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, 2025

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) 453-3596

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, 2025, the last business day of the Registrant's most recently completed second fiscal quarter, was approximately $64.4 million, as computed by reference to the closing price of the common stock on the Nasdaq Global Select Market on that date. Shares of the registrant's common stock held by executive officers, directors, and their affiliates have been excluded from this calculation. The determination of affiliate status is not necessarily a conclusive determination for other purposes.

As of March 20, 2026, the Registrant had 62,831,246 shares of common stock, $0.001 par value per share, outstanding.

DOCUMENTS INCORPORATED BY REFERENCE

Portions of the registrant's definitive proxy statement for its 2026 Annual Meeting of Stockholders, which the registrant intends to file pursuant to Regulation 14A with the Securities and Exchange Commission not later than 120 days after the registrant's fiscal year ended December 31, 2025, are incorporated by reference into Part III of this Annual Report on Form 10-K.

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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 continue as a going concern;
- our ability to develop and advance our current product candidate and program, and to successfully initiate and complete clinical trials;
- the ability of our clinical trials to demonstrate the safety, purity and potency of our product candidate and other positive results;
- the size of the market opportunity for our product candidate, including our estimates of the number of patients who suffer from the cancers we are targeting;
- our manufacturing, commercialization and marketing capabilities and strategy;
- the timing or likelihood of regulatory filings and approvals for our product candidate;
- regulatory developments in the United States 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 candidate;
- our continued reliance on third parties to manufacture our product candidate for clinical studies, and to conduct clinical trials and manufacture our product candidate 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 oncology company with a limited operating history and have incurred significant losses since our inception and anticipate that we will continue to incur losses over at least the next several years and may never achieve or maintain profitability.
- We have substantial doubt about our ability to continue as a going concern and 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 not be able to continue as a going concern or 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 our lead product candidate, micvotabart pelidotin (MICVO), formerly known as PYX-201, which is in the early stages of clinical development. If our lead product candidate is not successful in clinical trials or does not receive regulatory approval or licensure or is not successfully commercialized, our business will be materially and adversely affected.
- Our product candidate may fail in development or suffer delays that materially and adversely affect its 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 candidate or experience significant delays in doing so, our business will be materially harmed.
- Our product candidate may cause undesirable and unforeseen side effects or have other properties impacting safety that could halt its clinical development, delay or prevent its regulatory licensure, limit its commercial potential or result in significant negative consequences.
- We may face significant competition from other oncology-focused biotechnology and pharmaceutical entities, and our operating results will suffer if we fail to compete effectively.
- 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 candidate.
- The regulatory licensure and approval processes of the FDA and other comparable foreign regulatory authorities are lengthy, time-consuming and inherently unpredictable and, if we are unable to obtain marketing licensure or approval for our product candidate, 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 candidate. Any failure by a third party manufacturer to produce acceptable raw materials or product candidate 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.
- If we are unable to obtain or protect our intellectual property in and to our product candidates, 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 candidate 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 Pfizer license agreement or any of the other agreements under which we acquired, or will acquire, intellectual property rights covering our product candidate, we could lose the ability to continue the development and commercialization of the related product candidate(s).

- 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.
- Our information technology systems, or those of any of our existing or future CROs, manufacturers, other contractors, consultants, or collaborators, may be compromised, which could result in additional costs, significant liabilities, harm to our reputation and material disruption of our operations.

PART I

Item 1. Business.

Overview

Pyxis Oncology is a clinical-stage oncology company advancing a development strategy focused on addressing unmet medical needs in patients with solid tumors with an immediate focus on head and neck squamous cell carcinoma (HNSCC).

Our lead product candidate, micvotabart pelidotin (MICVO, formerly PYX-201), is an investigational novel antibody-drug conjugate (ADC) that uniquely targets the splice variant of fibronectin, extradomain-B of fibronectin (EDB+FN), a non-cellular structural component of the extracellular matrix (ECM) in the tumor microenvironment (TME). EDB+FN is an isoform of fibronectin present in tumors that is negligibly expressed in normal adult tissues and facilitates cancer progression by playing multiple roles including promoting cell proliferation, adhesion, and migration, activating the integrin signaling pathway, stimulating angiogenesis and vascular remodeling, driving epithelial-mesenchymal transition (EMT), and establishing the pre-metastatic niche. We believe EDB+FN is a compelling target for cancer therapeutics as the physiological expression of EDB+FN is very low in healthy adult tissues, yet it is found to be highly expressed in a variety of solid tumors.

Our ADC, MICVO, consists of a fully human IgG1 monoclonal antibody that is site-specifically conjugated to a cleavable linker with an optimized auristatin (Aur0101) microtubule inhibitor payload. Unlike conventional ADCs which bind to an antigen on the surface of a cancer cell, MICVO is designed to bind to EDB+FN in the tumor ECM, where extracellular proteases under acidic conditions cleave the linker to release the Aur0101 payload. The payload diffuses through the membrane of cancer cells to kill them directly, which is the first component of MICVO's three-pronged mechanism of action (MOA). The dying cancer cells release the payload which diffuses into nearby cancer cells and kills them via the bystander effect, representing the second component of MICVO's MOA. The dying cancer cells also release neoantigens which trigger immunogenic cell death (ICD), the final component of its MOA. Together with its purpose-built design and postulated three-pronged MOA, MICVO has the potential for improved stability and anti-tumor activity compared to conventional ADCs.

MICVO is currently being studied as monotherapy in recurrent and metastatic head and neck squamous cell carcinoma (R/M HNSCC) and in combination with KEYTRUDA® (pembrolizumab) in 1L/2L+ R/M HNSCC and other solid tumors.

MICVO Monotherapy

PYX-201-101 Phase 1 (Part 1) Monotherapy Dose Escalation Study

As part of our Phase 1 monotherapy study, referred to as PYX-201-101, we conducted a dose escalation study to evaluate MICVO monotherapy in patients with advanced solid tumors known to express EDB+FN. In November 2024, we reported positive preliminary results from the dose escalation study, which included a total of 80 patients dosed across nine solid tumor types at doses ranging from 0.3 mg/kg to 8 mg/kg, with a data cut-off of October 4, 2024. Of the nine solid tumor types included in the study, the strongest tumor regression response was observed in R/M HNSCC. Among the six efficacy evaluable heavily pre-treated patients with R/M HNSCC, the confirmed objective response rate (ORR) was 50% per RECIST v1.1 at the therapeutically active dose response range of 3.6 mg/kg – 5.4 mg/kg administered intravenously every three weeks (IV Q3W), including one confirmed complete response (CR) and two confirmed partial responses (PRs), with a disease control rate (DCR) of 100%. Based on observations from the dose-escalation study, 5.4 mg/kg IV Q3W presented an optimal benefit-risk profile within the efficacious dose range and was selected for dose expansion. Subsequent translational data indicated reduction in ctDNA TF after treatment with MICVO, particularly at the 5.4 mg/kg dose, supported a positive molecular response to MICVO, providing further validation of the dose selection strategy for dose expansion.

PYX-201-101 Phase 1 (Part 2) Monotherapy Dose Expansion in R/M HNSCC

In January 2025, we initiated the dose expansion portion (Part 2) of the Phase 1 PYX-201-101 monotherapy study to further evaluate MICVO as a monotherapy at a dose of 5.4 mg/kg IV Q3W and to assess preliminary efficacy in R/M HNSCC. The Part 2 dose-expansion phase includes the following two cohorts:

- Arm 1: MICVO monotherapy for second line (2L) and third line (3L) R/M HNSCC patients who have received prior platinum-based chemotherapy and prior PD-(L)1 inhibitor therapy; and
- Arm 2: MICVO monotherapy for 2L and 3L R/M HNSCC patients who have received prior epidermal growth factor receptor (EGFR) directed therapy and prior PD-(L)1 inhibitor therapy.

In December 2025, we reported positive preliminary data from our ongoing Phase 1 monotherapy study evaluating MICVO in patients with 2L+ R/M HNSCC, based on a data cut-off date of November 3, 2025, which included all R/M HNSCC patients dosed at 5.4 mg/kg total body weight (TBW) in Part 1 and in Part 2. As of the data cut-off, 18 R/M HNSCC patients had been treated and 13 patients were efficacy evaluable. All treated patients had received prior systemic therapy, with a median of three prior lines of therapy. All treated patients had received prior platinum-based and checkpoint inhibitor therapies while 67% of treated patients had received prior taxanes and 50% of treated patients had received prior EGFR-targeted therapies, specifically cetuximab. Among the 13 efficacy evaluable patients, the confirmed ORR was 46% (6/13, one patient confirmed response after November 3, 2025 data cut-off) per RECIST v1.1, including one confirmed complete response. Confirmed responses were observed in both dose-expansion cohorts, including patients previously treated with platinum-based therapy and anti-PD(L)1 therapy (Arm 1) and patients previously treated with an EGFR inhibitor and/or anti-PD(L)1 therapy (Arm 2), and were observed in patients regardless of HPV status. The preliminary data also showed a DCR of 92%, with 12 of 13 efficacy evaluable patients demonstrating significant tumor regression or tumor control.

Preliminary data reported in December 2025 indicated that MICVO was generally well tolerated. No Grade 4 ADC payload treatment-related adverse events (TRAEs) of interest were observed, and no Grade 5 events occurred. TRAEs were reported in 89% (16/18) of patients, with Grade ≥3 TRAEs reported in 56% (10/18) of patients. TRAEs leading to treatment discontinuation occurred in 28% (5/18) of patients. We observed a higher discontinuation rate and incidence of Grade ≥3 TRAEs in high body weight patients (defined as at least 10% above adjusted ideal body weight, or AIBW). In the preliminary dataset, all patients (5/5) who experienced TRAEs leading to treatment discontinuation had high body weight. Several approved ADCs have demonstrated comparable associations among patient body weight, systematic drug exposure, and tolerability profiles. Many of these ADCs, such as Padcev, Adcetris, and Elahere, have addressed such observations through dosing modifications that resulted in an improved tolerability profile while sustaining efficacy, including through capping the maximum allowable dose or employing AIBW dosing. We are actively evaluating both of these approaches to optimize MICVO's benefit-risk profile.

MICVO Combination Therapy

In November 2024, we announced a Clinical Trial Collaboration and Supply Agreement with Merck & Co, Inc. or Merck (known as MSD outside of the United States and Canada), for a Pyxis Oncology-sponsored study of MICVO in combination with Merck's anti-PD-1 therapy, KEYTRUDA® (pembrolizumab). In January 2025, we initiated the Phase 1/2 combination study with KEYTRUDA®, PYX-201-102, and are actively enrolling and dosing patients in this study. PYX-201-102 is a Phase 1/2 open label, global, multicenter dose escalation and dose expansion study designed to evaluate the safety, tolerability, pharmacokinetics (PK), pharmacodynamics (PD) and preliminary efficacy of MICVO in combination with pembrolizumab in patients with advanced solid tumors. Patients with histologically or cytologically confirmed advanced solid tumors, including 1L R/M HNSCC, 2L+ R/M HNSCC, cervical cancer, gastric cancer, HR+/HER2- breast cancer, and locally advanced or metastatic triple-negative breast cancer (TNBC), are eligible to enroll.

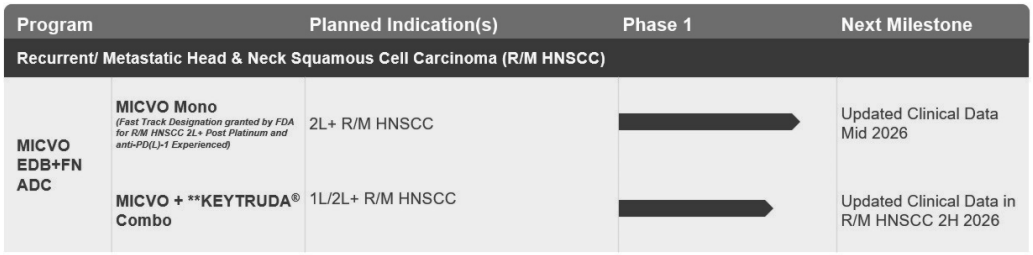
PYX-201-102 Phase 1/2 Preliminary Combination Data in R/M HNSCC

In December 2025, we reported positive preliminary data from this study, evaluating MICVO at 3.6 mg/kg and 4.4 mg/kg IV Q3W, each administered in combination with a fixed 200 mg dose of pembrolizumab Q3W, in patients with 1L/2L+ R/M HNSCC. As of the data cut-off date of November 3, 2025, seven patients had been treated, including four patients at 3.6 mg/kg and three patients at 4.4 mg/kg of MICVO, each in combination with pembrolizumab. All treated patients had received prior systemic therapy, including four patients with 1L R/M HNSCC (median of one prior systemic therapy administered in the neoadjuvant or adjuvant setting) and three patients with 2L+ R/M HNSCC (median of three prior lines of therapy, some of which were administered prior to the R/M setting). Among the seven efficacy-evaluable patients, the confirmed ORR was 71% (5/7, one patient confirmed response after November 3, 2025 data cut-off) and the DCR was 100% (7/7), with all seven patients demonstrating meaningful tumor regression. Responses were observed across a range of PD-L1 combined positive scores (CPS), from CPS≥1 to CPS>20, and included responses in patients who had previously received checkpoint inhibitor treatment and had experienced disease progression while receiving checkpoint inhibitor treatment. Preliminary safety data indicated that MICVO in combination with pembrolizumab was generally well tolerated, with no Grade 3 or Grade 4 ADC payload TRAEs of interest and no Grade 5 events reported. TRAEs were reported in 86% (6/7) of patients. No TRAEs led to treatment discontinuation, and, as of the data cut-off date, no overlapping toxicities between MICVO and pembrolizumab (KEYTRUDA®) had been observed.

