employees and non-statutory stock options that can be granted to the Company's employees, consultants, advisors and directors. The 2019 Plan also permits the Company to issue restricted stock awards. Unless earlier terminated by the Board, the 2019 Plan will terminate on the tenth anniversary of the effective date.

Prior to the IPO, the exercise prices, vesting and other restrictions of the awards granted under the 2019 Plan were determined by the board of directors, except that no stock option may be issued with an exercise price less than the fair market value of the common stock at the date of the grant or have a term in excess of ten years. Options granted under the 2019 Plan are exercisable in whole or in part at any time subsequent to vesting. As of December 31, 2023, options to purchase 2,272,833 shares of common stock and 962,390 restricted stock units were outstanding under the 2019 Plan and 52,299 shares remained available for future issuance under the 2019 Plan.

2022 Equity Incentive Plan

Upon the Merger, the Company assumed Apexigen's 2022 Equity Incentive Plan (the "2022 Plan"), which allows the Company to grant options and restricted stock to eligible employees and non-employees. The Company initially reserved 443,912 shares of its common stock for the issuance of awards under the 2022 Plan. The number of shares of common stock reserved for issuance under the 2022 Plan will automatically increase on January 1 of each calendar year, starting on January 1, 2023 through January 1, 2032, in an amount equal to the lesser of (i) 0.8625% of the total number of shares of common stock outstanding on the last day of the calendar month before the date of each automatic increase, (ii) 554,890 shares, or (iii) such number of shares determined by the administrator of the 2022 Plan. On January 1, 2023, the number of shares of common stock available for issuance under the 2022 Plan increased by 554,890 shares as a result of the evergreen provision. The maximum number of shares of common stock that may be issued pursuant to the exercise of incentive options under the 2022 Plan is 597,077. Unless earlier terminated by the Board, the 2022 Plan will terminate on the tenth anniversary of the effective date. As of December 31, 2023, options to purchase 843,806 shares of common stock and 77,670 RSUs were outstanding under the 2022 Plan and 77,326 shares remained available for future issuance under the 2022 Plan.

The Company also assumed Apexigen's 2020 Equity Incentive Plan, ("2020 Plan") as a result of the Merger. Outstanding awards granted under the 2020 Plan will remain subject to the terms of the plan, and shares underlying awards granted under such plan that are cancelled or forfeited will be available for issuance under the 2022 Plan, as applicable.

2021 Employee Stock Purchase Plan

On September 27, 2021, the Company's board of directors and stockholders approved the 2021 Employee Stock Purchase Plan (the "2021 ESPP"), which became effective on October 7, 2021, when the Company's registration statement was declared effective by the SEC. The 2021 ESPP initially reserved and authorized the issuance of up to a total of 424,595 shares of common stock to participating employees. The number of shares of common stock reserved for issuance under the ESPP will automatically increase annually on the first day of each fiscal year, beginning with the fiscal year ending December 31, 2022, and continuing until (and including) the fiscal year ending December 31, 2031 by the lesser of (i) 110,080 shares, (ii) 1% of the total number of shares of common stock outstanding on December 31st of the immediately preceding fiscal year and (iii) the number of shares as may be determined by the board of directors. On January 1, 2023, the number of shares of common stock available for issuance under the 2021 ESPP increased by 110,080 shares as a result of the evergreen provision. During the year ended December 31, 2023, the Company issued 79,350 shares of common stock pursuant to the ESPP. As of December 31, 2023, the authorized number of shares and shares available for issuance under the 2021 ESPP is 565,405.

Repricing of Outstanding and Unexercised Options

On March 24, 2023 and in accordance with the terms of the 2019 Plan, the board of directors approved a stock option repricing (the "Repricing") where the exercise price of each Relevant Option (as defined below) was reduced to $2.21 per share, the closing stock price on the date of approval by the board of directors. "Relevant Options" are all outstanding stock options as of March 24, 2023 (vested or unvested) to acquire shares of the Company's common stock that were issued to current employees of the Company under the 2019 Plan prior to the Company's IPO. Members of the board of directors did not participate in the Repricing. The board of directors believes that the Repricing is in the best interests of the Company, as the amended stock options will provide added incentives to retain and motivate key contributors of the Company without incurring the stock dilution resulting from significant additional equity grants or significant additional cash expenditures resulting from additional cash compensation. The board of directors also believes that the Repricing better aligns the interests of the key contributors with the goals of the Company.

The option repricing resulted in incremental stock-based compensation of $1.1 million, of which $0.9 million was recorded as expense during the year ended December 31, 2023. The remaining expense will be recognized over the requisite service period in which the stock options vest.

Apexigen Replacement Options and Replacement RSU Awards

As described in Note 3, *Acquisition of Apexigen*, pursuant to the Merger Agreement, each outstanding stock option issued by Apexigen as of the Closing Date was assumed and converted into an option to acquire the Company's common stock and each outstanding restricted stock unit awarded by Apexigen as of the Closing Date was assumed and converted into an award of the Company's common stock, on substantially similar terms and conditions as were applicable under such Apexigen equity plans.

At the Closing Date, the Company issued approximately 712,181 Replacement Options and 34,500 Replacement RSU Awards to Apexigen grantholders. The acquisition date fair value of the Replacement Options was determined by the Black-Scholes option-pricing model and the acquisition date fair value attributable to the pre-combination services of $0.1 million is included in the purchase price, which is included in Note 3, *Acquisition of Apexigen*.

The Replacement Options and Replacement RSU Awards will continue to vest over the remaining vesting period through the earlier of exercise, expiration or forfeiture. The number of stock options, RSUs and warrants and their respective exercise prices were adjusted by the Exchange Ratio.

Stock Options

Stock options granted under the 2022 Inducement Plan, 2022 Plan, 2020 Plan, 2021 Plan and 2019 Plan (together, the "Plans") to employees generally vest over four years and expire after 10 years.

The following table summarizes stock option activity for the year ended December 31, 2023 (in thousands, except share and per share amounts):

	Number of Options	Weighted Average Exercise Price		Weighted Average Remaining Contractual Term (Years)		Aggregate Intrinsic Value	
Outstanding at January 1, 2023	5,720,415	$ 9.68		8.8		$ 72	
Granted	1,078,717	1.87					
Replacement Options [1]	712,181	17.57					
Exercised	(83,235)	1.49					
Expired	(721,598)	13.63					
Forfeited	(724,016)	8.23					
Outstanding at December 31, 2023	**5,982,464**	**$ 7.31**	**(1)**	**7.6**		**$ 141**	**(2)**
Options exercisable at December 31, 2023	**3,300,648**	**$ 7.97**	**(1)**	**6.8**		**$ 44**	**(2)**

(1) Represents Replacement Options issued to Apexigen grantholders pursuant to the Merger Agreement.

(2) The weighted average exercise price and aggregate intrinsic value as of December 31, 2023 reflect the impact of the stock option repricing discussed above.

The weighted-average grant-date fair value of options granted during the years ended December 31, 2023 and 2022, was $1.87 and $3.06 per share, respectively. The aggregate intrinsic value is calculated as the difference between the exercise price of all outstanding and exercisable stock options and the fair value of the Company's common stock of $1.80 per share as of December 29, 2023, the last trading day prior to the year-end 2023. The aggregate intrinsic value of stock options exercised during both of the years ended December 31, 2023 and 2022 was approximately $0.1 million.

The Company has an aggregate $9.1 million of gross unrecognized stock-based compensation expense as of December 31, 2023, remaining to be amortized over a weighted average period of 1.95 years. The Company has not recognized and does not expect to recognize in the near future, any tax benefit related to employee stock-based compensation expense as a result of the full valuation allowance related to its net deferred tax assets.

The Company estimated the fair value of each option on the date of grant using the Black-Scholes option-pricing model applying the range of assumptions in the following table:

	Year Ended December 31,	
	2023	2022
Expected volatility	97.11% - 118.90%	96.09% - 101.66%
Risk-free interest rate	3.58% - 5.57%	1.60% - 4.02%
Expected dividend yield	0.00%	0.00%
Expected term (in years)	0.25 - 6.08	6.00 - 6.11

Restricted Stock Units

Under the Plans, during the year ended December 31, 2023, the Company granted 4,200,428 RSUs to employees and non-employees. Compensation costs related to these RSUs were recorded based on the Company's stock price on the date of issuance and amortized over the service period.

Additionally, the Company issued certain shares of restricted common stock awards ("RSA") to the employee co-founders and certain non-employee consultants in 2019. The shares of restricted common stock were issued pursuant to standalone restricted stock purchase agreements that are independent of the Plans. The shares of RSAs pursuant to standalone restricted stock purchase agreements carried a purchase price equivalent of $0.01 per share. As of December 31, 2023, no RSAs were outstanding and all RSAs were fully vested and converted into fully paid common stock.

The following table summarizes restricted stock awards and restricted stock units for the year ended December 31, 2023:

	Number of Shares	Weighted Average Grant Date Fair Value
Non-vested and unsettled at January 1, 2023	3,015,387	$ 3.64
Granted	4,200,428	2.09
Replacement RSU Awards [1]	34,500	2.30
Forfeited	(918,845)	3.12
Vested and settled	(2,700,039)	2.91
Non-vested and unsettled at December 31, 2023	**3,631,431**	**$ 2.51**

(1) Represents Replacement RSU Awards issued to eligible Apexigen grantholders pursuant to the Merger Agreement.

During the year ended December 31, 2023, the Company issued 2,476,301 shares of its common stock from the settlement of 2,700,039 restricted common stock, with the remaining shares withheld for taxes.

The total fair value of restricted common stock that vested during the years ended December 31, 2023 and 2022 was $8.0 million and $0.5 million, respectively.

The Company has an aggregate $6.8 million of gross unrecognized restricted stock-based compensation expense as of December 31, 2023, remaining to be amortized over a weighted average period of 2.48 years.

Summary of Stock-Based Compensation Expense

The following tables summarize the total stock-based compensation expense for the years ended December 31, 2023 and 2022, respectively (in thousands):

	Year Ended December 31,	
	2023	2022
Stock options	$ 10,635	$ 11,947
Restricted stock	6,311	3,817
Total	**$ 16,946**	**$ 15,764**

	Year Ended December 31,	
	2023	2022
General and administrative	$ 12,537	$ 10,548
Research and development	4,409	5,216
Total	**$ 16,946**	**$ 15,764**

Total stock-based compensation expense for stock options includes expense related to the 2021 ESPP of less than $0.1 million and $0 for the years ended December 31, 2023 and December 31, 2022, respectively.