We believe the totality of our preliminary data supports continued clinical development of both MICVO monotherapy expansion and combination therapy trials.

Our Clinical Pipeline

The following table summarizes our clinical pipeline:



The combination trial is part of a Clinical Trial Collaboration Agreement with Merck (known as MSD outside of the US and Canada)

**KEYTRUDA® is a registered trademark of Merck Sharp & Dohme LLC, a subsidiary of Merck & Co., Inc., Rahway, NJ, USA.

MICVO Monotherapy Pipeline

The dose expansion phase of our PYX-201-101 monotherapy study is ongoing with the objective of further evaluating the preliminary safety, efficacy and durability signals observed with MICVO in R/M HNSCC at the 5.4mg/kg dose. We completed target enrollment of approximately 40 patients in the Phase 1 monotherapy dose expansion study of MICVO in 2L+ R/M HNSCC in the first quarter of 2026 and are actively treating patients in two monotherapy R/M HNSCC cohorts at the 5.4 mg/kg IV Q3W dose. The dose expansion phase includes the following R/M HNSCC cohorts across sites in the United States (US), European Union (EU) and other countries:

- MICVO monotherapy for 2L and 3L R/M HNSCC patients who have received prior platinum-based chemotherapy and prior PD-(L)1 inhibitor therapy. We expect to enroll approximately 20 patients in this expansion cohort at the 5.4 mg/kg IV Q3W dose and anticipate reporting updated clinical data from this cohort in mid-2026; and
- MICVO monotherapy for 2L and 3L R/M HNSCC patients who have received prior epidermal growth factor receptor (EGFR) directed therapy and prior PD-(L)1 inhibitor therapy. We expect to enroll approximately 20 patients in this expansion cohort at the 5.4 mg/kg IV Q3W dose and anticipate reporting updated clinical data from this cohort in mid-2026.

MICVO Phase 1 monotherapy data in 2L+ R/M HNSCC expected in mid-year 2026 will include patients dosed at 5.4 mg/kg IV Q3W with a dose cap for patients with higher body weight, as well as patients previously dosed at 5.4 mg/kg IV Q3W based on total body weight. The results are expected to include detailed analyses of the effect of the modified weight-based dosing strategy on safety and efficacy. AIBW dosing, which has demonstrated improved tolerability without apparent loss of activity in clinical studies of other antibody-drug conjugates, is being implemented in ongoing clinical studies as well.

During the fourth quarter of 2025, we obtained feedback and alignment from the U.S. Food and Drug Administration (FDA) regarding the clinical trial design for a planned pivotal monotherapy study in 2L+ R/M HNSCC.

MICVO Combination Therapy Pipeline

Our Phase 1/2 combination study with KEYTRUDA® (PYX-201-102) is ongoing and we are conducting the dose escalation phase of PYX-201-102 across multiple tumor types with the objective of identifying the Recommended Phase 2 Dose (RP2D) of MICVO in combination with pembrolizumab. We are currently enrolling and dosing patients across several dose levels between 3.6 mg/kg and 5.4 mg/kg of MICVO, in combination with pembrolizumab at the fixed dose of 200 mg IV Q3W, in order to accurately characterize the RP2D for MICVO in combination with pembrolizumab, subject to ongoing safety review, enrollment progress, and clinical data evaluation.

We expect to report updated data from the PYX-201-102 study in patients with 1L/2L+ R/M HNSCC in the second half of 2026.

Our Team

Pyxis Oncology was founded in 2018 and began operations in 2019 with a mission to address difficult-to-treat cancers. We have assembled a multidisciplinary team with experience across core oncology research and development functions and corporate and administrative operations. Collectively, our team brings experience spanning early- through late-stage development and, in certain cases, commercialization, across biotechnology and pharmaceutical organizations.

Our Strategy

Our goal is to improve the lives of patients with difficult-to-treat cancers. Key elements of our strategy include:

- **Building a leading ADC oncology company.** We believe our team, with its deep oncology knowledge, functional biology expertise, ADC modality technical know-how and biologics development capabilities, positions us to build a leading ADC-focused oncology company.
- **Successfully developing our lead product candidate, MICVO, to address significant unmet need in R/M HNSCC.** We are prioritizing development of our lead product candidate, MICVO, for R/M HNSCC, where we believe there is significant unmet need for durable therapeutic options. HNSCC is among the most common cancers, and it has been estimated that approximately one million new cases could occur worldwide annually by 2030. Our prioritization reflects, among other factors, the unmet need in this patient population and the preliminary activity observed to date in the PYX‑201‑101 monotherapy and PYX-201-102 combination program.
- **Selectively forging alliances to provide strategic or financial support to our lead MICVO program.** We intend to seek strategic collaborations to facilitate the capital efficient development of our pipeline. We believe various potential alliance structures including collaborations, licenses and future agreements could potentially provide significant funding to advance our pipeline and could allow us to benefit from the additional resources, development and commercialization expertise of our collaborators.
- **Maximize value from our intellectual property and technology platforms.** We continue to engage in discussions with potential partners regarding opportunities to monetize elements of our intellectual property portfolio, including certain programs that are not currently being actively resourced. We also seek to maximize the value of our biologics technology platforms, including our Flexible Antibody Conjugation Technology (FACT) platform for ADC development and our APXiMAB platform for antibody discovery and development.

Unmet Need in Head and Neck Cancer and Treatment Paradigm

Head and Neck Cancer (HNC) is the seventh most common cancer in the world (Source: NIH), with 940,000 new cases and 480,000 deaths from HNC per 2022 GLOBOCAN estimates. GLOBOCAN is a cancer surveillance branch of the World Health Organization's International Agency for Research on Cancer (Source: https://pmc.ncbi.nlm.nih.gov/articles/PMC12507627/). Squamous Cell Carcinoma presents as the most common HNC subtype and is derived from the mucosal lining of the oral cavity, oropharynx, hypopharynx and larynx. It is estimated that by 2030 there will be approximately one million new cases of HNSCC worldwide annually per 2022 GLOBOCAN estimates. HNC accounts for approximately 4.5% of cancer diagnoses and deaths globally with over 90% of cases presenting with squamous cell origin.

HNSCC commonly originates in the mouth and throat, from the mucosa of the oral cavity, oropharynx, hypopharynx and larynx. There are approximately 60,000 cases of HNSCC each year in the U.S. with a 13% 5-year survival rate in the R/M (Stage IVC) setting. 15% of HNSCC patients are diagnosed with de novo metastatic disease and almost 50% of locally advanced cases will suffer a recurrence post initial treatment and/or become metastatic. There are approximately 31,000 cases of R/M HNSCC each year in the U.S. with ~67% (~21,000) of patients progressing from 1L to 2L and facing a sharp decline in survival. The median Overall Survival (OS) for patients with 1L R/M HNSCC ranges from 9 months (HPV unrelated) to about 14 months (HPV+). The overall incidence of HNSCC is expected to rise with a predicted 30% increase annually by 2030. The increase has been associated with multiple factors, including but not limited to tobacco use, alcohol consumption, a rise in HPV infections and other environmental catalysts. Approximately 80% of patients in the U.S. with R/M HNSCC are HPV unrelated. Globally, these numbers vary with higher rates of HPV+ cancers in countries such as New Zealand and parts of Northern Europe. The vast majority of HPV+ HNSCC cases are detected in the oropharyngeal cavity versus other locations (oral cavity, pharynx, larynx etc.) with approximately 5,500 cases of virally driven tumors diagnosed in the U.S. each year. Furthermore, HPV+ HNSCC is also on the rise in the U.S. with a greater number of oropharyngeal cancer cases diagnosed every year, suggesting potential shifts in how patients will be diagnosed and treated based on possible HPV segmentation.

Current Treatment Paradigm of R/M HNSCC

The standard of care (SOC) first line therapy for R/M HNSCC globally is determined by the Combined Positive Score (CPS) which corresponds to the number of PD-L1 positive cells in relation to the total number of viable tumor cells. Patients with high CPS scores tend to respond better to PD-(L)1 checkpoint inhibitors, as observed across multiple tumor types. In R/M HNSCC, pembrolizumab monotherapy (was previously approved for CPS≥20) is recommended for patients with a CPS≥1 post label expansion based on KEYNOTE-048 (KN_048) (~26,000 addressable patients). However, addition of platinum-based chemotherapy is strongly considered in these patients if they are symptomatic or present with aggressive disease. Pembrolizumab combined with platinum and 5-fluorouracil is recommended for patients with any PD-L1 status of CPS≥1 essentially providing a monotherapy or combo option to all patients considered PD-L1+ with different treatment options adopted by region worldwide. While approved, the chemo combination is not always reimbursed by the health authorities in certain parts of Europe but is the most commonly used regimen in the U.S. The addition of chemotherapy to pembrolizumab increases the response rate; however, it also significantly reduces the duration of response while increasing toxicity and leads to roughly equivalent median overall survival (OS) with both treatments. For patients with a CPS<1 and no PD-L1 expression, the typical standard of care is the EXTREME regimen (not in the U.S.), a combination of cetuximab and chemotherapy, which has low response rates and survival (10 months), as well as a difficult tolerability profile. The EXTREME regimen is more commonly used in Europe and other ex-US countries with less than 5% usage in the U.S. Patients with CPS<1 in the US receive a chemotherapy combination consisting of platinum (cisplatin or carboplatin) with 5-fluorouracil to lower toxicity associated with addition of cetuximab. While the 1L R/M HNSCC treatment paradigm is well defined, globally, limited options are available for patients that fail therapy and move into 2L and beyond. If patients are treated with immuno-oncology (IO) in 1L, they are not eligible for re-treatment and the only therapy approved is chemotherapy. Cetuximab (with or without chemo) does not have an approved FDA or EMA label post IO but is recommended by certain clinical practice and regulatory guidelines set forth by some countries including the NCCN in the US. Patients that are platinum refractory or not treated with IO in 1L are eligible for pembrolizumab or nivolumab monotherapy in 2L but progression free survival (mPFS) benefit remains modest at 2-3 months, highlighting need for a more efficacious option in these patients.

The Phase 3 KN-048 trial conducted by Merck investigated pembrolizumab as a monotherapy or in combination with chemotherapy, compared to cetuximab with chemotherapy in first line R/M HNSCC. The pembrolizumab monotherapy and pembrolizumab and chemotherapy combination response rates of 19% and 36%, respectively, were comparable to the 36% ORR for cetuximab and chemotherapy combination in patients with CPS≥1. In these patients, pembrolizumab monotherapy and in combination with chemotherapy led to median OS of 12.3 and 13.0 months, respectively, compared to 10.7 months in the active control arm. While this represents a step forward, there remains significant unmet need in R/M HNSCC for more efficacious therapies that can extend survival, especially for chemotherapy-free alternatives with superior tolerability and also differentiated treatment modalities that can serve the emerging unmet need populations as the treatment paradigms may evolve. Patients that are not eligible for 1L pembrolizumab (CPS<1) represent ~3500 patients and lack efficacious treatment options that offer durable survival and quality of life. Furthermore, pembrolizumab was also recently approved in the adjuvant and neo-adjuvant setting allowing subsets of localize/locally advanced patients to benefit from IO in the peri-operative setting. Use of IO in earlier disease may impact use in the R/M setting which may result in additional shifts to the R/M HNSCC landscape.

HPV status also does not play a role in patient segmentation and treatment choices based on approved SOC but a shift may occur as emerging therapies may prove to be superior in one patient segment versus another. This could open up newer patient groups with unmet needs that may not be fulfilled by current or emerging therapies, particularly in the 2L+ setting given that HPV+ patients have historically shown poor response rates to EGFR therapies.

Emerging Treatment Landscape of R/M HNSCC

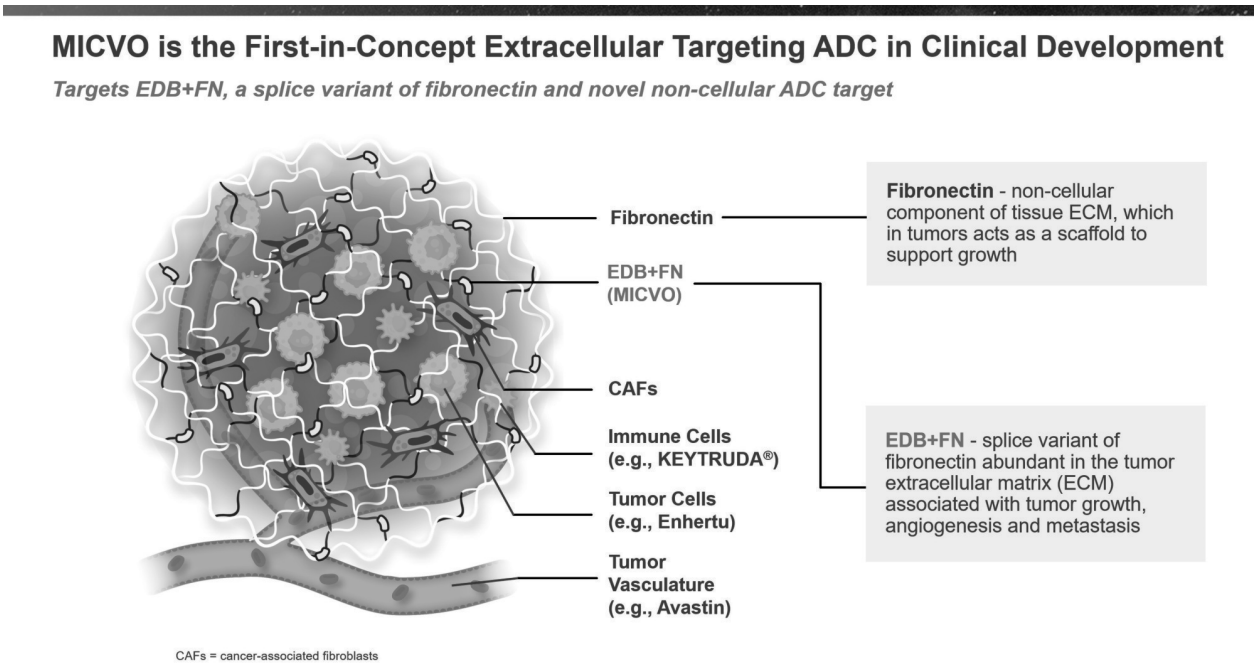
Currently, several companies are innovating next-generation EGFR assets and bi-specific antibodies to address the needs of HNSCC patients, including Genmab A/S (Genmab) via its acquisition of Merus N.V (Merus), Bicara Therapeutics Inc. (Bicara) and Johnson & Johnson (JNJ). Genmab, Bicara and JNJ have ongoing clinical trials evaluating antibodies targeting EGFR - petosemtamab, ficerafusp alfa (BCA101), and RYBREVANT FASPRO™ (amivantamab and hyaluronidase-lpuj), respectively, as a monotherapy or as a combination therapy with pembrolizumab for the treatment of R/M HNSCC solid tumors, with a focus on combination therapy for 1L. All assets have been granted breakthrough designation (BTD) by the U.S. Food and Drug Administration (FDA) in R/M HNSCC. Genmab has two Phase 3 clinical trials ongoing, 1L treatment of R/M PD-L1+ (CPS≥1) HNSCC in combination with pembrolizumab and 2L/3L R/M HNSCC monotherapy. Bicara has ongoing trials for the treatment of 1L R/M HNSCC, including a Phase 2/3 combination trial with pembrolizumab in HPV unrelated patients only (1L, CPS>1). JNJ also has ongoing trials for the treatment of 1L R/M HNSCC in HPV unrelated patients only. Aside from these next-generation EGFR assets, Corbus Pharmaceuticals has ongoing clinical trials evaluating a Nectin-4 targeting ADC, CRB-701, for the treatment of 2L+ R/M HNSCC with monotherapy and 1L R/M HNSCC in combination with pembrolizumab. Additionally, other agents like Nanobiotix's radioenhancer, NBTRX3, are in clinical development and may be used earlier in the treatment sequence such as in localized or locally advanced settings. Other modalities including but not limited to T cell engagers may segment market further into HPV+ specific treatments along with other emerging segmentations that may trigger a change in clinical practice. These evolving shifts naturally result in the development of new patient populations (particularly in the R/M setting) that are left with limited treatments and generate a new unmet need. For example, the use of IO in the surgical setting may limit its use in the 1L segments while the use of next-generation of EGFRi in 1L may create a growing need for therapies post IO and EGFRi. Emerging therapies may be potentially limited to specific patient segments such as HPV+ or HPV unrelated patients or CPS>1 only. Furthermore, patients that fail existing and emerging therapies are more likely to have poor performance status, which will necessitate that the next tranche of treatment options be tolerable so patients can stay longer on the treatment and derive a survival benefit.

Our Solution: MICVO, a Novel ADC

MICVO is an investigational novel ADC that is designed to uniquely target the splice variant of fibronectin, EDB+FN, a non-cellular structural component of the ECM in the TME. The TME is a complex ecosystem consisting of cancer cells, stroma, immune cells, blood vessels and secreted factors like cytokines. The tumor stroma consists of cancer-associated fibroblasts (CAFs) and ECM which is interspersed throughout the TME. The tumor ECM consists of many proteins like fibronectin and some, not all, fibronectin proteins in the tumor ECM are EDB+FN.

Fibronectin is a key component of healthy ECM and is involved in the regulation of cell adhesion, migration, differentiation and wound healing. In tumors, fibronectin strands within the ECM, along with other proteins and polysaccharides, form a complex scaffold that gives the tumor shape and play critical roles in the tumor ECM remodeling process to promote progression and metastasis. EDB+FN is an isoform of fibronectin present in tumors and negligibly expressed in normal adult tissues resulting from alternative splicing, a process that occurs when ribonucleic acid (RNA) is re-arranged to produce multiple variants of the same protein. EDB+FN facilitates cancer progression by playing multiple roles including promoting cell proliferation, adhesion, and migration, activating the integrin signaling pathway, stimulating angiogenesis and vascular remodeling, driving epithelial-mesenchymal transition (EMT), and establishing the pre-metastatic niche. The localization of EDB+FN in the tumor ECM is illustrated in Figure 1 below.

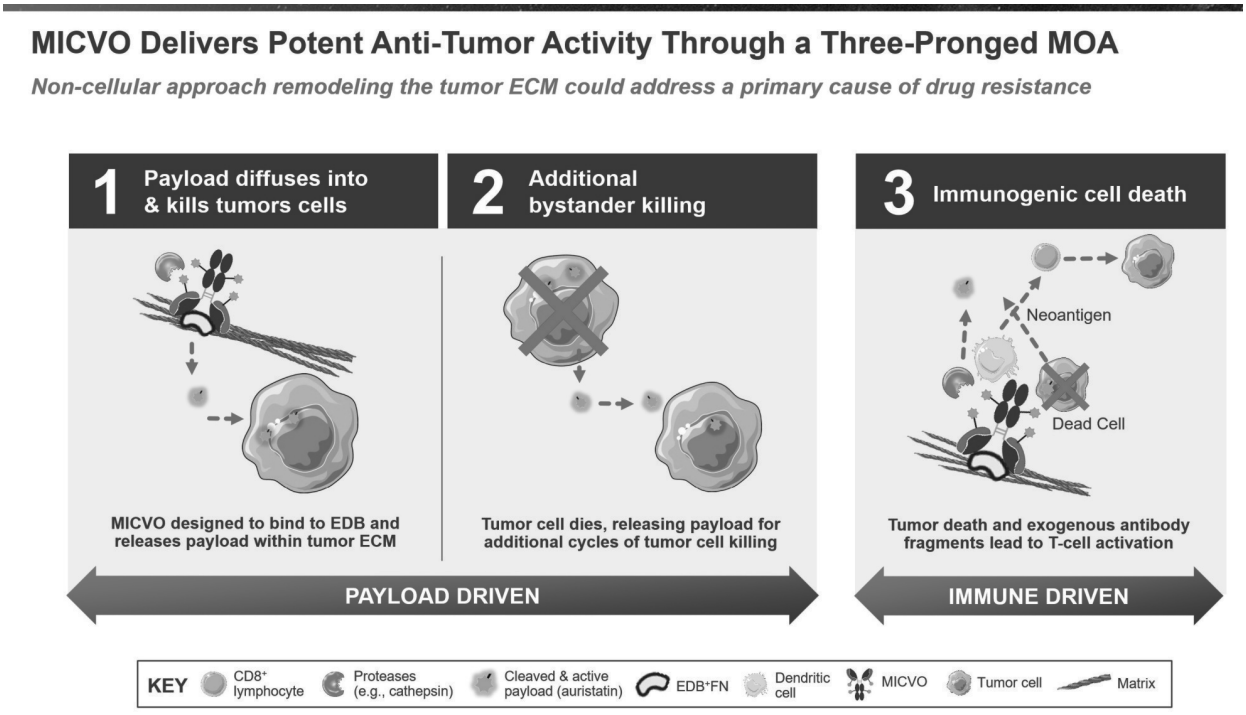
Figure 1



The tumor ECM can form an effective barrier to entry of therapeutic agents such as some chemotherapies. Although the tumor ECM plays a significant role in the initiation, growth, survival, invasion and drug resistance of solid tumors, few therapeutics specifically target tumor-specific ECM proteins.

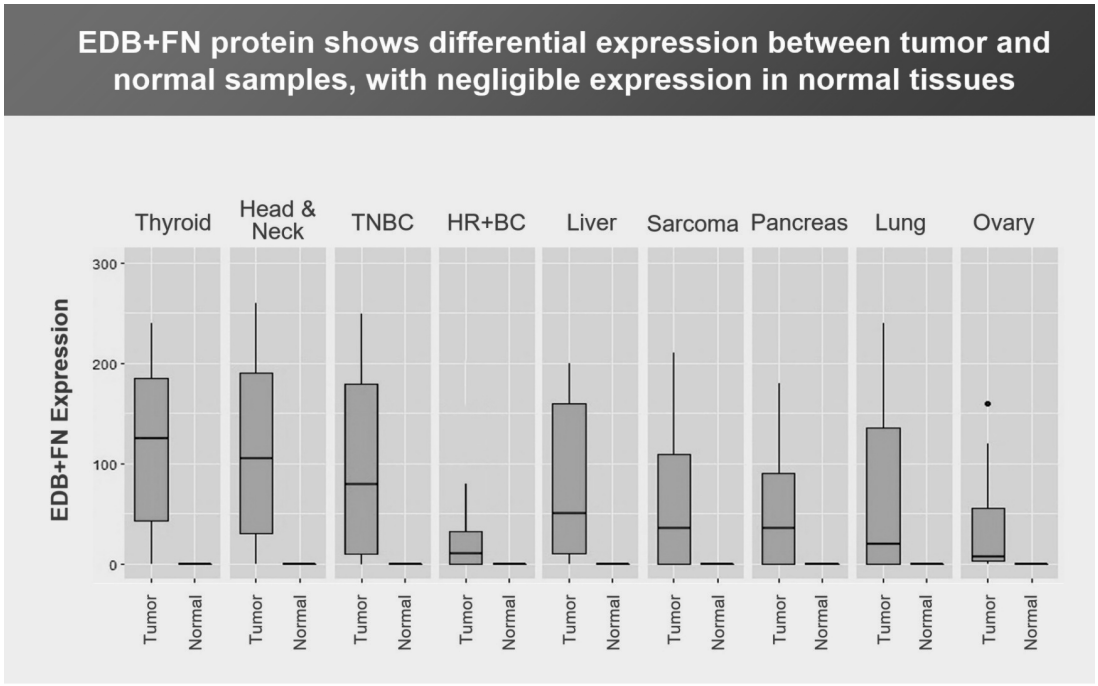
Our ADC, MICVO, consists of a fully human IgG1 monoclonal antibody that is site-specifically conjugated to a cleavable linker with an optimized auristatin (Aur0101) microtubule polymerization inhibitor payload. MICVO was developed using the Flexible Antibody Conjugation Technology (FACT) Platform, developed by Pfizer, to produce an ADC designed to be highly stable with a predictable and homogenous drug-to-antibody ratio (DAR) of four. The complementarity determining regions of the EDB+FN antibody used in MICVO, which is the part of the antibody responsible for binding to EDB+FN, is well characterized and has been tested clinically in the form of a radiolabel-conjugated antibody for tumor imaging demonstrating a high degree of tumor-directed specificity. Unlike conventional ADCs which bind to an antigen on the surface of a cancer cell, MICVO is designed to bind to EDB+FN in the tumor ECM, where extracellular proteases under acidic conditions cleave the linker to release the Aur0101 payload. The payload diffuses through the membrane of cancer cells to kill them directly, which is the first component of MICVO's three-pronged MOA. The dying cancer cells release the payload which diffuses into nearby cancer cells and kills them via the bystander effect, representing the second component of MICVO's MOA. The dying cancer cells also release neoantigens which trigger immunogenic cell death (ICD), the final component of its MOA. Together with its purpose-built design and postulated three pronged MOA, MICVO has the potential for improved stability and anti-tumor activity compared to conventional ADCs. The MOA for MICVO is illustrated in Figure 2 below.

Figure 2



EDB+FN is highly expressed in a variety of cancers, including, but not limited to, cancers of the head and neck, breast, lung, ovary, pancreas, and thyroid as compared to a matched set of normal tissues. EDB+FN expression is detectable as early as stage 1 of cancer progression and increases in more advanced stages. Furthermore, EDB+FN expression is maintained in distant metastasis in human cancer. The broad expression of EDB+FN protein in the ECM of the tumor of many cancer types as compared to negligible expression in normal adult tissues is shown in Figure 3 below.