16. Income Taxes

During the years ended December 31, 2023 and 2022, the Company recorded no current or deferred income tax expenses or benefits as the Company has incurred losses since inception and has provided a full valuation allowance against its deferred tax assets. The Company has recorded a current state income tax expense for Massachusetts in the amount of less than $0.1 million for the years ended December 31, 2023 and 2022.

A reconciliation of the expected income tax benefit computed using the federal statutory income tax rate to the Company's effective income tax rate is as follows for the years ended December 31, 2023 and 2022:

	Year Ended December 31,	
	2023	2022
Income tax computed at federal statutory rate %	21.0%	21.0%
State taxes, net of federal benefit	2.1%	5.6%
Share based compensation	-3.5%	-1.7%
Change in valuation allowance	-19.3%	-26.6%
Change in state apportionment	0.0%	-0.1%
Provision to tax return differences	-3.0%	-0.4%
Research and development credit carryovers	3.0%	1.7%
Permanent differences	-0.3%	0.5%
Effective income tax rate %	**0.0%**	**0.0%**

The Company's effective tax rate was 0% for the years ended December 31, 2023 and 2022, as a result of the valuation allowance that eliminates the company's net deferred tax assets.

Deferred income taxes reflect the net tax effects of temporary differences between the carrying amounts of assets and liabilities for financial reporting purposes and the amounts used for income tax purposes. Significant components of the Company's net deferred tax assets as of December 31, 2023 and 2022 are as follows (in thousands):

	Year Ended December 31,	
	2023	2022
Deferred tax assets:		
Net operating losses	$ 67,569	$ 13,108
Tax credit carryforwards	10,689	3,674
Derivative	1,319	1,455
Stock-based compensation	3,204	2,645
Reserves and accruals	1,156	1,105
Capitalized research expenditures	23,423	20,059
License fees	13,555	14,235
Operating lease liability	3,996	5,107
Deferred revenue	2,027	—
Intangibles	—	69
Other	183	29
Total gross deferred tax assets before valuation allowance	127,121	61,486
Less: valuation allowance	(119,504)	(57,812)
Total deferred tax assets	**$ 7,617**	**$ 3,674**
Deferred tax liabilities:		
Operating lease ROU assets	(3,459)	(3,674)
Intangibles	(6,322)	—
Total deferred tax liabilities	(9,781)	(3,674)
Net deferred tax liabilities	**$ (2,164)**	**$ —**

As of December 31, 2023, the Company's federal and state net operating losses in the United States were $56.4 million ($268.5 million before tax) and $11.2 million ($167.4 million before tax) respectively. The federal net operating loss carryforward generated in the United States after tax year 2017 can be carried forward indefinitely but may be subject to annual usage limitations to the extent certain substantial changes in the entity's ownership occur. The federal net operating loss carryforward relating to tax years prior to 2017 of $5.9 million ($28.3 million before tax), acquired with Apexigen, begin to expire in 2033. The state net operating loss carryforwards begin expiring in 2035. In addition, as of December 31, 2023, the Company had $7.8 million and $3.6 million of federal and state credit carryovers which begin to expire in 2030. These loss and credit carryforwards are subject to review and possible adjustment by the relevant taxing authorities.

The Company assesses the realizability of the deferred tax assets at each balance sheet based on the available positive and negative evidence in order to determine the amount which is more likely than not to be realized and records a valuation allowance as necessary. Due to the Company's cumulative loss position which provides significant negative evidence, which is difficult to overcome, the Company has recorded a valuation allowance of $119.5 million as of December 31, 2023, representing the portion of the deferred tax asset that is not more likely than not to be realized. For the years ended December 31, 2023 and 2022, the valuation allowance for deferred tax assets increased by $61.7 million and $32.1 million, respectively. The amount of the deferred tax asset considered realizable, could be adjusted for future factors that would impact the assessment of the objective and subjective evidence. The Company will continue to assess the realizability of deferred tax assets at each balance sheet date in order to determine the proper amount, if any, required for a valuation allowance.

The U.S. tax attributes may be subject to an annual limitation under Section 382 of the Internal Revenue Code of 1986 (the "Code"), and similar state provisions if the Company experiences one or more ownership changes, which would limit the amount of the tax attributes that can be utilized to offset future taxable income. In general, an ownership change as defined by Section 382, results from the transactions increasing ownership of certain stockholders or public groups in the stock of the corporation of more than fifty percentage points over a three-year period. If a change in ownership occurs in the future, the net operating loss and research and development credit carryforwards could be eliminated or restricted. If eliminated, the related asset would be removed from the deferred tax asset schedule 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 is subject to tax and will continue to file federal income tax returns in the United States as well as in certain state and local jurisdictions. The Company is subject to tax examinations for tax years ended December 31, 2020 and forward in all applicable income tax jurisdictions. Tax audits and examinations can involve complex issues, interpretations and judgments. The resolution of matters may span multiple years particularly if subject to litigation or negotiation. The Company believes that it has appropriately recorded its tax position using reasonable estimates and assumptions, however the potential tax benefits may impact the results of operations or cashflows in the period of resolution, settlement, or when the statutes of limitations expire. The Company has recorded reserves related to unrecognized tax benefits on historical positions taken by Apexigen in periods before the merger. No interest or penalties have been calculated on the reserves for unrecognized tax benefits due to taxable losses in the years in which the benefits were recorded. The Company does not believe that it is reasonably possible that the resolution of tax exposures within the next twelve months would have a material impact on the consolidated financial statements as of December 31, 2023.

A reconciliation of the beginning and ending amounts of unrecognized tax benefits is as follows (in thousands):

	Year Ended December 31,	
	2023	2022
Gross unrecognized tax benefit at January 1	$ —	$ —
Additions for positions taken during a prior period	2,003	—
Gross unrecognized tax benefit at December 31	$ 2,003	$ —

17. Net Loss per Share

The Company's potentially dilutive securities, which include restricted stock, and stock options, have been excluded from the computation of diluted net loss per share as the effect would be to reduce the net loss per share. Therefore, the weighted-average number of common shares outstanding used to calculate both basic and diluted net loss per share attributable to common stockholders is the same.

Basic and diluted net loss per share was calculated as follows (in thousands, except share and per share amounts):

	Year Ended December 31,	
	2023	2022
Numerator:		
Net loss	$ (73,790)	$ (120,717)
Denominator:		
Weighted-average common shares outstanding, basic and diluted	39,904,603	33,033,081
Net loss per share, basic and diluted	**$ (1.85)**	**$ (3.65)**

The following potentially dilutive securities have been excluded from the calculation of diluted net loss per common share due to their anti-dilutive effect:

	December 31,	
	2023	2022
Stock options outstanding	5,982,464	5,720,415
Unvested restricted stock awards and units	3,631,431	3,015,387
Shares reserved for future issuance	1,013,840	1,697,166
Common stock warrants	1,003,191	—
Employee stock purchase plan	565,405	534,675
Total	**12,196,332**	**10,967,643**

18. Related Parties

The Company was founded out of Dr. Thomas Gajewski's laboratory at the University of Chicago. In 2020, the Company entered into the License Agreement with the University of Chicago, as well as a sponsored research agreement. The Company incurred expenses of $0.2 million and $0.3 million during the years ended December 31, 2023 and 2022, respectively, with regards to the University License Agreement. Refer to Note 4, *Licensing Agreements,* for additional discussion.

Pfizer owns more than 10% of the Company and is considered the principal owner of the Company. The Company incurred expenses of $0 and $17.3 million during the years ended December 31, 2023 and 2022, respectively, with regards to the Pfizer A&R License Agreement. Refer to Note 4, *Licensing Agreements*, for additional discussion.

The Company and Alloy formed a joint venture company, Voxall Therapeutics, LLC ("Voxall") to leverage the Company's technology and Alloy's ATX-Gx™ platform and antibody discovery services. The Company and Alloy contributed $50 thousand each to Voxall along with certain license in 2021. The Company did not incur expenses during the years ended December 31, 2023 and 2022 with regards to Voxall. Refer to Note 5, *Joint Venture*, and Note 20, *Subsequent Events*, for additional discussion.

19. Commitments and Contingencies

Legal Proceedings

From time to time, the Company may become involved in various legal proceedings that arise in the ordinary course of business. The Company is not currently a party to any material legal proceedings and is not aware of any pending or threatened legal proceeding against it that the Company believes could have an adverse effect on its business, operating results or financial condition.

Commitments

In the normal course of business, the Company enters into agreements with various third parties for clinical trials, preclinical research studies and testing, manufacturing and other services and products for operating purposes, which are generally cancellable by the Company at any time, subject to payment of remaining obligations under binding purchase orders and, in certain cases, nominal early-termination fees. These commitments are not deemed significant.

20. Subsequent Event

ATM Offering Program

On January 30, 2024, the Company completed the sale of an aggregate of 3,600,000 shares of common stock under the ATM offering program, with an average sale price of $3.00 per share, resulting in gross proceeds of $10.8 million, before deducting placement agent fees under the ATM offering program. The issuance and sale of common stock under the ATM offering program is made pursuant to our registration statement on Form S-3 (file number 333-268100), which was declared effective by the SEC on November 14, 2022.

Dissolution of Voxall Joint Venture

In February 2024, the Board of Directors of Voxall approved to dissolve the joint venture. The mutual decision to dissolve comes as a result of the corporate reorganization announced in November 2023, as the Company continues to align its resources and refocus its efforts on its progressing the clinical trials. Upon dissolution, Alloy retained rights to certain intellectual property and may develop and commercialize at its sole discretion. Any amounts owed by Voxall to either the Company or Alloy were discharged in their entirety without further liability upon the dissolution. The Company will absorb its portion of the cumulative losses, which is limited to its initial investment in the joint venture of $50 thousand and which was fully provided for in 2021.

Private Placement Funding

On February 26, 2024, the Company entered into a securities purchase agreement (the “Securities Purchase Agreement”) for a private placement (the “Private Placement”) with certain institutional and accredited investors (each, a “Purchaser” and collectively, the “Purchasers”).

Pursuant to the Securities Purchase Agreement, the Company agreed to issue and sell to the Purchasers an aggregate of (i) 8,849,371 shares (the “Shares”) of the Company’s common stock, par value $0.001 per share (the “Common Stock”), at a purchase price of $4.78 per share, and (ii) pre-funded warrants (the “Pre-Funded Warrants”) to purchase up to an aggregate of 1,611,215 shares of Common Stock (the “Pre-Funded Warrant Shares”) at a purchase price of $4.779 per Pre-Funded Warrant, which represents the per share purchase price of the Shares less the $0.001 per share exercise price for each Pre-Funded Warrant. The Pre-Funded Warrants will be exercisable at any time after the date of issuance and will not expire.