Figure 3



Source: Pyxis Oncology nonclinical data

We believe EDB+FN is a compelling target for cancer therapeutics as the physiological expression of EDB+FN is very low in healthy adult tissues, yet it is found to be highly expressed in a variety of solid tumors. By targeting EDB+FN in the tumor ECM, our goal is to deliver a cytotoxic payload directly to the tumor and be released extracellularly within the acidic tumor ECM to permeate the tumor, diffuse into and kill cancer cells and stimulate an immune response to further enhance cancer cell killing, all without requiring the ADC itself to reach the cancer cell and be internalized. Additionally, MICVO may also remodel the TME to destabilize the barrier that protects, feeds and provides structure to the tumor while sparing healthy cells.

MICVO is designed to exhibit anti-tumor activity through three distinct modes of action:

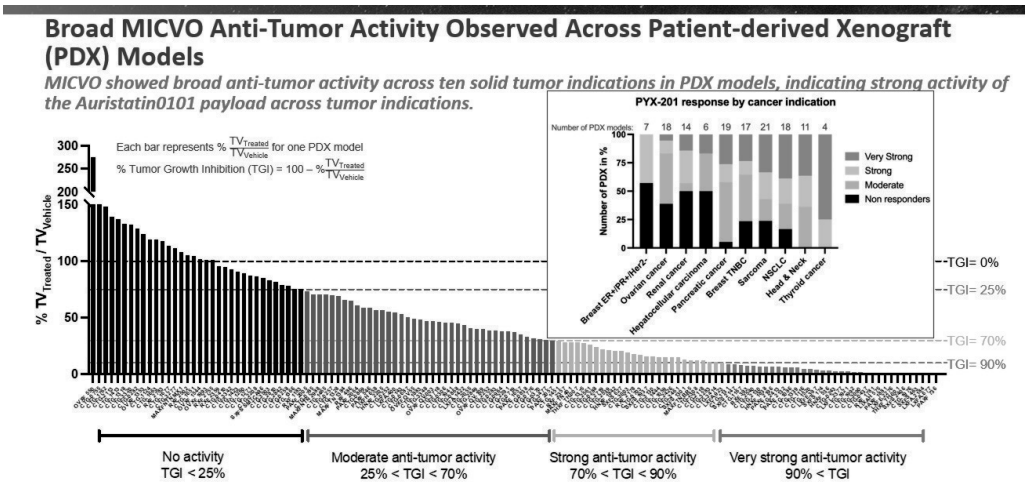
- **Direct cancer cell killing activity**: MICVO targets EDB+FN within the tumor ECM where active extracellular proteases in an acidic microenvironment cleave the linker and release the cytotoxic chemotherapy payload which then diffuses into and kills the cancer cells.
- **Additional bystander killing**: Dying cancers cells release the free payload which then diffuses into and kills nearby cancer cells via the bystander effect.
- **Immunogenic cell death**: Lastly, dying cancer cells release neoantigens which stimulate immune cell activation and induce immunogenic cell death.

Preclinical Data

In April 2025, we presented preclinical data at the 2025 American Association for Cancer Research (AACR) Annual Meeting in Chicago, Illinois. We observed broad anti-tumor activity for MICVO across ten solid tumor indications in PDX models. Tumor responsiveness to the optimized cytotoxic Auristatin0101 payload did not correlate with EDB+FN target expression but did associate with gene expression signatures indicative of proteolytic activity for MICVO linker cleavage. The preclinical data are summarized below and shown in Figure 4:

- 45% of models demonstrated strong to very strong tumor growth inhibition (TGI%) activity (70%<TGI<90% or TGI>90% respectively), with only 25% of models showing no response (TGI<25%).
- PDX models with very strong activity (TGI>90%) were found across nine out of ten solid tumor indications.
- Complete responses to MICVO (tumor volume reached 0mm3 for at least two consecutive measurements) were found across several tumor indications, consistent with previous analysis.
- MICVO was observed to be well-tolerated (3mg/kg, Q4Dx4).

Figure 4



We also performed differential gene expression analysis, which enabled us to identify gene signatures linked to anti-tumor activity consistent with our extracellular linker cleavage ADC hypothesis. We observed that enzyme and tumor stroma gene signatures were the gene sets with the greatest number of differentially expressed genes. Further, the preclinical data showed upregulation of certain proteases that may contribute to increased linker cleavage and subsequent increased anti-tumor activity for MICVO, supporting our extracellular linker cleavage hypothesis.

We also conducted preclinical studies combining a mouse analog of MICVO with anti-PD-1 therapy in a syngeneic mouse model of triple negative breast cancer (EMT6) known to be sensitive to PD-1 blockade. The combination of a mouse analog of MICVO with anti-PD-1 therapy inhibited EMT6 tumor growth and improved survival compared to either treatment alone, suggesting potential benefit for combination therapy to deepen anti-tumor responses in solid tumors. The preclinical studies combining a mouse analog of MICVO with anti-PD-1 therapy are summarized below:

- Monotherapy of mouse analog of MICVO inhibited dose-dependent tumor outgrowth of EDB+FN expressing EMT6 tumors and was well-tolerated at 6 mg/kg.
- The mouse analog of MICVO boosted the immune response by activating dendritic cells and increasing CD45+ immune cell infiltration, including PD-1+ T cells, into tumors, transforming EMT6 tumors into immune-infiltrated, "hot" tumors.
- Significant TGI observed with mouse analog of MICVO (TGI=94%) and anti-PD-1 therapy (TGI=54%) as monotherapies.
- The combination of the mouse analog of MICVO and anti-PD-1 therapy resulted in TGI of 91% and complete response was seen in 9/15 animals – greater tumor regression and clearance than either treatment alone.
- Mouse analog of MICVO in combination with anti-PD-1 therapy induced lasting immunological memory, enhancing tumor clearance and protecting against tumor recurrence in rechallenged mice.

The preclinical data indicated MICVO alone may be eliciting immune responses in immune excluded/immunologically cold tumors, as observed with the infiltration of T cells into the tumor, representing potential for MICVO to drive immunogenic cell death (ICD). Together, these preclinical data further support the three-pronged mechanism of action of MICVO driving anti-tumor activity via direct tumor killing, bystander effect and ICD.

Recent Translational Data

In October 2025, we presented translational data at the European Society of Medical Oncology (ESMO) Congress 2025 in Berlin, Germany and at the AACR-NCI-EORTC International Conference on Molecular Targets and Cancer Therapeutics in Boston, Massachusetts. Data presented build on preclinical data previously presented in April 2025 at AACR Annual Meeting in Chicago.

The poster presentations at the ESMO and AACR-NCI-EORTC meetings provide deeper insights into the pharmacodynamic responses of tumors to MICVO as well as MICVO's unique mechanism of action and its potential to exert anti-tumor activity through three mechanisms: direct cancer cell killing, bystander killing and ICD. These translational findings highlight MICVO's effects on TME remodeling, immune activation and tumor infiltration, further reinforcing the potential benefit of MICVO as both monotherapy and in combination with anti-PD-1 therapy.

Additional data supporting MICVO's MOA indicate this ADC binds very specifically to EDB+FN in the TME, an important trait for the non-cellular tumor ECM targeting MOA, locally delivering the ADC close to the malignant cells for cancer cell killing after extracellular linker cleavage. Data also indicate MICVO binds strongly to EDB+FN, which enables the ADC to stay anchored in the TME longer allowing more time for extracellular linker cleavage by proteases. In vitro data presented indicate MICVO's linker can be cleaved extracellularly via specific cathepsins and pH conditions that exist in the TME, which allows the payload to be released extracellularly to then diffuse into cancer cells.

Multiple posters supported MICVO's ability to induce ICD and a mouse analog of MICVO (maMICVO) stimulated an immune response in tumors from a syngeneic triple negative breast cancer model (4T1) that had been refractory to anti-PD-1. Synergistic antitumor activity was observed in this anti-PD-1 refractory model when maMICVO was combined with anti-PD-1. The preclinical studies combining maMICVO with anti-PD-1 therapy in the 4T1 model are summarized below:

- Mouse anti-PD-1 alone had no effect on tumor growth, consistent with published studies.
- maMICVO alone inhibited 4T1 tumor growth.
- Synergistic anti-tumor activity was observed when both treatments were combined.
- maMICVO induced the infiltration of progenitor exhausted T cells (Tpex) into 4T1 tumors.

Observations of translational data from clinical samples include changes in circulating tumor DNA (ctDNA) tumor fraction (TF) after treatment with MICVO to the vast majority of 37 clinical samples tested from the monotherapy dose escalation study. Notably, reduction in ctDNA TF after treatment with MICVO, particularly in HNSCC and at the 5.4 mg/kg dose, supported a positive molecular response to MICVO and strengthened rationale for continued development of this tumor type and dose in the monotherapy dose expansion study. Analysis of baseline tumor tissues from participants in the monotherapy dose escalation trial showed EDB+FN protein level did not directly correlate with sensitivity to MICVO, which was consistent the preclinical PDX study. However, features observed in nonclinical samples of the stromal architecture detected using digital pathology may correlate with sensitivity to MICVO, a finding that may be unique compared to tumor cell surface targeting ADCs, due to MICVO's targeting of a non-cellular structural component of the tumor ECM. Preliminary analysis of clinical tumor biopsy samples revealed that MICVO remodeled the TME as well as induced an immune response, consistent with observations in tumors from the preclinical syngeneic EMT6 mouse model. The findings observed from the clinical biopsy studies are summarized below:

- Histological evaluation of a limited set of matched pair biopsies from participants treated with MICVO demonstrated pharmacodynamic effects on both cancer cells and stromal remodeling across clinical responses, reflective of the mechanism of action of this novel non-cellular targeting ADC.
- MICVO reduced cellular density in both tumor epithelium and stroma compartments after two cycles of treatment but did not deplete EDB+FN expression in the cancer stroma, maintaining target expression.
- Pharmacodynamic effects of MICVO on stroma included increased FN fluorescence intensity and changes in stromal cell composition, reflective of stromal remodeling.
- MICVO increased the density of non-immunosuppressive T-cells in the tumor parenchyma, with increased infiltration associated with better clinical response (see example in Figure 5 below).
- Greater MICVO-induced T-cell infiltration was correlated with longer time on study.
- MICVO increased immune gene expression signatures within tumors.

Figure 5

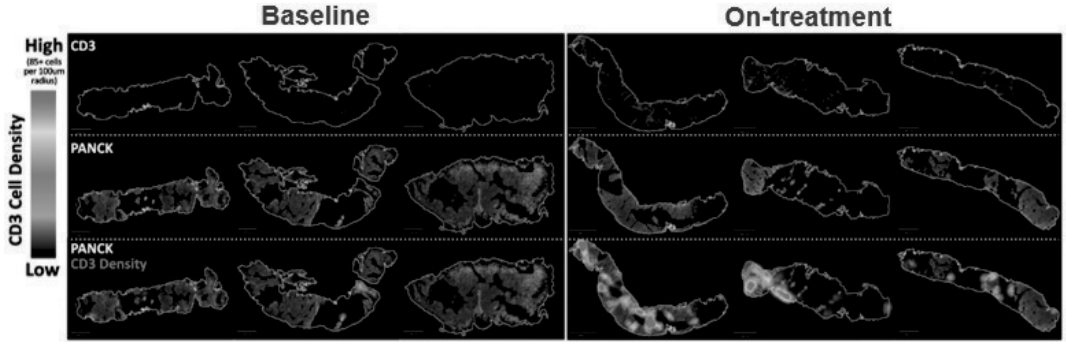


Figure 5 shows a representative image of multiplex immunofluorescence CD3 density maps on a matched baseline and on-treatment tumor biopsy pair from a MICVO monotherapy trial participant with ovarian cancer showing increased density of CD3 cells in the tumor after treatment with MICVO.

Taken together, we believe that MICVO may generate a multi-pronged attack on difficult-to-treat cancers by specifically targeting the ADC to the tumor ECM where the extracellularly released cytotoxic payload can permeate the tumor and directly kill cancer cells, impact ECM remodeling and mobilize an anti-tumor immune response (as illustrated in Figure 2 above). Further, we believe that the non-cellular approach targeting the tumor ECM may potentially avoid the primary cause of drug resistance identified for therapeutics targeting cell surface receptors. Downregulated expression of therapeutic targets on cancer cells such as HER2 and EGFR has been demonstrated to be a resistance mechanism for therapies targeting these cell-surface proteins. Given the non-cellular expression profile of EDB+FN, we believe this resistance mechanism does not apply to MICVO and is supported by the observed maintenance of target expression in on-treatment biopsies evaluated thus far.

Upcoming Translational Data

In March 2026, we announced the publication of an abstract at the 2026 AACR Annual Meeting describing the anti-tumor activity of a murine analog of MICVO (maMICVO) in the poorly immunogenic and immunotherapy-refractory mouse oral carcinoma 2 (MOC2) syngeneic HNSCC model. The abstract also reported that image analysis suggested modulation of the tumor immune microenvironment following maMICVO treatment, which provided a scientific rationale for evaluating maMICVO in combination with anti-PD-1 in this refractory model. We expect to present this preclinical data at the AACR Annual Meeting in San Diego, CA, in April 2026.

Clinical Development of MICVO

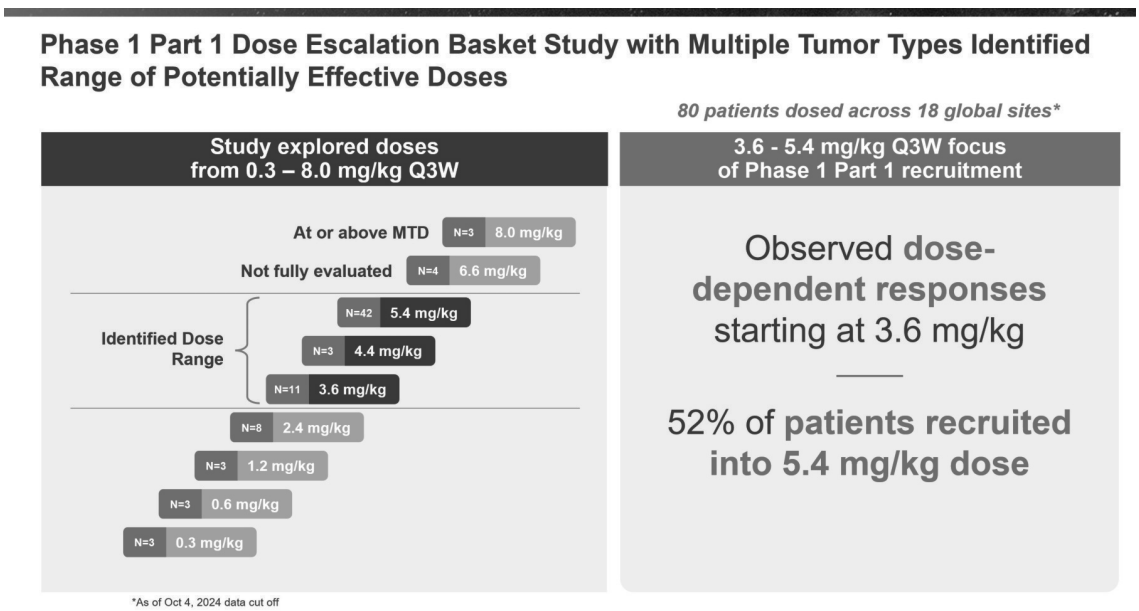
PYX-201-101 Monotherapy Phase 1 Trial of MICVO

We are conducting a multi-part Phase 1 trial of MICVO, referred to as PYX-201-101, which initiated patient dosing in March 2023. The study is evaluating MICVO as a monotherapy in patients with advanced solid tumors known to express EDB+FN. PYX-201-101 (Part 1) is an open-label, multicenter, dose-escalation Phase 1 trial designed to assess the safety and tolerability of MICVO, characterize its PK and PD profile, evaluate preliminary anti-tumor activity, and identify recommended dose levels for further clinical development. Eligible patients include those with relapsed or refractory advanced solid tumors, including patients with R/M HNSCC, hepatocellular carcinoma (HCC), hormone receptor-positive/human epidermal growth factor receptor 2-negative (HR+/HER2-) breast cancer, locally advanced or metastatic non-small cell lung cancer (NSCLC), ovarian cancer, pancreatic ductal adenocarcinoma (PDAC), renal cell carcinoma (RCC), sarcoma, thyroid cancer, and TNBC. Information regarding this clinical trial is available at ClinicalTrials.gov under identifier NCT05720117.

PYX-201-*101 Phase 1 Dose Escalation (Part 1) Preliminary Clinical Data*

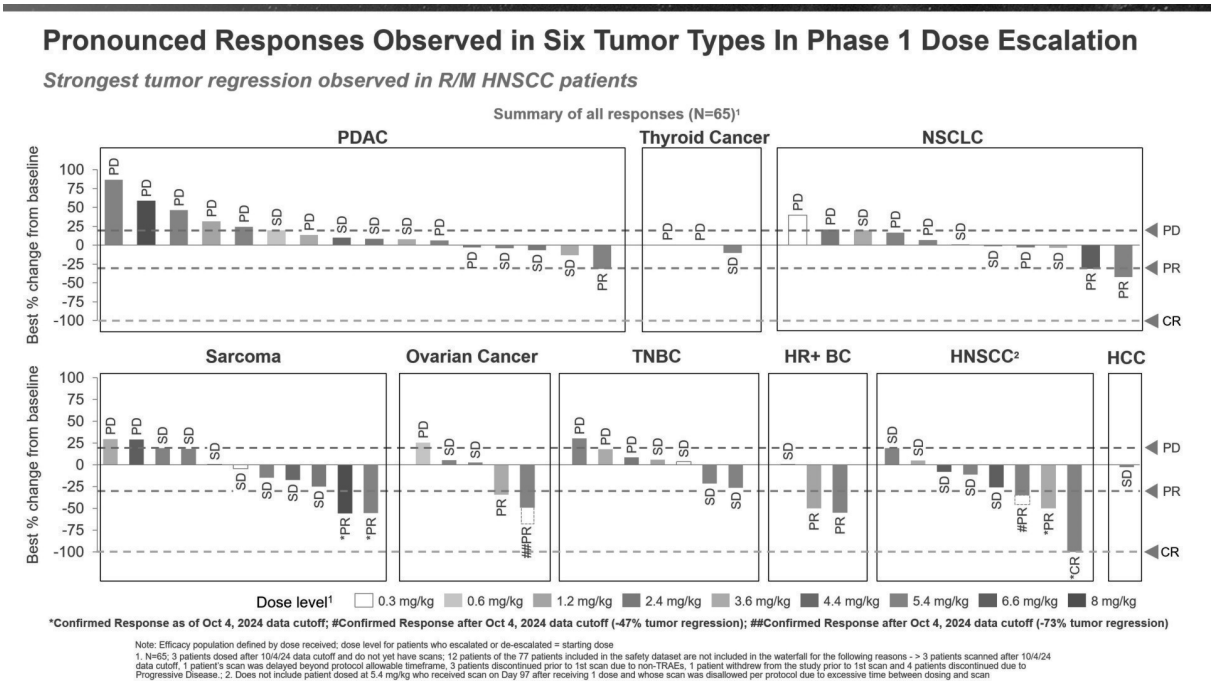
In November 2024, we reported positive preliminary data from Part 1 of our Phase 1 dose escalation study of PYX-201-101. A total of 80 patients were enrolled and treated with MICVO in the Part 1 dose-escalation portion of the study, as of the data cut-off of October 4, 2024, at dose levels ranging from 0.3 mg/kg to 8.0 mg/kg IV Q3W across multiple advanced solid tumor types. We identified a therapeutically active dose response range of 3.6 mg/kg – 5.4 mg/kg IV Q3W where we observed clinical benefit and a manageable safety profile. The dose-escalation schema and the number of patients treated at each dose level from trial initiation in March 2023 through the October 4, 2024 data cut-off are summarized in Figure 6 below.

Figure 6



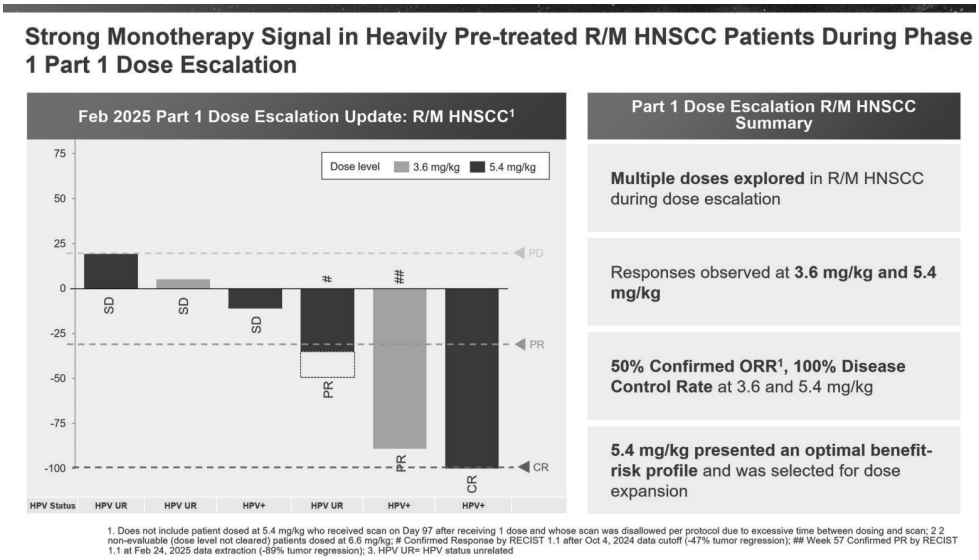
The preliminary efficacy analysis dataset included 65 patients, of whom 44 patients were treated within the dose range of 3.6 mg/kg to 5.4 mg/kg IV Q3W. As illustrated in Figure 7 below, tumor regression from baseline was observed across all nine tumor types evaluated in the study. Reductions in target lesion measurements were observed in multiple tumor types, with more pronounced responses noted in six tumor types of interest: including R/M HNSCC, HR+/HER2- breast cancer, NSCLC, ovarian, sarcoma and TNBC, at the therapeutically active dose response range of 3.6 mg/kg – 5.4 mg/kg IV Q3W.

Figure 7



The R/M HNSCC patients demonstrated the strongest tumor regression response in the dataset. Among the six efficacy-evaluable, heavily pre-treated patients with R/M HNSCC, at the therapeutically active dose response range of 3.6 mg/kg – 5.4 mg/kg IV Q3W, the confirmed ORR was 50% (3/6) as assessed per RECIST v1.1, including one confirmed CR and two confirmed PRs with a DCR of 100%. The R/M HNSCC patients had received a median of four prior lines of systemic therapy in the advanced disease setting. Additionally, clinical activity was observed in patients with either HPV+ or HPV unrelated tumors as illustrated in Figure 8 below.

Figure 8



PYX-201-101 Phase 1 Dose Expansion (Part 2) Monotherapy Study

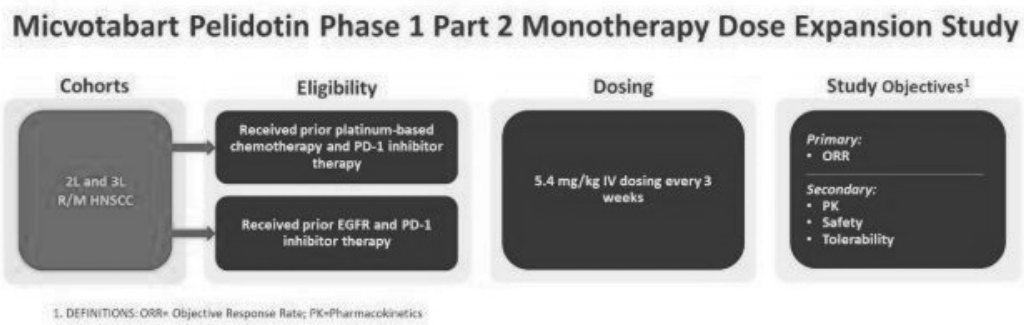
In January 2025, we initiated the dose expansion portion (Part 2) of the Phase 1 PYX-201-101 monotherapy study (NCT05720117). Part 2 is designed to further evaluate MICVO as a monotherapy at a dose of 5.4 mg/kg IV Q3W and to assess preliminary efficacy in R/M HNSCC. Based on observations from the dose-escalation study, 5.4 mg/kg IV Q3W presented an optimal benefit-risk profile within the efficacious dose range and was selected for dose expansion. Subsequent translational data indicated reduction in ctDNA TF after treatment with MICVO, particularly at the 5.4 mg/kg dose, supported a positive molecular response to MICVO, providing further validation of the dose selection strategy for dose expansion. In February 2025, the FDA granted Fast Track designation to MICVO for the monotherapy treatment of adult patients with R/M HNSCC whose disease has progressed following treatment with platinum-based chemotherapy and an anti-PD-(L)1 antibody. Fast Track designation is intended to facilitate the development and expedite the review of drugs that treat serious conditions and fill an unmet medical need.

We completed target enrollment of approximately 40 patients in the Phase 1 monotherapy dose expansion study of MICVO in 2L+ R/M HNSCC in the first quarter of 2026 and are actively treating patients in two monotherapy R/M HNSCC cohorts at the 5.4 mg/kg IV Q3W dose. The dose expansion phase includes the following R/M HNSCC cohorts across sites in the United States (US), European Union (EU) and other countries:

- Arm 1: MICVO monotherapy for 2L and 3L R/M HNSCC patients who have received prior platinum-based chemotherapy and prior PD-(L)1 inhibitor therapy. We expect to enroll approximately 20 patients in this expansion cohort at the 5.4 mg/kg IV Q3W dose; and
- Arm 2: MICVO monotherapy for 2L and 3L R/M HNSCC patients who have received prior epidermal growth factor receptor (EGFR) directed therapy and prior PD-(L)1 inhibitor therapy. We expect to enroll approximately 20 patients in this expansion cohort at the 5.4 mg/kg IV Q3W dose.

The clinical trial design of MICVO monotherapy in R/M HNSCC is summarized in Figure 9 below.