The Private Placement closed on February 29, 2024. The Company received gross proceeds from the Private Placement of approximately $50 million, before deducting placement agent fees and offering expenses directly related to the Private Placement.

Exhibit 4.1

DESCRIPTION OF REGISTRANT'S SECURITIES
REGISTERED PURSUANT TO SECTION 12 OF THE
SECURITIES EXCHANGE ACT OF 1934

Pyxis Oncology, Inc. has one class of securities registered under Section 12 of the Securities Exchange Act of 1934, as amended (the "Exchange Act"): its common stock, par value $0.001 per share (the "common stock"). For purposes of this exhibit, unless the context otherwise requires, the words "we," "our," "us" and "our company" refer to Pyxis Oncology, Inc., a Delaware corporation.

Description of Common Stock

General

The following summary sets forth some of the general terms of our common stock. Because this is a summary, it does not contain all of the information that may be important to you. For a more detailed description of our common stock, you should read our amended and restated certificate of incorporation and the amended and restated bylaws, each of which is an exhibit to our Annual Report on Form 10-K to which this summary is also an exhibit, and the applicable provisions of the Delaware General Corporation Law (the "DGCL").

Our amended and restated certificate of incorporation authorizes 190,000,000 shares of common stock, $0.001 par value per share, and 10,000,000 shares of undesignated preferred stock, $0.001 par value per share, the rights, preferences and privileges of which may be designated from time to time by our board of directors.

Dividend Rights

Subject to preferences that may apply to shares of preferred stock outstanding at the time, the holders of outstanding shares of our common stock are entitled to receive dividends out of funds legally available if our board of directors, in its discretion, determines to issue dividends and only then at the times and in the amounts that our board of directors may determine.

Voting Rights

The holders of our common stock are entitled to one vote per share. Stockholders do not have the ability to cumulate votes for the election of directors. We have a classified board of directors consisting of three classes of approximately equal size, each serving staggered three-year terms. Only one class of directors will be elected at each annual meeting of our stockholders, with the other classes continuing for the remainder of their respective three-year terms.

No Preemptive or Similar Rights

Our common stock is not entitled to preemptive rights and is not subject to redemption or sinking fund provisions.

Right to Receive Liquidation Distributions

Upon our liquidation, dissolution or winding-up, the assets legally available for distribution to our stockholders would be distributable ratably among the holders of our common stock and any participating preferred stock outstanding at that time, subject to prior satisfaction of all outstanding debt and liabilities and the preferential rights of and the payment of liquidation preferences, if any, on any outstanding shares of preferred stock.

Preferred Stock

Our board of directors is authorized, subject to limitations prescribed by Delaware law, to issue preferred stock in one or more series, to establish from time to time the number of shares to be included in each series and to fix the designation, powers, preferences and rights of the shares of each series and any of its qualifications, limitations or restrictions, in each case without further vote or action by our stockholders. Our board of directors can also increase or decrease the number of shares of any series of preferred stock, but not below the number of shares of that series then outstanding, without any further vote or action by our stockholders. Our board of directors may authorize the issuance of preferred stock with voting or conversion rights that could adversely affect the voting power or other rights of the holders of our common stock. The issuance of preferred stock, while providing flexibility in connection with possible acquisitions and other corporate purposes, could, among other things, have the effect of delaying, deferring or preventing a change in our control and might adversely affect the market price of our common stock and the voting and other rights of the holders of our common stock.

Anti-Takeover Provisions

The provisions of the Delaware General Corporation Law, or the DGCL, our amended and restated certificate of incorporation and our bylaws could have the effect of delaying, deferring or discouraging another person from acquiring control of our company. These provisions, which are summarized below, are expected to discourage certain types of coercive takeover practices and inadequate takeover bids and encourage persons seeking to acquire control of our company to first negotiate with our board of directors. We believe that the benefits of increased protection of our potential ability to negotiate with an unfriendly or unsolicited acquirer outweigh the disadvantages of discouraging a proposal to acquire us because negotiation of these proposals could result in an improvement of their terms.

Section 203 of the DGCL

We are subject to the provisions of Section 203 of the DGCL regulating corporate takeovers. In general, Section 203 prohibits a publicly held Delaware corporation from engaging in a "business combination" with an "interested stockholder" for a three-year period following the date that this stockholder becomes an interested stockholder, unless the business combination is approved in a prescribed manner. Under Section 203, a business combination between a corporation and an interested stockholder is prohibited unless it satisfies one of the following conditions:

- before the stockholder became interested, our board of directors approved either the business combination or the transaction, which resulted in the stockholder becoming an interested stockholder;
- upon consummation of the transaction, which resulted in the stockholder becoming an interested stockholder, the interested stockholder owned at least 85% of the voting stock of the corporation outstanding at the time the transaction commenced, excluding for purposes of determining the voting stock outstanding, shares owned by persons who are directors and also officers, and employee stock plans in some instances, but not the outstanding voting stock owned by the interested stockholder; or
- at or after the time the stockholder became interested, the business combination was approved by our board and authorized at an annual or special meeting of the stockholders by the affirmative vote of at least two-thirds of the outstanding voting stock, which is not owned by the interested stockholder.

Section 203 defines a business combination to include:

- any merger or consolidation involving the corporation and the interested stockholder;
- any sale, transfer, lease, pledge or other disposition involving the interested stockholder of 10% or more of the assets of the corporation;
- subject to exceptions, any transaction that results in the issuance of transfer by the corporation of any stock of the corporation to the interested stockholder;
- subject to exceptions, any transaction involving the corporation that has the effect of increasing the proportionate share of the stock of any class or series of the corporation beneficially owned by the interested stockholder; and
- the receipt by the interested stockholder of the benefit of any loans, advances, guarantees, pledges or other financial benefits provided by or through the corporation.

In general, Section 203 defines an interested stockholder as any entity or person beneficially owning 15% or more of the outstanding voting stock of the corporation and any entity or person affiliated with or controlling or controlled by the entity or person.

Amended and Restated Certificate of Incorporation and Bylaw Provisions

Our amended and restated certificate of incorporation and our bylaws include a number of provisions that may have the effect of deterring hostile takeovers, or delaying or preventing changes in control of our management team or changes in our board of directors or our governance or policy, including the following:

Board Vacancies

Our amended and restated certificate of incorporation and bylaws authorize generally only our board of directors to fill vacant directorships resulting from any cause or created by the expansion of our board of directors. In addition, the number of directors constituting our board of directors may be set only by resolution adopted by a majority vote of our entire board of directors. These provisions prevent a stockholder from increasing the size of our board of directors and gaining control of our board of directors by filling the resulting vacancies with its own nominees.

Classified Board

Our amended and restated certificate of incorporation and bylaws provide that our board of directors is classified into three classes of directors. The existence of a classified board of directors could delay a successful tender offeror from obtaining majority control of our board of directors, and the prospect of that delay might deter a potential offeror.

Directors Removed Only for Cause

Our amended and restated certificate of incorporation provides that stockholders may remove directors only for cause.

Supermajority Requirements for Amendments of Our Amended and Restated Certificate of Incorporation and Bylaws

Our amended and restated certificate of incorporation further provides that the affirmative vote of holders of at least two-thirds of the voting power of our outstanding common stock is required to amend certain provisions of our amended and restated certificate of incorporation, including provisions relating to the classified board, the size of the board of directors, removal of directors, special meetings, actions by written consent and designation of our preferred stock. The affirmative vote of holders of at least two-thirds of the voting power of our outstanding common stock is required to amend or repeal certain provisions of our bylaws, although our bylaws may be amended by a simple majority vote of our board of directors.

Stockholder Action; Special Meetings of Stockholders

Our amended and restated certificate of incorporation provides that our stockholders may not take action by written consent, but may only take action at annual or special meetings of our stockholders. As a result, holders of our capital stock are not able to amend our bylaws or remove directors without holding a meeting of our stockholders called in accordance with our bylaws. Our amended and restated certificate of incorporation and our bylaws provide that special meetings of our stockholders may be called only by a majority of our board of directors, the chairperson of our board of directors or our chief executive officer, thus prohibiting a stockholder from calling a special meeting. These provisions might delay the ability of our stockholders to force consideration of a proposal or for stockholders to take any action, including the removal of directors.

Advance Notice Requirements for Stockholder Proposals and Director Nominations

Our bylaws provide advance notice procedures for stockholders seeking to bring business before our annual meeting of stockholders or to nominate candidates for election as directors at our annual meeting of stockholders. To be timely, a stockholder's notice generally must be delivered to us not later than the close of business on the 90th day nor earlier than the close of business on the 120th day prior to the first anniversary of the preceding year's annual meeting of stockholders. Our bylaws also specify certain requirements regarding the form and content of a stockholder's notice. With respect to nominations of persons for election to our board of directors, the notice shall provide information about the nominee, including, among other things, name, age, address, principal occupation, ownership of our capital stock and whether they meet applicable independence requirements. With respect to the proposal of other business to be considered by our stockholders at an annual meeting, the notice shall provide a brief description of the business desired to be brought before the meeting, the text of the proposal or business, the reasons for conducting such business at the meeting and any material interest in such business by such stockholder and any beneficial owners and associated persons on whose behalf the notice is made, or the proposing persons. In addition, a stockholder's notice must set forth certain information related to the proposing persons, including, among other things:

- the name and address of the proposing persons;
- information as to the ownership by the proposing persons of our capital stock and any derivative interest or short interest in any of our securities held by the proposing persons;
- information as to any material relationships and interest between the proposing persons and us, any of our affiliates and any of our principal competitors;
- a representation that the stockholder is a holder of record of our stock entitled to vote at that meeting and that the stockholder intends to appear in person or by proxy at the meeting to propose such nomination or business; and
- a representation whether the proposing persons intend or are part of a group which intends to deliver a proxy statement or form of proxy to holders of at least the percentage of our outstanding capital stock required to elect the nominee or carry the proposal.

These provisions may preclude our stockholders from bringing matters before our annual meeting of stockholders or from making nominations for directors at our annual meeting of stockholders. We expect that these provisions might also 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 our company.

No Cumulative Voting

The DGCL provides that stockholders are not entitled to the right to cumulate votes in the election of directors unless a corporation's certificate of incorporation provides otherwise. Our amended and restated certificate of incorporation and bylaws do not provide for cumulative voting.