Figure 9



PYX-201-101 Phase 1 Dose Expansion Monotherapy Study (Part 2) Preliminary Clinical Data

In December 2025, we reported positive preliminary data from our ongoing Phase 1 monotherapy study evaluating MICVO in patients with 2L+ R/M HNSCC, based on a data cut-off date of November 3, 2025, which included all R/M HNSCC patients dosed at 5.4 mg/kg in Part 1 and in Part 2. As of the data cut-off date, 18 patients had been treated at the 5.4 mg/kg IV Q3W dose level, and 13 patients were efficacy-evaluable. All treated patients had received prior systemic therapy, including platinum-based chemotherapy, checkpoint inhibitor therapy, taxanes, and EGFR-targeted therapies. Patients had received a median of three prior lines of systemic therapy in the advanced disease setting. Patient demographics and the prior treatment characteristics of treated patients are illustrated in Figure 10 below.

Figure 10

MICVO Phase 1 Monotherapy Patient Demographics and Disease Characteristics at 5.4 mg/kg

Data as of Nov 3, 2025

Demographics	Total (N=18)
Age	**Years**
Median (min-max)	63 (41- 72)
Sex	
Male	12 (67%)
Race	
White	14 (78%)
Black or African American	1 (6%)
Not Reported	3 (16%)
Baseline ECOG Performance Status	
0	3 (17%)
1	15 (83%)
Baseline Weight	**Kg**
Median (min-max)	72 (48, 103)
BMI	
Median (min-max)	25 (19, 32)

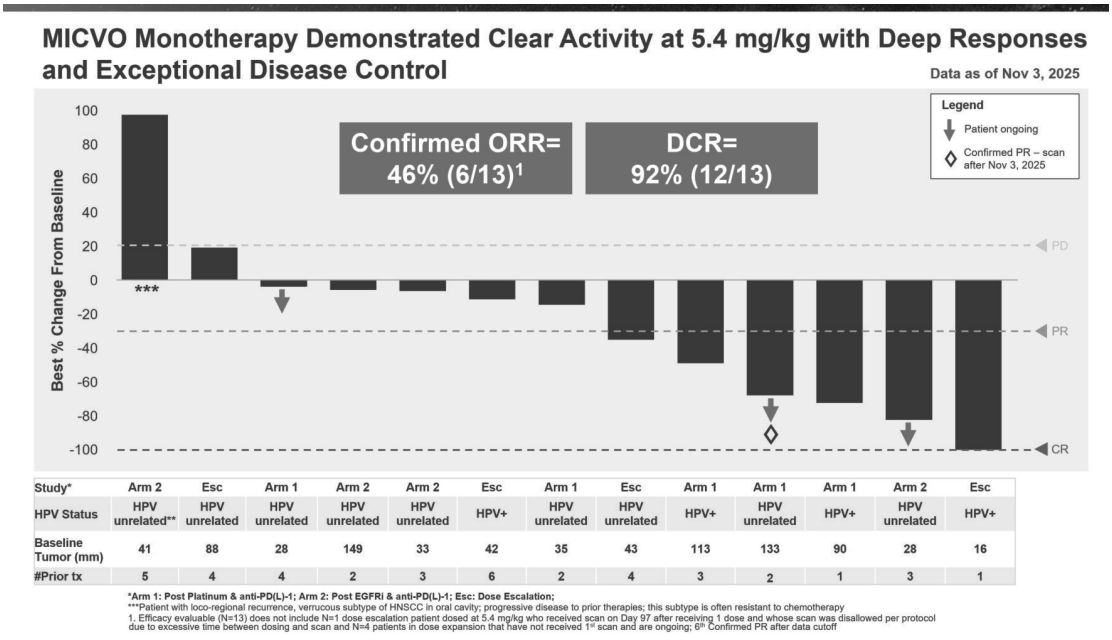
Disease Characteristics	Total (N=18)
HPV Status	**n (%)**
HPV +, n (%)	7 (39%)
HPV unrelated, n (%)	11 (61%)

Prior anti-Cancer Therapy	Total (N=18)
Elapsed Time Since Initial Diagnosis (Yr), Median (min-max)	4.0 (1.0-13.2)
Prior Systemic Therapy, Median Lines (min-max)	3 (1-6)
Taxane, n (%)	12 (67%)
Platinum, n (%)	18 (100%)
Checkpoint Inhibitor, n (%)	18 (100%)
EGFR Targeting Agent, n (%)	9 (50%)

Preliminary Efficacy

The preliminary efficacy analysis dataset consisted of 13 efficacy-evaluable Part 1 and Part 2 patients with R/M HNSCC treated at 5.4 mg/kg IV Q3W. Figures 11 and 12 below present waterfall plots depicting the percentage change in target lesion size from baseline for individual patients, including stratification by expansion cohort (Arm 1 and Arm 2) and HPV status. Among the 13 efficacy-evaluable patients with R/M HNSCC treated at 5.4 mg/kg IV Q3W, the confirmed ORR was 46% (6/13) (one patient confirmed response after November 3, 2025 data cut-off), as assessed per RECIST v1.1, including one confirmed complete response. Confirmed responses were observed in both dose-expansion cohorts and in patients regardless of HPV status. The preliminary data also showed a DCR of 92% (12/13). One out of the 13 efficacy-evaluable patients experienced progressive disease. This patient had a verrucous subtype of HNSCC, a histologic variant that is generally managed with surgery and may demonstrate limited responsiveness to systemic therapy.

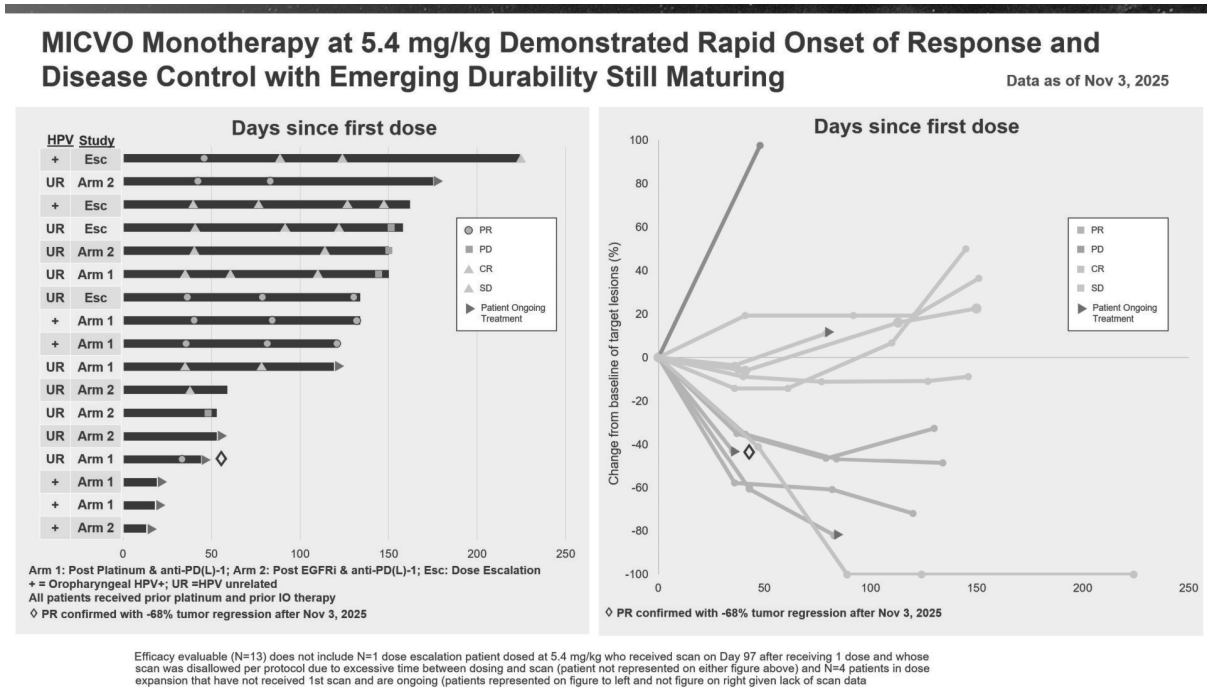
Figure 11



Study*	Arm 2	Esc	Arm 1	Arm 2	Arm 2	Esc	Arm 1	Esc	Arm 1	Arm 1	Arm 1	Arm 2	Esc
HPV Status	HPV unrelated**	HPV unrelated	HPV unrelated	HPV unrelated	HPV unrelated	HPV+	HPV unrelated	HPV unrelated	HPV+	HPV unrelated	HPV+	HPV unrelated	HPV+
Baseline Tumor (mm)	41	88	28	149	33	42	35	43	113	133	90	28	16
#Prior tx	5	4	4	2	3	6	2	4	3	2	1	3	1

*Arm 1: Post Platinum & anti-PD(L)-1; Arm 2: Post EGFRi & anti-PD(L)-1; Esc: Dose Escalation;
***Patient with loco-regional recurrence, verrucous subtype of HNSCC in oral cavity; progressive disease to prior therapies; this subtype is often resistant to chemotherapy
1. Efficacy evaluable (N=13) does not include N=1 dose escalation patient dosed at 5.4 mg/kg who received scan on Day 97 after receiving 1 dose and whose scan was disallowed per protocol due to excessive time between dosing and scan and N=4 patients in dose expansion that have not received 1st scan and are ongoing; 6th Confirmed PR after data cutoff

Figure 12



Efficacy evaluable (N=13) does not include N=1 dose escalation patient dosed at 5.4 mg/kg who received scan on Day 97 after receiving 1 dose and whose scan was disallowed per protocol due to excessive time between dosing and scan (patient not represented on either figure above) and N=4 patients in dose expansion that have not received 1st scan and are ongoing (patients represented on figure to left and not figure on right given lack of scan data

Safety and Tolerability

The preliminary safety data in Figure 13 summarizes key TRAEs observed as of the November 3, 2025 data cut-off date. Preliminary data indicated that MICVO was generally well tolerated. As of the data cut-off, 18 patients had been treated with MICVO at 5.4 mg/kg IV Q3W. TRAEs were reported in 89% (16/18) of patients. Grade 3 or higher TRAEs were reported in 56% (10/18) of patients. No Grade 4 ADC Payload treatment-related adverse events (TRAEs) of interest were observed, and no Grade 5 events occurred. TRAEs leading to treatment discontinuation occurred in 28% (5/18) of treated patients as of the November 3, 2025 data cut-off date.

Figure 13

MICVO Safety at 5.4 mg/kg in R/M HNSCC*

No Grade 4 or Grade 5 ADC payload TRAEs of interest observed

Data as of Nov 3, 2025

TRAEs	Part 1 Dose Escalation	Part 2 Dose Expansion	Total
N	**5**	**13**	**18**
All TRAEs	5 (100%)	11 (85%)	16 (89%)
Grade 1/2 TRAEs	2 (40%)	4 (31%)	6 (33%)
Grade 3/4 TRAEs	3 (60%)	7 (54%)	10 (56%)
TRAEs leading to **treatment discontinuation**	2 (40%)	3 (23%)	5 (28%)
TRAEs leading to **dose reduction**	2 (40%)	4 (31%)	6 (33%)
TRAEs leading to **dose delay**	1 (20%)	4 (31%)	5 (28%)
Treatment related **Deaths (Grade 5)**	**0**	**0**	**0**

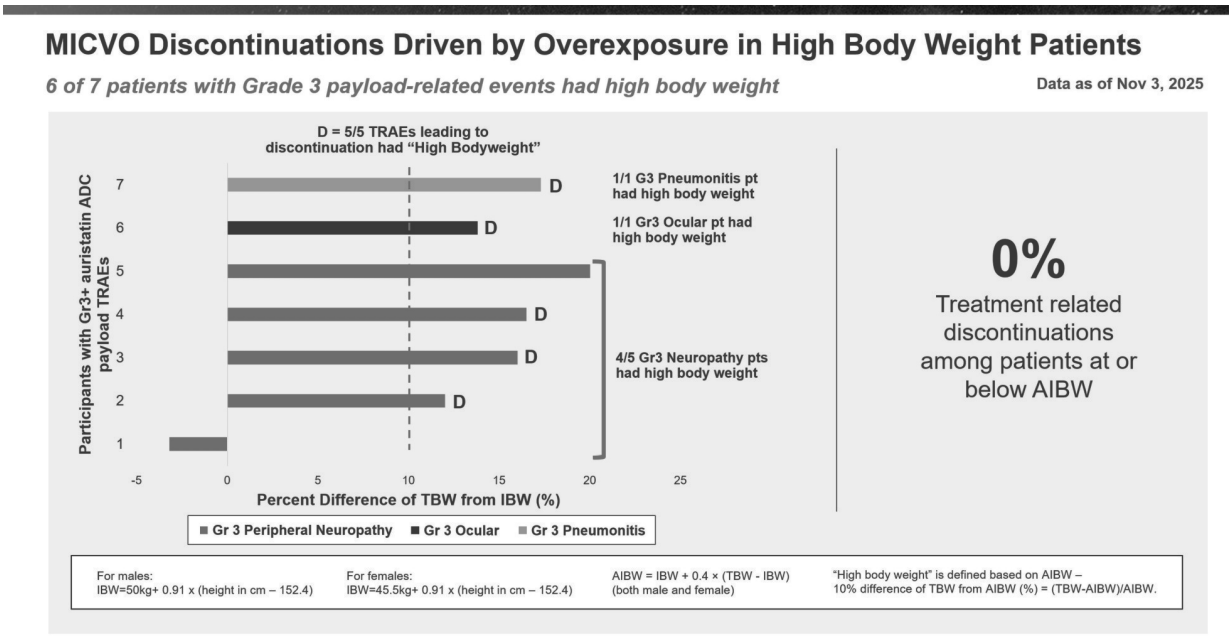
ADC payload TRAEs of interest	Part 1 Dose Escalation		Part 2 Dose Expansion		Total	
	Grade 1/2	Grade 3	Grade 1/2	Grade 3	Grade 1/2	Grade 3
Cutaneous	1 (20%)	0	7 (54%)	0	8 (44%)	0
Neuropathy	0	2 (40%)	1 (8%)	3 (23%)	1 (6%)	5 (28%)
Neutropenia	0	1 (20%)	2 (15%)	1 (8%)	2 (11%)	2 (11%)
Ocular	1 (20%)	0	1 (8%)	1 (8%)	2 (11%)	1 (6%)
Anemia	0	0	3 (23.1%)	0	3 (17%)	0%
Pneumonitis	1 (20%)	0	1 (8%)	1 (8%)	2 (11%)	1 (6%)

*No prophylactic treatments dictated or administered to-date

Impact of Body Weight on MICVO Tolerability and Dosing Optimization Strategies

We observed a higher discontinuation rate and incidence of Grade ≥3 TRAEs at the 5.4 mg/kg dose level in high body weight patients (defined as at least 10% above AIBW). In the preliminary dataset, all patients (5/5) who experienced TRAEs leading to treatment discontinuation had high body weight, as shown in Figure 14. Several approved ADCs have demonstrated comparable associations among patient body weight, systematic drug exposure, and tolerability profiles.

Figure 14

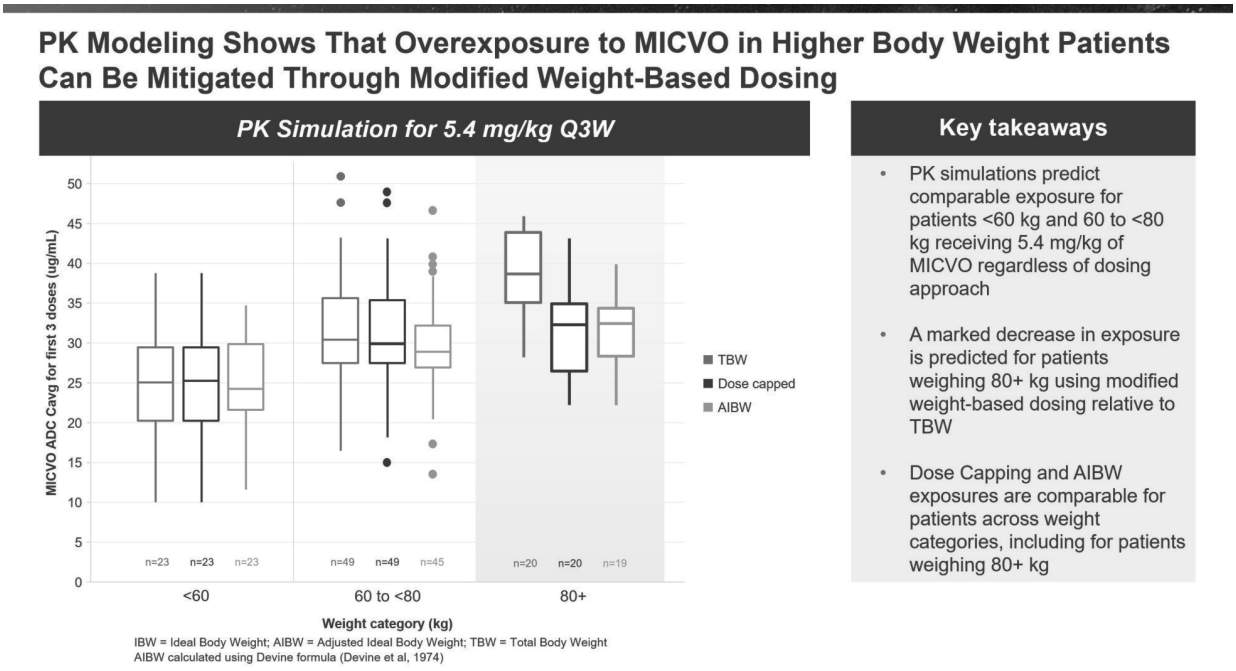


Following the November 3, 2025, data cut-off date and based on an integrated assessment of safety, pharmacokinetic, and exposure-response data, we implemented modified dosing strategies for MICVO in the ongoing study with the goal of mitigating adverse events and improving tolerability in higher body weight patients while preserving clinical efficacy. These strategies include dose capping and AIBW-based dosing, both intended to reduce variability in systemic drug exposure among heavier patients. Such approaches are consistent with precedent established by approved ADCs.

For example, Padcev and Adcetris, which both have auristatin payloads similar to MICVO, incorporated dose caps for patients weighing more than 100 kg and have demonstrated improved tolerability while maintaining efficacy. Similarly, Elahere and Pfizer's PDL1V ADC in clinical development, have implemented AIBW-based dosing to address tolerability findings in higher bodyweight patients.

We believe the higher frequency of TRAEs observed in higher bodyweight patients treated with ADCs is primarily attributable to the nonlinear relationship between body weight and drug clearance. Due to this nonlinearity, higher bodyweight patients may experience disproportionately greater systemic exposure, creating an opportunity to enhance the benefit–risk profile through dose reduction without materially compromising efficacy. Preliminary PK/PD modeling presented in Figure 15 below, indicate both dose capping and AIBW dosing for MICVO effectively mitigate exposure in heavier patients. We plan to present clinical data in 2026 that informs this hypothesis with the intention of optimizing MICVO's benefit-risk profile.

Figure 15



MICVO Monotherapy Next Milestone

During the fourth quarter of 2025, we received feedback from the U.S. FDA regarding the clinical trial design for a planned pivotal monotherapy study in patients with 2L+ R/M HNSCC. Based on these interactions, we believe we have alignment with the FDA on key elements of the proposed study design.

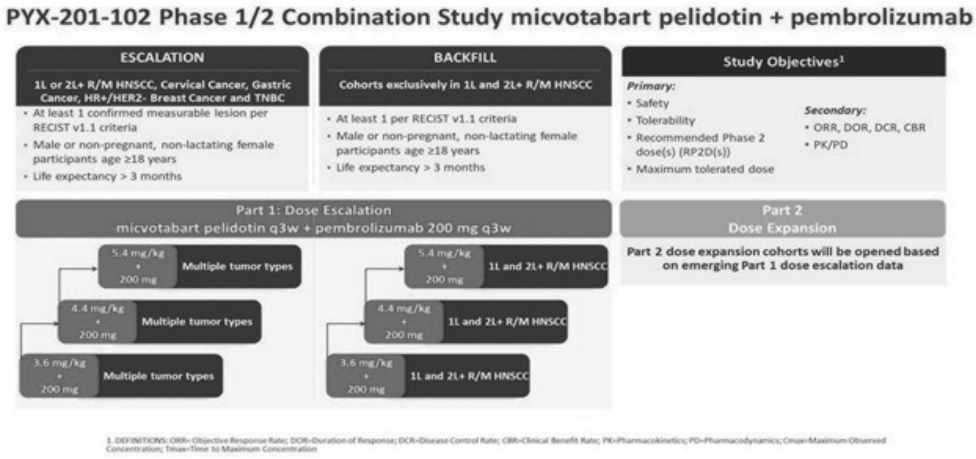
Our Part 2 dose-expansion phase of the PYX-201-101 monotherapy study has completed target enrollment of approximately 40 patients in 2L+ R/M HNSCC in the first quarter of 2026. We are continuing patient follow-up, monitoring clinical outcomes, and conducting related study activities. Updated MICVO Phase 1 monotherapy data in 2L+ R/M HNSCC are expected in mid-year 2026 and will include patients dosed at 5.4 mg/kg IV Q3W with a dose cap for patients with higher body weight, as well as patients previously dosed at 5.4 mg/kg IV Q3W TBW. The results are expected to include detailed analyses of the effect of the modified weight-based dosing strategy on safety and efficacy. AIBW dosing, which has demonstrated improved tolerability without apparent loss of activity in clinical studies of other antibody-drug conjugates, is being implemented in ongoing clinical studies as well.

PYX-201-102 Combination Therapy Phase 1/2 Trial

In November 2024, we entered into a Clinical Trial Collaboration and Supply Agreement with Merck & Co., Inc. (“Merck”) (known as MSD outside of the United States and Canada), pursuant to which we are conducting a Pyxis Oncology-sponsored clinical study evaluating MICVO in combination with Merck’s anti-PD-1 therapy, KEYTRUDA® (pembrolizumab). Under the terms of the agreement, we are responsible for conducting and funding the study, and Merck is supplying pembrolizumab for use in the trial with no cost to us. The agreement does not provide Merck with any rights to MICVO outside of the collaboration study.

In January 2025, we initiated the Phase 1/2 combination study with KEYTRUDA®, PYX-201-102, and we are actively enrolling patients. PYX-201-102 is a Phase 1/2, open label, global, multicenter, dose-escalation and dose-expansion study to evaluate the safety, tolerability, PK, PD, and preliminary efficacy of MICVO in combination with pembrolizumab in patients with advanced solid tumors. Eligible patients include those with histologically or cytologically confirmed advanced solid tumors, including 1L R/M HNSCC, 2L+ R/M HNSCC, cervical cancer, gastric cancer, HR+/HER2- breast cancer, and locally advanced or metastatic TNBC. The Phase 1 portion of the trial consists of a dose-escalation phase designed to determine the recommended Phase 2 dose of MICVO in combination with pembrolizumab. The Phase 2 portion includes dose-expansion cohorts in selected tumor types to further evaluate safety and preliminary efficacy. Information regarding this study is available at ClinicalTrials.gov under identifier NCT06795412. The clinical trial design of the MICVO combination therapy in R/M HNSCC and other tumor types is summarized in Figure 16 below.

Figure 16



We are currently conducting the Part 1 dose-escalation portion of the PYX-201-102 Phase 1/2 study. Part 1 is designed to evaluate escalating dose levels of MICVO administered Q3W in combination with a fixed standard dose of pembrolizumab (200 mg IV Q3W). Three planned dose levels of MICVO are being evaluated in combination with pembrolizumab, ranging from 3.6 mg/kg to 5.4 mg/kg. The primary objective of the dose-escalation portion is to assess safety and tolerability and to identify the RP2D for further evaluation in the Phase 2 dose-expansion cohorts. Dose-escalation decisions are based on an evaluation of safety, dose-limiting toxicities, pharmacokinetics, and other clinical data.

The study initiated dose escalation at 3.6 mg/kg of MICVO administered in combination with pembrolizumab 200 mg IV Q3W. The DESC has reviewed available safety data and cleared escalation through the 3.6 mg/kg and 4.4 mg/kg MICVO dose levels, each administered in combination with the fixed 200 mg dose of pembrolizumab. We are currently enrolling and dosing patients across several dose levels between 3.6 and 5.4 mg/kg of MICVO, in combination with pembrolizumab at the fixed dose of 200 mg IV Q3W, in order to accurately characterize the RP2D for MICVO in combination with pembrolizumab, subject to ongoing safety review, enrollment progress, and clinical data evaluation.

PYX-201-102 Phase 1/2 Combination Therapy Preliminary Clinical Data

In December 2025, we reported positive preliminary data from our ongoing MICVO Phase 1/2 combination study, PYX-201-102, evaluating MICVO at doses of 3.6 mg/kg and 4.4 mg/kg, each administered IV Q3W in combination with a fixed 200 mg dose of pembrolizumab, in patients with 1L/2L+ R/M HNSCC. The data were based on a cut-off date of November 3, 2025. As of the data cut-off, seven patients had been treated in the dose-escalation portion of the study, including four patients treated at 3.6 mg/kg and three patients treated at 4.4 mg/kg of MICVO, each in combination with pembrolizumab 200 mg IV Q3W.

All treated patients had received prior systemic therapy. The patient population included:

- Four patients with 1L R/M HNSCC, with a median of one prior systemic therapy administered in the neoadjuvant or adjuvant setting and
- Three patients with 2L+ R/M HNSCC, with a median of three prior lines of therapy, some of which were received prior to the R/M setting.

As shown in Figure 17 below, among the four patients with 1L R/M HNSCC, all had previously received platinum-based therapy administered with radiation in the adjuvant or definitive setting, and one patient had also received a prior taxane in the neoadjuvant setting. Among the three patients with 2L+ R/M HNSCC, all had previously received platinum-based therapy and prior checkpoint inhibitor therapy, and one patient had additionally received prior taxane therapy.