Issuance of Undesignated Preferred Stock

Our board of directors has the authority, without further action by the stockholders, to issue up to 10,000,000 shares of undesignated preferred stock with rights and preferences, including voting rights, designated from time to time by our board of directors. The existence of authorized but unissued shares of preferred stock enables our board of directors to render more difficult or to discourage an attempt to obtain control of us by means of a merger, tender offer, proxy contest or otherwise.

Exclusive Forum

Our amended and restated certificate of incorporation provides that, unless we consent in writing to the selection of an alternative forum, to the fullest extent permitted by law, the sole and exclusive forum for (1) any derivative action or proceeding brought on our behalf under Delaware law, (2) any action asserting a claim of breach of a fiduciary duty owed by any of our directors, officers or other employees to us or our stockholders, (3) any action arising pursuant to any provision of the Delaware General Corporation Law or our amended and restated certificate of incorporation or bylaws, (4) any other action asserting a claim that is governed by the internal affairs doctrine or (5) any other action asserting an "internal corporate claim," as defined in Section 115 of the Delaware General Corporation Law, shall be the Court of Chancery of the State of Delaware (or, if the Court of Chancery does not have jurisdiction, another state court located within the State of Delaware, or the federal district court for the District of Delaware) in all cases subject to the court having jurisdiction over indispensable parties named as defendants. These exclusive-forum provisions do not apply to claims under the Securities Act or the Exchange Act. Our amended and restated certificate of incorporation also provides that, unless we consent in writing to the selection of an alternative forum, the federal district courts of the United States shall be the exclusive forum for the resolution of any complaint asserting a cause of action arising under the Securities Act or the Exchange Act. Any person or entity purchasing or otherwise acquiring any interest in our securities shall be deemed to have notice of and consented to this provision. Although we believe these provisions benefit us by providing increased consistency in the application of Delaware law for the specified types of actions and proceedings, the provisions may have the effect of discouraging lawsuits against us or our directors and officers.

Transfer Agent and Registrar

The transfer agent and registrar for our common stock is Broadridge Corporate Issuer Solutions, Inc.

Exchange Listing

Our common stock is listed on the Nasdaq Global Select Market under the symbol "PYXS."

Exhibit 10.34

CERTAIN INFORMATION CONTAINED IN THIS DOCUMENT, MARKED BY [***], HAS BEEN OMITTED BECAUSE IT IS NOT MATERIAL AND IS THE TYPE THAT THE REGISTRANT TREATS AS PRIVATE OR CONFIDENTIAL.

November 21, 2023

Via Email Only
Ken Kobayashi [***]

RE: EXECUTIVE EMPLOYMENT AGREEMENT

Dear Dr. Kobayashi:

On behalf of Pyxis Oncology, Inc. ("***Pyxis***", or the "***Company***"), it is my pleasure to confirm the terms and conditions of your employment as Pyxis's Chief Medical Officer, with such duties and responsibilities as commensurate with such position, as disclosed in the position description and as directly by the Company or the Board. You shall report during your employment to the Company's Chief Executive Officer (the "***CEO***"), commencing on November 27, 2023 (the "***Start Date***"). During your employment with Pyxis, you will devote substantially all of your professional efforts to the business of Pyxis, except that you may engage in the business activities described on Appendix A of this employment agreement (this "***Agreement***"), and other activities that may be approved in advance by the Company's Chief Executive Officer, with advice from the Board (which together with the activities set forth on Appendix A may include one for-profit board membership(s)), in each case, so long as these activities do not interfere or conflict with your obligations to the Company. Your employment under the terms of this Agreement shall continue until it terminates in accordance with Section 5 below.

This Agreement supersedes, amends, and restates in all respects all prior agreements and understandings between you and the Company regarding the subject matter herein.

This Agreement is intended to summarize some of the terms and conditions of your employment.

1. Location. Your primary place of employment will be remote from a location you select. From time to time you will be required to travel to Pyxis's principal offices in the Boston metropolitan area or other locations as determined by the CEO. You will be reimbursed for any travel expenses from your place of residence to Pyxis offices and Pyxis meetings when work activities necessitate in-person presence. If permanent or semi-permanent relocation to or near the Company's principal offices is required, then the Company will provide a customary relocation package to the extent any such expenses are not able to be reimbursed by the Company under its travel and entertainment policies.

2. Compensation.

a. *Base Salary* . Your initial annualized base salary rate will be $500,000, less standard deductions and withholding and payable bi-weekly in accordance with Pyxis's regular payroll practices. Your salary shall be reviewed annually and may be adjusted in connection with any such review.

b.*Bonus Program*. You will be eligible for an annual target bonus of 40% of your annual base salary, as determined by the Board in its sole discretion based upon, among other things, the achievement of pre-determined performance milestones. Any annual bonus, if earned, will be paid no later than March 31st of the year immediately following the year to which the applicable annual bonus relates. Any bonus for the fiscal year in which your employment begins will be prorated, based on the number of days you are employed by the Company during that fiscal year.

c.*Option Grants.*

i.Upon commencement of your employment, and as an inducement for you to accept employment with the Company, you will be granted Pyxis stock options (the "***Initial Options***") to purchase 1.25% of the Pyxis's common stock outstanding as of the date of this Agreement. The Initial Options will be granted under the Company's 2022 Inducement Plan. Subject to the approval of the Company's Board of Directors or it's Compensation Committee, the Initial Stock Options will be granted on or before January 1st, 2024 and will have an exercise price per share equal to the closing market price of Pyxis's common stock on Nasdaq on the date of grant. Vesting terms of Initial Options to purchase 1.00% of the Pyxis's common stock outstanding will be as below:

• 25% of the stock option vests on the first anniversary of your Start Date, and

• Thereafter, the remaining 75% of the stock option vests in 36 equal monthly installments until fully vested, on the fourth anniversary of your Start Date.

The remaining Initial Options to purchase 0.25% of the Pyxis's common stock outstanding will vest upon your achievement of negotiated milestone, which we expect to finalize immediately after commencement of your employment with the Company and prior to actual grant of stock options. In the event of a conflict between the terms of this Agreement and the terms of the 2022 Inducement Plan and the underlying Stock Option Agreement, the terms of the 2022 Inducement Plan and the Stock Option Agreement shall prevail.

ii. The Initial Options are subject to the terms of the Company's 2022 Inducement Plan and the applicable Stock Agreement.

iii.Beginning in calendar year 2024 and subsequent to your Initial Options grant, you will be eligible to participate in the Company's stock compensation program based on the applicable policies and procedures of the Company. However, it is hereby clarified that the Company is not obligated to maintain your stock option ownership percentage of 1.25%.

d.*Withholding.* Pyxis shall withhold from any compensation or benefits payable to you by Pyxis any federal, state and/or local income, employment and/or other similar taxes as may be required to be withheld pursuant to any applicable law or regulation.

3.Benefits.

a.*Other*. You will be eligible to participate in the benefits to be offered by Pyxis on the same terms and conditions as it will make such benefits available to similarly situated senior executives of the Company. The benefits are currently expected to include health insurance and such other benefits provided by similar companies of a similar stage, as approved by the Board.

b. *Expenses*. Pyxis shall reimburse you for all reasonable expenses of the type authorized by Pyxis and incurred by you in the performance of your duties under this Agreement, all in accordance with the Company's reimbursement policies.

c. *Terms*. As is the case of all employee benefits, such benefits will be governed by the terms and conditions of applicable Pyxis plans or policies, which are subject to change or discontinuation at any time.

4. Severance.

a. *Definitions.* For purposes of this Agreement:

i. "***Accrued Benefits***" means: (i) any unpaid base salary for services rendered prior to the date of termination of employment; (ii) any earned but unpaid annual bonus for any completed fiscal year prior to the year in which termination of employment occurs; (iii) reimbursement of any unreimbursed business expenses incurred as of the date of termination of employment in accordance with Pyxis's reimbursement policy, (iv) accrued but unused vacation (if applicable), earned through the date of termination of employment; and (v) all other payments, benefits or fringe benefits to which you shall be entitled under the terms of any applicable compensation arrangement or benefit, equity or fringe benefit plan or program or grant with or by Pyxis or this Agreement.

ii. "***Cause***" means conduct involving one or more of the following by you: (i) material failure to perform a substantial portion of your duties and responsibilities in accordance with the terms or requirements of this Agreement and your position, except in the case of your physical or mental illness; (ii) disloyalty, gross negligence, willful misconduct, or dishonesty that materially injures Pyxis or a breach of fiduciary duty to Pyxis; (iii) the conviction of (x) a felony or (y) a misdemeanor involving moral turpitude or fraud that materially injures Pyxis; (iv) the commission of an act of embezzlement or fraud; or (v) your material breach of this Agreement or any other written agreement between Pyxis and you; provided, in the case of clauses (i), (ii) and (v), that the Company provides you with written notice that specifically identifies the conduct that the Company believes to constitute Cause, and you fail to remedy such conduct within 15 days following your receipt of such notice. Notwithstanding the foregoing, "Cause" shall not include or be predicated upon any act or omission by you which is taken or made either at the direction of the Board or the CEO.

iii. "***Change in Control***" shall mean the occurrence of any of the following events: (A) the consummation of merger, consolidation or similar transaction involving (directly or indirectly) the Company and, immediately after the consummation of such transaction, the stockholders of the Company immediately prior thereto do not hold, directly or indirectly, voting securities representing more than 50% of the outstanding voting power of the surviving entity; or (B) the sale of all or substantially all of the Company's stock or assets.

iv. "***Good Reason***" means, without your express written consent, (i) any reduction in your annual base salary as in effect immediately prior to such reduction other than a reduction which is proportional to general reductions affecting other senior executive officers of Pyxis generally or reduction in annual base target bonus, (ii) any diminution in title or position, change in reporting line to anyone other than the CEO of the Company, or a material reduction in your duties or responsibilities (including without limitation your removal as a Section 16 officer of the Company); (iii) any directive by the Company that you act in conflict with your professional medical obligations or

otherwise in violation of law or regulation; or (iv) a material breach by the Company of this Agreement; provided, in each case, that (a) you provide the Company with written notice that specifically identifies the event that you believe to constitute Good Reason within 30 days after you first have knowledge of such event, (b) the Company fails to remedy such event within 30 days following the Company's receipt of such notice and (c) you actually resign your employment with the Company within 30 days following the end of such 30-day remedy period.

b. *Severance Benefits and Payment*.

i. *Generally*. If your employment with Pyxis is terminated (x) by Pyxis for any reason other than Cause, or (y) by you for Good Reason, Pyxis will pay you (1) the Accrued Benefits; and (2) subject to your compliance with Section 4(c) below, after the execution and delivery of the Separation Agreement and General Release in the form attached hereto as Appendix B (the "***Separation Agreement and General Release***") and the expiration of any revocation period without the release being revoked, (A) nine (9) months' base salary, less standard deductions, payable in bi-weekly installments in accordance with the Company's regular payroll policies over the nine (9) month period following such termination of employment, commencing within 60 days following such termination of employment and with the first payment to include the amounts that would have been paid following such termination of employment but were delayed subject to the effectiveness of the Separation Agreement and General Release; and (B) if you elect to continue your health insurance coverage pursuant to your rights under the Consolidated Omnibus Budget Reconciliation Act of 1985, as amended ("***COBRA***"), following the termination of your employment, your monthly premium under COBRA (plus tax gross-up) on a monthly basis until the earlier of (1) nine (9) months following the effective termination date, or (2) the date upon which you commence full-time employment (or employment that provides you with eligibility for healthcare benefits substantially comparable to those provided by Pyxis). A termination of your employment by Pyxis due to physical or mental illness which is not a Disability (as defined herein) shall be treated as an involuntary termination other than for Cause. The term "***Disability***" shall mean that you have not been able to materially engage in your duties and responsibilities after reasonable accommodation by reason of any medically determinable physical or mental impairment for a period of not less than 90 consecutive days or not less than 120 days during any one-year period.

ii. *In connection with the Change in Control Period.*

1. If your employment with Pyxis is terminated (x) by Pyxis for any reason other than Cause, or (y) by you for Good Reason during the period commencing three (3) months prior to a Change in Control and continuing until the twelve (12) month anniversary of a Change in Control (the "***Change in Control Period***"), in lieu of the benefits set forth in Section 5(b)(i), Pyxis will pay you (1) the Accrued Benefits; (2) subject to your compliance with Section 5(c) below, after the execution and delivery of the Separation Agreement and General Release and the expiration of any revocation period without the release being revoked, (A) twelve (12) months' base salary plus your annual bonus at one hundred percent (100%) of target, payable in a single lump sum on the 60th day following the termination of your employment (or, if later, on the 60th day following the Change in Control less the base salary continuation previously paid under Section 5(b)(i)(2)(A)); provided, however, that if the termination of employment occurs within three (3) months prior to the Change in Control and the twelve (12) months' of base salary under this clause (2)(A) constitutes non-qualified deferred compensation within the meaning of Section 409A of the Code, then such base salary shall be payable in bi-weekly installments in accordance with the Company's regular payroll practices over the twelve (12) month period following such termination of employment in accordance with Section

5(b)(i)(2) to the extent required to comply with Section 409A of the Code, and (B) if you elect to continue your health insurance coverage pursuant to your rights under COBRA following the termination of your employment, your monthly premium under COBRA (plus a tax gross-up) on a monthly basis until the earlier of (1) twelve (12) months following the effective termination date, or (2) the date upon which you commence full-time employment (or employment that provides you with eligibility for healthcare benefits substantially comparable to those provided by Pyxis). A termination of your employment by Pyxis due to physical or mental illness which is not a Disability shall be treated as an involuntary termination other than for Cause.

2. In addition to the severance benefits and payments set forth in Section 5(b)(ii)(1), if your employment with Pyxis is terminated during the Change in Control Period (x) by Pyxis for any reason other than Cause or (y) by you for Good Reason, then the Equity Grants shall immediately vest with respect to 100% of the shares subject to the applicable Equity Grants and become exercisable; provided, however, that if the Company or its successor entity (if applicable) does not assume, substitute or continue the unvested portion of any Equity Grants in connection with the Change in Control, then 100% of the unvested portion of the applicable Equity Grants will vest and the applicable Equity Grants will become exercisable immediately prior to the date of the Change in Control, contingent on the consummation of the Change in Control.

c. *Eligibility for Severance*. Eligibility for receipt of the items in Section 4(b) above, shall be conditioned on your (i) returning to Pyxis promptly upon termination of your employment all of its property, including confidential information and all electronically stored information, and (ii) signing and not revoking the Separation Agreement and General Release.

d. *Accrued Benefits*. The Accrued Benefits shall be paid to you (or your estate in the event of your death) upon termination of employment regardless of the circumstances giving rise to such termination.

5. At-Will Employment. Your employment with Pyxis is at will, meaning it may be terminated by you or Pyxis at any time, subject to Section 4above, for any reason with or without Cause. You understand that this Agreement is not a contract for employment for a definite term.

6. Proprietary Information, Inventions and Non-Solicitation Agreement. This offer of employment is subject to the Proprietary Information, Inventions and Non-Solicitation Agreement attached as Appendix C, which shall be effective as of the date set forth therein. For the avoidance of doubt, nothing in the Proprietary Information Agreement or otherwise will prohibit or restrict you from responding to any inquiry, or otherwise communicating with, any federal, state or local administrative or regulatory agency or authority or participating in an investigation conducted by any governmental agency or authority. You cannot be held criminally or civilly liable under any Federal or State trade secret law for the disclosure of a trade secret that is made (A) in confidence to a Federal, State, or local government official, either directly or indirectly, or to an attorney, and (B) solely for the purpose of reporting or investigating a suspected violation of law; or that is made in a complaint or other document filed in a lawsuit or other proceeding, if such filing is made under seal. As a result, the Company and you shall have the right to disclose trade secrets in confidence to Federal, State, and local government officials, or to an attorney, for the sole purpose of reporting or investigating a suspected violation of law. Each of the Company and you also have the right to disclose trade secrets in a document filed in a lawsuit or other proceeding, but only if the filing is made under seal and protected from public disclosure.

Nothing in the Proprietary Information Agreement is intended to conflict with that right or to create liability for disclosures of trade secrets that are expressly allowed by the foregoing.

7. No Inconsistent Obligations. By accepting this offer of employment, you represent and warrant to Pyxis that you are under no obligations or commitments, whether contractual or otherwise, that are inconsistent with your obligations set forth in this Agreement or that would be violated by your employment by Pyxis. You agree that you will not take any action on behalf of Pyxis or cause Pyxis to take any action that will violate any agreement that you have with a prior employer.

8. Delayed Commencement Date for Payments and Benefits.

a. The intent of the parties hereto is that payments and benefits under this Agreement comply with, or be exempt from, Section 409A of the Internal Revenue Code of 1986, as amended, and the regulations and guidance promulgated thereunder (collectively " ***Code Section 409A*** ") and, accordingly, to the maximum extent permitted, this Agreement shall be interpreted to be in compliance therewith or exempt therefrom. If you notify Pyxis (with specificity as to the reason therefor) that you believe that any provision of this Agreement (or of any award of compensation, including equity compensation or benefits) would cause you to incur any additional tax or interest under Code Section 409A and Pyxis concurs with such belief or Pyxis independently makes such determination, Pyxis shall, after consulting with you, reform such provision to try to comply with Code Section 409A through good faith modifications to the minimum extent reasonably appropriate to conform with Code Section 409A. To the extent that any provision hereof is modified in order to comply with Code Section 409A, such modification shall be made in good faith and shall, to the maximum extent reasonably possible, maintain the original intent and economic benefit to you and Pyxis of the applicable provision without violating the provisions of Code Section 409A.

b. A termination of employment shall not be deemed to have occurred for purposes of any provision of this Agreement providing for the payment of any amounts or benefits upon or following a termination of employment that are considered "nonqualified deferred compensation" under Code Section 409A unless such termination is also a "separation from service" within the meaning of Code Section 409A and, for purposes of any such provision of this Agreement, references to a "termination," "termination of employment" or like terms shall mean "separation from service." Notwithstanding any provision to the contrary in this Agreement, no payments or benefits that are considered "nonqualified deferred compensation" under Code Section 409A, then (i) each such payment which is conditioned upon your execution and non- revocation of the Release and which is to be paid or provided during a designated period that begins in one taxable year and ends in a second taxable year, shall be paid or provided in the later of the two taxable years and (ii) each such payment to which you become entitled under this Agreement in connection with your termination of employment, shall be made or provided to you prior to the earlier of (x) the expiration of the 6 month period measured from the date of your "separation from service" with Pyxis (as such term is defined in Code Section 409A) or (y) the date of your death, if you are deemed at the time of such separation from service to be a "specified employee" under Code Section 409A and if, in the absence of such delay, the payments would be subject to additional tax under Code Section 409A. Upon the expiration of the applicable Code Section 409A(a)(2) deferral period, all payments and benefits deferred pursuant to this Section 8(b) (whether they would have otherwise been payable in a single sum or in installments in the absence of such deferral) shall be paid or reimbursed to you in a lump sum, and any remaining payments and benefits due under this Agreement shall be paid or provided in accordance with the normal payment dates specified for them herein. For clarity, a Change in Control shall not be deemed to have occurred for purposes of any

provision of this Agreement unless such Change in Control also constitutes a “change in control event” within the meaning of Code Section 409A.

c. For purposes of Code Section 409A, your right to receive any installment payment pursuant to this Agreement shall be treated as a right to receive a series of separate and distinct payments. Whenever a payment under this Agreement specifies a payment period with reference to a number of days (*e.g.* , “payment shall be made within 30 days following the date of termination”), the actual date of payment within the specified period shall be within the sole discretion of Pyxis. Notwithstanding any other provision of this Agreement to the contrary, in no event shall any payment under this Agreement that constitutes “nonqualified deferred compensation” for purposes of Code Section 409A be subject to offset, counterclaim or recoupment by any other amount payable to you unless otherwise permitted by Code Section

d. All in-kind benefits provided and expenses eligible for reimbursement under this Agreement shall be provided by Pyxis or incurred by you during the time periods set forth in this Agreement. All reimbursements shall be paid as soon as administratively practicable, but in no event shall any reimbursement be paid after the last day of the taxable year following the taxable year in which the expense was incurred. The amount of in-kind benefits provided or reimbursable expenses incurred in one taxable year shall not affect the in-kind benefits to be provided or the expenses eligible for reimbursement in any other taxable year. Such right to reimbursement or in-kind benefits is not subject to liquidation or exchange for another benefit.

e. If under this Agreement an amount is to be paid in installments, each installment shall be treated as a separate payment for purposes of Treasury Regulation Section 1.409A-2(b)(2)(iii).