Figure 17

MICVO 1L/2L+ R/M HNSCC Combo Dose Escalation Patient Demographics

Data as of Nov 3, 2025

Demographics	Total (N=7)
Race	
Asian	0
Black African American	0
White	7 (100%)
Other	0
Age (years)	
Median (min-max)	69 (57 – 76)
Baseline weight (kg)	
Median (min-max)	83 (65 – 107)
Gender	
Male	7 (100%)
Baseline ECOG Performance Status	
0	3 (43%)
1	4 (57%)

Disease Characteristics	Total (N=7)
Line of Disease Setting	**n (%)**
1L HNSCC	4 (57%)
2L+ HNSCC	3 (43%)
HPV Status	N=7 (% of total N=7)
HPV Positive, n (%)	7 (100%)

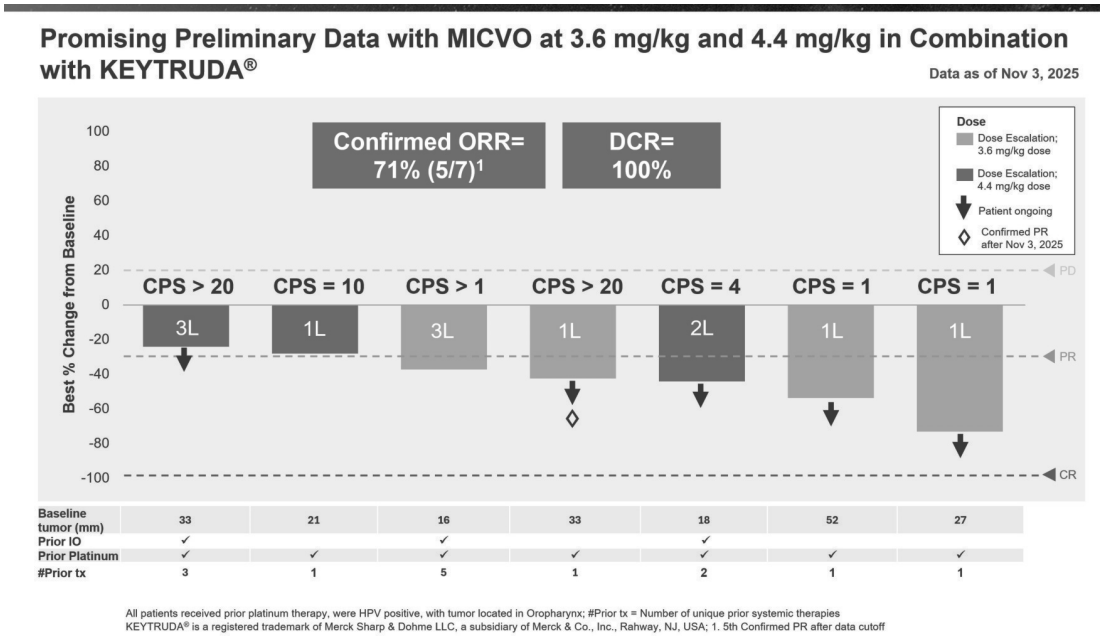
1L HNSCC Prior anti-Cancer Therapy	Total (N=4)
Elapsed Time Since Initial Diagnosis (Yr), Median (min-max)	1.7 (1.3-3.9)
Prior Systemic Therapy, Median Lines (min-max)	1 (1)
Taxane, n (%)	1 (25%)
Platinum, n (%)	4 (100%)
Checkpoint Inhibitor, n (%)	0
EGFR Targeting Agent, n (%)	0
ADC, n (%)	0

2L+ HNSCC Prior anti-Cancer Therapy	Total (N=3)
Elapsed Time Since Initial Diagnosis (Yr), Median (min-max)	4.3 (2.4-6.8)
Prior Systemic Therapy, Median Lines (min-max)	3 (2-5)
Taxane, n (%)	1 (33%)
Platinum, n (%)	3 (100%)
Checkpoint Inhibitor, n (%)	3 (100%)
EGFRi, n (%)	2 (67%)
ADC, n (%)	0

Preliminary Efficacy

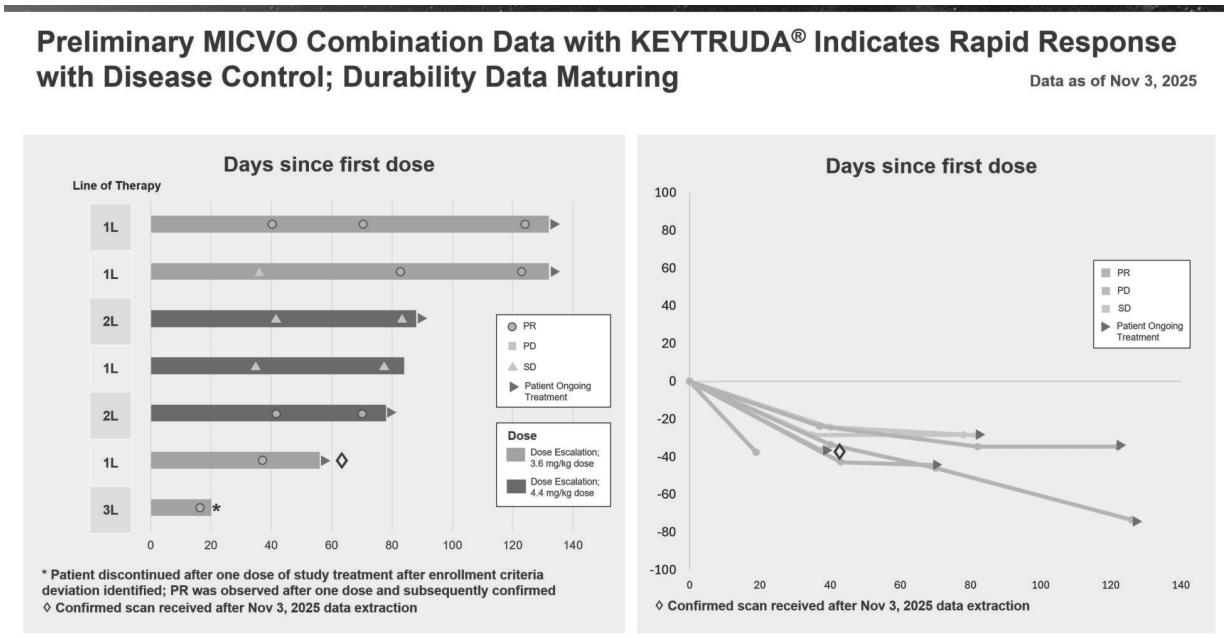
Among the seven response-evaluable patients as of the November 3, 2025 data cut-off, the confirmed ORR was 71% (5/7, one patient confirmed response after November 3, 2025 data cut-off) per RECIST v1.1. Responses were observed across a range of PD-L1 CPS, including patients with CPS≥1 and patients with CPS>20. Responses were also observed in patients who had previously received checkpoint inhibitor therapy and experienced disease progression while receiving checkpoint inhibitor treatment. All seven efficacy-evaluable patients demonstrated tumor regression from baseline measurements. Figures 18 and 19 below present waterfall plots depicting the percentage change in target lesion size from baseline for individual patients, including subgroup stratification by line of therapy (1L or 2L+ R/M HNSCC) and CPS score.

Figure 18



All patients received prior platinum therapy, were HPV positive, with tumor located in Oropharynx; #Prior tx = Number of unique prior systemic therapies
KEYTRUDA® is a registered trademark of Merck Sharp & Dohme LLC, a subsidiary of Merck & Co., Inc., Rahway, NJ, USA; 1. 5th Confirmed PR after data cutoff

Figure 19



Safety and Tolerability

Figure 20 presents TRAEs reported as of the November 3, 2025 data cut-off date. Based on preliminary safety data from the seven patients treated in the dose-escalation cohorts evaluated at 3.6 mg/kg and 4.4 mg/kg of MICVO in combination with pembrolizumab, TRAEs were reported in 86% (6 of 7) of patients. No Grade 5 adverse events were reported. No Grade 3 or Grade 4 treatment-related adverse events associated with the ADC payload of MICVO were observed as of the data cut-off date. No TRAEs resulted in permanent treatment discontinuation. As of the data cut-off date, no overlapping toxicities between MICVO and pembrolizumab had been observed.

Figure 20

MICVO + KEYTRUDA® Dose Escalation Safety in R/M HNSCC

No Grade 3, Grade 4 or Grade 5 ADC payload TRAEs of interest

Data as of Nov 3, 2025

TRAEs	3.6 mg/kg	4.4 mg/kg	Total
N	4	3	7
All TRAEs	3 (75%)	3 (100%)	6 (86%)
Grade 3/4 TRAEs	0	0	0
TRAEs leading to treatment discontinuation	0	0	0
TRAEs leading to dose reduction	0	1 (33%)	1 (14%)
TRAEs leading to dose delay	0	0	0
Treatment related Deaths (Grade 5)	0	0	0

ADC payload TRAEs of interest	3.6 mg/kg			4.4 mg/kg			Total		
	Grade 1/2	Grade 3	Grade 4	Grade 1/2	Grade 3	Grade 4	Grade 1/2	Grade 3	Grade 4
N	4	4	4	3	3	3	7	7	7
Cutaneous	3 (75%)	0	0	2 (67%)	0	0	5 (71%)	0	0
Neuropathy	1 (25%)	0	0	0	0	0	1 (14%)	0	0
Neutropenia	0	0	0	0	0	0	0	0	0
Ocular	0	0	0	0	0	0	0	0	0
Anemia	1 (25%)	0	0	1 (33%)	0	0	2 (29%)	0	0
Pneumonitis	0	0	0	0	0	0	0	0	0

KEYTRUDA® is a registered trademark of Merck Sharp & Dohme LLC, a subsidiary of Merck & Co., Inc., Rahway, NJ, USA

MICVO Combination Therapy Next Milestone

We are currently enrolling and dosing patients across several dose levels between 3.6 mg/kg and 5.4 mg/kg of MICVO, in combination with a fixed 200 mg IV Q3W, in order to accurately characterize the RP2D for MICVO in combination with pembrolizumab, subject to ongoing safety review, enrollment progress, and clinical data evaluation. We expect to report updated data from the PYX-201-102 study in patients with 1L/2L+ R/M HNSCC in the second half of 2026.

Assets and Programs Available for Partnership or Collaboration

In addition to MICVO, we have certain clinical programs, assets, and preclinical programs that are currently paused. While these programs and assets are paused, we are focusing our development efforts and resources towards the clinical development of MICVO. We are seeking partnership opportunities that maximize potential value of these programs for patients and for our shareholders.

PYX-106 is 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. 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 licensed worldwide rights other than in Greater China (mainland China, Hong Kong, Macau and Taiwan) to PYX-106 from Biosion. In December 2024, after analysis of the program, PYX-106 was deprioritized and resources were reallocated toward advancing MICVO. At the time of deprioritization, the Phase 1 study of PYX-106, called PYX-106-101, was not complete. PYX-106-101 enrolled 45 patients with advanced solid tumors, with 41 patients being evaluable, and PYX-106 was observed as generally safe and well-tolerated across all tested doses, ranging from 0.5 mg/kg – 22.5 mg/kg. At the time of deprioritization, MTD had not been established, we decided to suspend further clinical investment in PYX-106 and not to open Part 2 dose expansion phase of the study.

Sotigalimab or PYX-107, acquired as part of the acquisition of Apexigen Inc. (Apexigen), is a CD40 agonist with demonstrated anti-cancer activity in patients with several cancer indications. 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% PR rate and a 30.3% stable disease rate along with a favorable tolerability profile. The FDA has granted Orphan Drug Designation for PYX-107 for the treatment of soft tissue sarcoma (STS), esophageal and gastroesophageal junction (EGJ) cancers and PDAC.

PYX-203, licensed from Pfizer, is an investigational ADC that 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 (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.

PYX-102 is an investigational immune-therapeutic that targets killer cell lectin-like receptor subfamily G member 1 (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.

Our Technology Platforms

We are capitalizing on years of industry innovation and advancement in ADC platforms to develop and design our product candidates. Our MICVO product candidate was built utilizing the 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 by Pfizer in 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 Therapeutic Index (TI).

The acquisition of Apexigen enhanced our ADC capabilities with the addition of Apexigen's antibody-discovery platform (APXiMAB) Platform, to use with our FACT Platform to support and potentially accelerate our existing ADC initiatives and our 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. For the Simcere suvemcitug/Enzeshu® program, during the year, the Company has sold its royalty rights under Simcere Royalty Agreement. Other than already approved programs (i.e. Simcere's Enzeshu®, 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.

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 immuno-oncology (IO) mechanisms and additional novel targets for our ADC platform.

We have large opportunities 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 MICVO.

Competition

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 candidate. 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. 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 candidate that we successfully commercialize may 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, 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 which could negatively impact our ability to execute our business plan.

If our product candidate is licensed, it 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 February 2026, there were approximately 900+ 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, Johnson & Johnson, Lyvgen Biopharma, Nextcure, Inc., Pfizer, Philogen S.p.A., Merck Sharpe & Dohme (MSD), Corbus Pharmaceuticals, and Rakuten Medical, Inc.

We may also face competition from alternative therapeutic modalities, such as cell therapies, bispecific antibodies, vaccines, radiopharmaceuticals and small molecules that are being developed for the same cancer types that we are targeting with our pipeline candidate. These approaches could achieve regulatory approval before our product candidate or prove to be more effective, safer, or convey other advantages over any products resulting