9. 280G. In the event that the amount of any compensation, payment or distribution by Pyxis or its affiliates to or for your benefit, whether paid or payable or distributed or distributable pursuant to the terms of this Agreement or otherwise, calculated in a manner consistent with Section 280G of the Code and the applicable regulations thereunder (the “***Aggregate Payments***”) would be subject to the excise tax imposed by Section 4999 of the Code, then the Aggregate Payments shall be reduced (but not below zero) so that the sum of all of the Aggregate Payments shall be $1.00 less than the amount at which you become subject to the excise tax imposed by Section 4999 of the Code; provided that such reduction shall only occur if it would result in you receiving a higher After Tax Amount (as defined below) than you would receive if the Aggregate Payments were not subject to such reduction. In such event, the Aggregate Payments shall be reduced in the following order, in each case, in reverse chronological order beginning with the Aggregate Payments that are to be paid the furthest in time from consummation of the transaction that is subject to Section 280G of the Code: (i) cash payments not subject to Section 409A of the Code; (ii) cash payments subject to Section 409A of the Code; (iii) equity- based payments and acceleration not subject to Section 409A of the Code; (iv) equity-based payments and acceleration subject to Section 409A of the Code; and (v) non-cash forms of benefits; provided that in the case of all the foregoing Aggregate Payments all amounts or payments that are not subject to calculation under Treas. Reg. § 1.280G-1, Q&A-24(b) or (c) shall be reduced before any amounts that are subject to calculation under Treasury Regulation §1.280G- 1, Q&A- 24(b) or (c). For purposes of this Section 9, the “***After Tax Amount***” means the amount of the Aggregate Payments less all federal, state, and local income, excise and employment taxes imposed on you as a result of your receipt of the Aggregate Payments. For purposes of determining the After Tax Amount, you shall be deemed to pay federal income taxes at the highest marginal rate of federal income taxation applicable to individuals for the calendar year in which the determination is to be made, and state and local income taxes at the highest marginal rates of

individual taxation in each applicable state and locality, net of the maximum reduction in federal income taxes which could be obtained from deduction of such state and local taxes. The determination as to whether a reduction in the Aggregate Payments shall be made pursuant to this Section 9 shall be made by a nationally recognized accounting firm or a firm specializing in Section 280G calculations selected by Pyxis, which shall provide detailed supporting calculations both to Pyxis and you. The costs of obtaining such determination and all related fees and expenses (including related fees and expenses incurred in any later audit) shall be borne by Pyxis. Notwithstanding the foregoing, if (i) Pyxis is not publicly traded prior to the occurrence of a change in control such that the private company exception pursuant to Q & A #7 of the regulations promulgated under Section 280G of the Code is applicable and (ii) you request that Pyxis seek shareholder approval of the portion of any payments to be made to you which are parachute payments under Section 280G and exceed 2.99 times your "base amount" (as such term is defined in Section 280G) in order that, upon obtaining such approval, all of the payments will be exempt from the excise taxes imposed under Sections 280G and 4999 of the Code, Pyxis shall use its reasonable best efforts to obtain such approval.

10. Miscellaneous.

a. This offer of employment is made subject to you having the legal right to work in the United States.

b. Your employment with Pyxis is subject to all Company policies and procedures, and Pyxis retains the right to change its policies or procedures at any time. Such policies may include, without limitation, stock ownership guidelines, clawback policies, insider trading policies and policies regarding hedging or pledging of Pyxis's common stock.

c. This Agreement may be executed in several counterparts, each of which shall be deemed to be an original but all of which together will constitute one and the same instrument.

d. Neither this Agreement nor any of your rights or obligations hereunder shall be assignable by you. Pyxis may assign this Agreement or any of its obligations hereunder to any subsidiary of Pyxis, or to any successor (whether by merger, purchase or otherwise) to all or substantially all of the equity, assets or businesses of Pyxis. This Agreement is intended to bind and inure to the benefit of and be enforceable to you and Pyxis and Pyxis's permitted successors and assigns.

e. No provision of this Agreement may be modified, waived or discharged unless such waiver, modification or discharge is agreed to in writing and signed by you and such officer or director as may be designated by the Board. No waiver by either party hereto at any time of any breach by the other party hereto of, or compliance with, any condition or provision of this Agreement to be performed by such other party shall be deemed a waiver of similar or dissimilar provisions or conditions at the same or at any prior or subsequent time.

f.The validity, interpretation, construction and performance of this Agreement shall be governed by the laws of the Commonwealth of Massachusetts without regard to the choice of law principles thereof.

g.The Company agrees that it will, with respect to your acts or failures to act in connection with your job duties and responsibilities during your employment with the Company and subject to all applicable terms, conditions, and limitations, provide you with the same indemnification protections (including but not limited to pursuant to the Company's by-laws and any applicable insurance policies) as it provides, if any, to the other senior officers of the Company.

[*remainder of page intentionally left blank*]

If the foregoing is acceptable, please indicate your agreement by signing below and returning the original signed Agreement (keeping a copy for your own records) to me on or before November 27, 2023. If you have any further questions or require additional information, please feel free to contact me.

Sincerely,

PYXIS ONCOLOGY, INC.

By: /s/ Lara Sullivan

Lara S. Sullivan, M.D.
President & Chief Executive Officer

ACCEPTED AND AGREED**:**

/s/ Ken Kobayashi
Date: 11/21/2023

Appendices: Appendix A - Approved Activities
Appendix B - Separation Agreement and General Release
Appendix C - Proprietary Information, Inventions and Non-Solicitation Agreement

Exhibit 10.35

CERTAIN INFORMATION CONTAINED IN THIS DOCUMENT, MARKED BY [***], HAS BEEN OMITTED BECAUSE IT IS NOT MATERIAL AND IS THE TYPE THAT THE REGISTRANT TREATS AS PRIVATE OR CONFIDENTIAL.

THIS DISSOLUTION AGREEMENT (the "**Agreement**") is entered into effective as of February 6, 2024 ("**Effective Date**"), by and among Voxall Therapeutics, LLC (formerly Kyma Therapeutics, LLC) ("**VOX**"), Pyxis Oncology, Inc. ("**PYXS**") and Alloy Therapeutics, Inc. ("**ATX**", each VOX, PYXS, and ATX, individually a "**Party**" and collectively the "**Parties**").

WHEREAS, PYXS and VOX entered into a Pyxis Contribution Agreement, Pyxis License Agreement, and Pyxis Services Agreement; ATX and VOX entered into an Alloy Contribution Agreement, Alloy Master Services Agreement, and Alloy License Agreement; and the Parties entered into an Amended and Restated Operating Agreement (the "**Operating Agreement**") and Collaboration Agreement ("**Collaboration Agreement**", all agreements in this paragraph collectively the "**VOX Agreements**");

WHEREAS, the Parties have agreed pursuant to the relevant provisions of each VOX Agreement to terminate all VOX Agreements, and the Operating Agreement to dissolve VOX; and

WHEREAS, the Parties now wish to clarify certain rights and responsibilities regarding the VOX programs, assets, and liabilities, including the program for Initial Selected Target 1 **[***]** ("**Initial Selected Target 1**"), in view of the dissolution of VOX.

NOW, THEREFORE, in consideration of the foregoing and the mutual agreements set forth below, and for other good and valuable consideration, the receipt and sufficiency of which are hereby acknowledged, the Parties agree as follows:

1. **Dissolution of Voxall Therapeutics, LLC**

1.1. Approval of Dissolution by Voxall Board of Directors and Founding Members . The VOX Board of Directors, and the VOX founding members PYXS and ATX, hereby elect to dissolve VOX per Section 12.01(ii) of the Operating Agreement.

1.2. Dissolution Process . Unless otherwise detailed in this Agreement, the Parties agree that VOX shall be liquidated and dissolved according to Sections 12.01-12.03 of the Operating Agreement and the Delaware Limited Liability Company Act as of the Effective Date of this Agreement.

1.3. Cancellation of Debts . PYXS and ATX agree that all promissory notes issued by VOX to each of PYXS and ATX under the VOX Agreements, and other amounts owed by VOX to each of PYXS and ATX, shall be discharged in their entirety without further liability. PYXS

and ATX further agree that no payments will be made by VOX to PYXS or ATX under Section 12.02 of the Operating Agreement unless specifically set forth in this Agreement.

1.4. Liquidation of Proceeds . The Parties agree that any proceeds remaining following the dissolution of VOX shall be split in the following manner: 50% of proceeds to PYXS and 50% of proceeds to ATX.

1.5. Assignment of Intellectual Property . The Parties agree that all intellectual property as pertaining to **[***]** (" **Initial Selected Target 1 IP** "), including but not limited to, antigens, animals, hybridomas, monoclonal and polyclonal antibodies, cell bank(s) and reagents, and any developments, discoveries, improvements or inventions (whether or not patentable or copyrightable), together with all patent or other intellectual property rights, shall be assigned, and hereby is assigned, to ATX, and ATX accepts such assignment of intellectual property. VOX and/or PYXS shall cooperate, at ATX's expense, with all reasonable requests of ATX to facilitate and perfect ATX's rights therein, including but not limited to, executing those documents as reasonably related to the application, prosecution, and maintenance of the Initial Selected Target 1 IP. Ownership of all other intellectual property originating from the VOX Agreements apart from the Initial Selected Target 1 IP, if any, shall follow inventorship and shall be assigned, and hereby is assigned, to the Party to which the inventor(s) owe an obligation of assignment, either contractually or by nature of their employment, of such intellectual property, either PYXS or ATX respectively.

1.6. Ownership of Materials . All antigens, sera, animals, hybridomas, monoclonal and polyclonal antibodies, cell bank(s) and reagents related to Initial Selected Target 1 IP (" **Initial Selected Target 1 Materials** ") shall be transferred to ATX and shall be owned by ATX without payment to VOX or PYXS. Ownership of any other materials originating from the VOX Agreements apart from Initial Selected Target 1 Materials, if any, shall follow inventorship and shall be assigned, and hereby is assigned, to the Party to which the inventor(s) owe an obligation of assignment, either contractually or by nature of their employment or which originally procured (*i.e.* , obtained by payment of consideration) and/or originally owned such materials.

1.7. Termination of VOX Agreements; Incorporation by Reference . As of the Effective Date, all VOX Agreements shall be terminated, without further action or notice required on behalf of any Party hereto, and corresponding rights, responsibilities, and obligations of the Parties under the VOX Agreements shall cease in their entirety. Notwithstanding the foregoing, wherever specifically referenced in this Agreement, or necessary to provide context to this Agreement, the relevant provisions of the VOX Agreements shall survive termination solely for such purpose.

1.8. Assumption of No Third-Party Claims . As of the Effective Date of this Agreement, the Parties are not aware of any third-party claims against VOX. However, upon or after liquidation, if such third-party claims arise, PYXS and ATX will negotiate an amendment to this Agreement in good faith to accommodate such claims.

2. **Rights of Alloy Therapeutics, Inc. Upon Dissolution**

2.1. Ownership and Management of Initial Selected Target 1 IP. Subject only to PYXS' rights detailed herein, the Initial Selected Target 1 IP shall be owned in its entirety by ATX, and any preparation, filing, prosecution, maintenance, enforcement, or defense of the Initial Selected Target 1 IP shall be managed by ATX at its sole discretion and expense. The other Parties hereto shall cooperate reasonably with ATX in carrying out this provision, at ATX's expense.

2.2. Development and Commercialization of Initial Selected Target 1 Program . Subject only to PYXS' rights detailed herein, ATX at its sole discretion and expense, may develop and commercialize the Initial Selected Target 1 Program. Any revenue derived from the commercialization, licensing, sale, or other monetization of the Initial Selected Target 1 (" **Program Commercialization** ") shall accrue solely to ATX.

2.3. Abandonment of the Initial Selected Target 1 Program . If ATX, at its sole discretion, decides to abandon the Initial Selected Target 1 (" **Program Abandonment** "), ATX shall inform PYXS in writing of this decision at least **[***]** before irreparable loss occurs to either Initial Selected Target 1 IP or Initial Selected Target 1 Materials, at which time PYXS may choose at its sole discretion and expense whether to assume the Initial Selected Target 1 Program. Upon written notice by ATX of Program Abandonment, if within **[***]** : (1) PYXS elects to assume responsibility for the Initial Selected Target 1 Program, as confirmed in written notice to ATX, ATX shall transfer and assign all rights in all Initial Selected Target 1 IP and Initial Selected Target 1 Materials to PYXS, including without limitation, any Initial Selected Target 1 IP and Initial Selected Target 1 Materials developed by or for ATX following the Effective Date, and PYXS shall have no further obligation to ATX regarding the Initial Selected Target 1 Program; or (2) if PYXS elects not to assume the Initial Selected Target 1 Program or fails to respond to ATX, then ATX shall have no further obligation to PYXS and may proceed with Program Abandonment at its sole discretion.

3. **Rights of Pyxis Oncology, Inc. Upon Dissolution**

3.1. Program Updates and Agreement to Negotiate . Until **[***]** , or the events of Section 3.2, per the terms of this Agreement, upon the request of PYXS, ATX will: (a) up to **[***]** , provide PYXS an update on the research and development of the Initial Selected Target 1 Program, or indicate if no progress has been made (" **Program Update** "); and/or (b) negotiate in good

faith with PYXS to exclusively license the Initial Selected Target 1 Program to PYXS at commercially reasonably terms, but in any case upon terms at least as favorable as PYXS would have been entitled to under the VOX Agreements.

3.2. **[***]**

4. **Releases**

Unless otherwise specifically detailed in this Agreement, each of the Parties, both for itself and for its affiliates, and any successors and assigns of any of the foregoing, and for good and valuable consideration, the receipt and adequacy of which are hereby acknowledged, hereby fully and completely forever release and discharge the other Parties, and each of their respective subsidiaries, affiliates, and any successors and assigns, from any and all claims, actions, causes of action, suits, debts, dues, sums of money, accounts, reckonings, covenants, contracts, controversies, agreements, promises, variances, trespasses, damages, judgments, expenses, executions, affirmative defenses, demands and other obligations or liabilities whatsoever arising from the VOX Agreements (collectively, "**Claims**"), in law or equity, whether known or unknown, fixed or contingent, based on or arising out of any matter, cause, act or omission whatsoever, occurring or existing at any time up to and including the date hereof; provided, however, that the foregoing shall not release any Party from any obligation of such Party under any provision of this Agreement arising on or after the date hereof.

5. **Miscellaneous**

5.1. Entire Agreement; Construction . This Agreement constitutes the entire agreement of the Parties with respect to the subject matter hereof and supersedes all prior understandings and agreements, whether written or oral, as to such subject matter. The language used in this Agreement will be deemed to be the language chosen by the Parties to express their mutual intent, and no rule of strict construction will be applied against any Party.

5.2. Confidentiality . The confidentiality provisions of Article 5 of the Collaboration Agreement shall be incorporated into this Agreement by reference and continue to apply as applicable.

5.3. Dispute Resolution . The dispute resolution provisions of Section 9.6 of the Collaboration Agreement shall be incorporated into this Agreement by reference and continue to apply as applicable.

5.4. Amendment, Assignment, Successors . This Agreement may be amended or modified only by a writing signed by the Parties, and may not be assigned by a Party without the written consent of the other Parties; provided that a Party may assign this Agreement upon written notice to the other Parties to an affiliate or a successor to that area of the assigning Party's

business to which this Agreement is related. This Agreement will be binding upon and will inure to the benefit of the respective successors and permitted assigns of the Parties hereto.

5.5. No Waiver . No provision of or right under this Agreement will be deemed to have been waived or amended by any act or acquiescence on the part of a Party, its affiliates, or their representatives, but only by an instrument in writing signed by an authorized representative of such Party. No waiver by a Party of any breach of this Agreement by another Party will be effective as to any other breach, whether of the same or any other term or condition and whether occurring before or after the date of such waiver.

5.6. Notices .

If to Pyxis:
Pyxis Oncology, Inc.
321 Harrison Ave., Floor 11 Suite 1
Boston, MA 02118
Attention: Chief Executive Officer
Email: [___]

If to Alloy:
Alloy Therapeutics, Inc.
275 Second Ave, Suite 200
Waltham, MA 02451
Attention: Legal Department
Email: [___]

5.7. Governing Law . This Agreement will be governed by and construed in accordance with the laws of Delaware without taking into account its principles on conflicts of law.

5.8. Severability . This Agreement is severable, and in the event that any of these covenants or provisions will for any reason be adjudged, decreed or ordered by any court of competent jurisdiction to be unenforceable in any respect, such covenants or provisions will be deemed modified to the extent necessary to render all of them enforceable and such judgment, decree or order will not affect, impair or invalidate any of the remaining covenants or provisions of this Agreement.

5.9. Execution; Counterparts . This Agreement may be executed by electronic transmission and in multiple counterparts, each of which will be deemed an original, but all of which together will constitute one and the same instrument.

IN WITNESS WHEREOF, the Parties have caused this Agreement to be executed as of the Effective Date.

[*Signature Page Follows*]

PYXIS ONCOLOGY, INC.

By: /s/ Lara Sullivan
Name: Lara Sullivan
Title: Chief Executive Officer

ALLOY THERAPEUTICS, INC.

By: /s/ Errik B. Anderson
Name: Errik B. Anderson
Title: CEO, Chairman, & Founder

VOXALL THERAPEUTICS, LLC

By: /s/ Errik B. Anderson
Name: Errik B. Anderson
Title: Director

By: /s/ Lara Sullivan
Name: Lara Sullivan
Title: Director

Exhibit 21.1

List of Subsidiaries

Subsidiary	Jurisdiction
Pyxis Securities Corporation	Massachusetts
Apexigen, Inc.	California
Apexigen America Inc.	Delaware

Exhibit 23.1

Consent of Independent Registered Public Accounting Firm

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

(1) Registration Statement (Form S-8 No. 333-260441) pertaining to the Pyxis Oncology, Inc. 2019 Stock Plan, Pyxis Oncology, Inc. 2021 Equity and Incentive Plan, and the Pyxis Oncology, Inc. 2021 Employee Stock Purchase Plan,

(2) Registration Statement (Form S-8 No. 333-263950) pertaining to the Pyxis Oncology, Inc. 2021 Equity and Incentive Plan,

(3) Registration Statement (Form S-8 No. 333-266005) pertaining to the Pyxis Oncology, Inc. 2022 Inducement Plan,

(4) Registration Statement (Form S-8 No. 333-270753) pertaining to the Pyxis Oncology, Inc. 2021 Equity and Incentive Plan and the Pyxis Oncology, Inc. 2021 Employee Stock Purchase Plan,

(5) Registration Statement (Form S-8 No. 333-274178) pertaining to the Apexigen, Inc. 2022 Equity Incentive Plan,

(6) Registration Statement (Form S-8 No. 333-272510) pertaining to the Apexigen, Inc. 2010 Equity Incentive Plan, the Apexigen, Inc. 2020 Equity Incentive Plan, and the Apexigen, Inc. 2022 Equity Incentive Plan, and

(7) Registration Statement (Form S-3 No. 333-268100) of Pyxis Oncology, Inc.;

of our report dated March 21, 2024, with respect to the consolidated financial statements of Pyxis Oncology, Inc., included in this Annual Report (Form 10-K) of Pyxis Oncology, Inc. for the year ended December 31, 2023.

/s/ Ernst & Young LLP

Boston, Massachusetts

March 21, 2024

Exhibit 31.1

CERTIFICATION

I, Lara Sullivan, M.D., certify that:

1. I have reviewed this Annual Report on Form 10-K of Pyxis Oncology, Inc.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report.

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report.

4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) for the registrant and have:

a. Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

b. Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

c. Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

d. Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

a. All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

b. Any fraud, whether or not material, which involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: March 21, 2024

By: /s/ Lara Sullivan
Lara Sullivan, M.D.
President and Chief Executive Officer

Exhibit 31.2

CERTIFICATION

I, Pamela Connealy, certify that:

1. I have reviewed this Annual Report on Form 10-K of Pyxis Oncology, Inc.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report.

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report.

4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) for the registrant and have:

a. Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

b. Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

c. Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

d. Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

a. All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

b. Any fraud, whether or not material, which involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: March 21, 2024

By: /s/ Pamela Connealy
Pamela Connealy
Chief Financial Officer and Chief Operating Officer

Exhibit 32.1

CERTIFICATION PURSUANT TO
18 U.S.C. SECTION 1350, AS ADOPTED PURSUANT TO
SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

In connection with the Annual Report of Pyxis Oncology, Inc. (the "Company") on Form 10-K for the fiscal year ended December 31, 2023 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I certify, pursuant to 18 U.S.C. § 1350, as adopted pursuant to § 906 of the Sarbanes-Oxley Act of 2002, that:

1. The Report fully complies with the requirements of section 13(a) or 15(d) of the Securities Exchange Act of 1934, as amended; and

2. The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Date: March 21, 2024

By: /s/ Lara Sullivan
Lara Sullivan, M.D.
President and Chief Executive Officer

Exhibit 32.2

CERTIFICATION PURSUANT TO
18 U.S.C. SECTION 1350, AS ADOPTED PURSUANT TO
SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

In connection with the Annual Report of Pyxis Oncology, Inc. (the "Company") on Form 10-K for the fiscal year ended December 31, 2023 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I certify, pursuant to 18 U.S.C. § 1350, as adopted pursuant to § 906 of the Sarbanes-Oxley Act of 2002, that:

1. The Report fully complies with the requirements of section 13(a) or 15(d) of the Securities Exchange Act of 1934, as amended; and

2. The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Date: March 21, 2024

By: /s/ Pamela Connealy
Pamela Connealy
Chief Financial Officer and Chief Operating Officer

Exhibit 97

PYXIS ONCOLOGY, INC.

POLICY ON RECOUPMENT OF INCENTIVE COMPENSATION

Introduction

The Compensation Committee (the "Compensation Committee") of the Board of Directors (the "Board") of Pyxis Oncology, Inc., a Delaware corporation (the "Company") has recommended to the Board and the Board has adopted this Policy on Recoupment of Incentive Compensation (this "Policy"), which provides for the recoupment of compensation in certain circumstances in the event of a restatement of financial results by the Company. This Policy shall be interpreted to comply with the requirements of U.S. Securities and Exchange Commission ("SEC") rules and The Nasdaq Stock Market ("Nasdaq") listing standards implementing Section 954 of the Dodd- Frank Wall Street Reform and Consumer Protection Act of 2010 (the "Dodd-Frank Act") and, to the extent this Policy is in any manner deemed inconsistent with such rules, this Policy shall be treated as retroactively amended to be compliant with such rules.

Administration

This Policy shall be administered by the Compensation Committee. Any determinations made by the Compensation Committee shall be final and binding on all affected individuals. The Compensation Committee is authorized to interpret and construe this Policy and to make all determinations necessary, appropriate or advisable for the administration of this Policy, in all cases consistent with the Dodd-Frank Act. The Board or Compensation Committee may amend this Policy from time to time in its discretion.

Covered Executives

This Policy applies to any current or former "executive officer," within the meaning of Rule 10D-1 under the Securities Exchange Act of 1934, as amended, of the Company or a subsidiary of the Company (each such individual, an "Executive"). This Policy shall be binding and enforceable against all Executives and their beneficiaries, executors, administrators, and other legal representatives. It is clarified that Board of Directors of Pyxis Oncology has approved "Named Executive Officer" as of the effective date of this policy and covers CEO, CFO & COO, CAO and CMO.

Recoupment Upon Financial Restatement

In the event of an Accounting Restatement (as defined below), the Compensation Committee shall cause the Company to recoup from each Executive, as promptly as reasonably possible, any erroneously awarded Incentive-Based Compensation, as defined below.

Accounting Restatement

Accounting Restatement means an accounting restatement due to the material noncompliance of the Company with any financial reporting requirement under the securities laws, including any required accounting restatement to correct an error in previously issued financial statements that is material to the previously issued financial statements, or that would result in a material misstatement if the error were corrected in the current period or left uncorrected in the current period (a "Financial Restatement").

No-Fault Recovery

Recoupment under this Policy shall be required regardless of whether the Executive or any other person was at fault or responsible for accounting errors that contributed to the need for the Financial Restatement or engaged in any misconduct.

Compensation Subject to Recovery; Enforcement

This Policy applies to all compensation granted after the effective date of this policy, earned or vested based wholly or in part upon the attainment of any financial reporting measure determined and presented in accordance with the accounting principles used in preparing the Company's financial statements, and any measure that is derived wholly or in part from such measures, whether or not presented within the Company's financial statements or included in a filing with the SEC, including stock price and total shareholder return ("TSR"), including but not limited to performance-based cash, stock, options or other equity-based awards paid or granted to the Executive ("Incentive-Based Compensation"). **Compensation that is granted, vests or is earned based solely upon the occurrence of non-financial events, such as base salary, restricted stock or options with time-based vesting, or a bonus awarded solely at the discretion of the Board or Compensation Committee and not based on the attainment of any financial measure, is not subject to this Policy.** It is further clarified that compensation granted, vests or is earned based solely upon non-financial performance measures such as attainment of clinical milestone or acquisition or disposal of pipeline assets or corporate scorecard in not subject to this policy.

In the event of a Financial Restatement, the amount to be recovered will be the excess of (i) the Incentive-Based Compensation received by the Executive during the Recovery Period (as defined below) based on the erroneous data and calculated without regard to any taxes paid or withheld, over (ii) the Incentive-Based Compensation that would have been received by the Executive had it been calculated based on the restated financial information, as determined by the Compensation Committee. For purposes of this Policy, "Recovery Period" means the three completed fiscal years immediately preceding the date on which the Company is required to prepare the Financial Restatement, as determined in accordance with the last sentence of this paragraph, or any transition period that results from a change in the Company's fiscal year (as set forth in Section 5608(b)(i)(D) of the Nasdaq Listing Rules). The date on which the Company is required to prepare a Financial Restatement is the earlier to occur of (A) the date the Board or a Board committee (or authorized officers of the Company if Board action is not required) concludes, or reasonably should have concluded, that the Company is required to prepare a Financial Restatement or (B) the date a court, regulator, or other legally authorized body directs the Company to prepare a Financial Restatement.

For Incentive-Based Compensation based on stock price or TSR, where the amount of erroneously awarded compensation is not subject to mathematical recalculation directly from the information in the Financial Restatement, then the Compensation Committee shall determine the amount to be recovered based on a reasonable estimate of the effect of the Financial Restatement on the stock price or TSR upon which the Incentive-Based Compensation was received and the Company shall document the determination of that estimate and provide it to the Nasdaq.

Incentive-Based Compensation is considered to have been received by an Executive in the fiscal year during which the applicable financial reporting measure was attained or purportedly attained, even if the payment or grant of such Incentive-Based Compensation occurs after the end of that period.

The Company may use any legal or equitable remedies that are available to the Company to recoup any erroneously awarded Incentive-Based Compensation, including but not limited to by collecting from the Executive cash payments or shares of Company common stock from or by forfeiting any amounts that the Company owes to the Executive.

No Indemnification

The Company shall not indemnify any Executive or pay or reimburse the premium for any insurance policy to cover any losses incurred by such Executive under this Policy or any claims relating to the Company's enforcement of rights under this Policy.

Exceptions

The compensation recouped under this Policy shall not include Incentive-Based Compensation received by an Executive (i) prior to beginning service as an Executive or (ii) if he or she did not serve as an Executive at any time during the performance period applicable to the Incentive- Based Compensation in question. The Compensation Committee (or a majority of independent directors serving on the Board) may determine not to seek recovery from an Executive in whole or part to the extent it determines in its sole discretion that such recovery would be impracticable because (A) the direct expense paid to a third party to assist in enforcing recovery would exceed the recoverable amount (after having made a reasonable attempt to recover the erroneously awarded Incentive-Based Compensation and providing corresponding documentation of such attempt to the Nasdaq), (B) recovery would violate the home country law that was adopted prior to November 28, 2022, as determined by an opinion of counsel licensed in the applicable jurisdiction that is acceptable to and provided to the Nasdaq, or (C) recovery would likely cause the Company's 401(k) plan or any other tax-qualified retirement plan to fail to meet the requirements of Section 401(a)(13) or Section 411(a) of the Internal Revenue Code of 1986, as amended, and the regulations thereunder.

Other Remedies Not Precluded

The exercise by the Compensation Committee of any rights pursuant to this Policy shall be without prejudice to any other rights or remedies that the Company, the Board or the Compensation Committee may have with respect to any Executive subject to this Policy, whether arising under applicable law (including pursuant to Section 304 of the Sarbanes-Oxley Act of 2002), regulation or pursuant to the terms of any other policy of the Company, employment agreement, equity award, cash incentive award or other agreement applicable to an Executive.

Notwithstanding the foregoing, there shall be no duplication of recovery of the same Incentive- Based Compensation under this Policy and any other such rights or remedies.

Acknowledgment

To the extent required by the Compensation Committee, each Executive shall be required to sign and return to the Company the acknowledgement form attached hereto as Exhibit A pursuant to which such Executive will agree to be bound by the terms of, and comply with, this Policy. For the avoidance of doubt, each Executive shall be fully bound by, and must comply with, the Policy, whether or not such Executive has executed and returned such acknowledgment form to the Company.

Effective Date and Applicability

This Policy has been adopted by the Board on November 14, 2023, and shall apply to any Incentive-Based Compensation that is received by an Executive on or after October 2, 2023. In the event, there is conflict between this policy and employment agreement or relevant Executive Officers stock options or RSUs grant agreement, then provisions of this policy will prevail.

IN WITNESS WHERE, the undersigned being all the members of the Board of Directors of Pyxis Oncology, Inc. have approved and executed this policy as of the date written below.

Name	Title	Date
/s/ Lara Sullivan **Lara Sullivan, M.D.**	President, Chief Executive Officer and Director	November 14, 2023
/s/ John Flavin **John Flavin**	Chairman of the Board of Directors	November 14, 2023
/s/ Thomas Civik **Thomas Civik**	Director	November 14, 2023
/s/ Darren Cline **Darren Cline**	Director	November 14, 2023
/s/ Freda Lewis-Hall, M.D. **Freda Lewis-Hall, M.D.**	Director	November 14, 2023
/s/ Rachel Humphrey, M.D. **Rachel Humphrey, M.D.**	Director	November 14, 2023
/s/ Jakob Dupont, M.D. **Jakob Dupont, M.D.**	Director	November 14, 2023

EXHIBIT A

DODD-FRANK COMPENSATION CLAWBACK POLICY ACKNOWLEDGEMENT FORM

Capitalized terms used but not otherwise defined in this Acknowledgement Form (this "***Acknowledgement Form***") shall have the meanings ascribed to such terms in the Policy.

By signing this Acknowledgement Form, the undersigned acknowledges, confirms and agrees that the undersigned: (i) has received and reviewed a copy of the Policy; (ii) is and will continue to be subject to the Policy and that the Policy will apply both during and after the undersigned's employment with the Company; and (iii) will abide by the terms of the Policy, including, without limitation, by reasonably promptly returning any Recoverable Compensation to the Company as required by the Policy, as determined by the Compensation Committee in its sole discretion.

Sign:

Name:

Date: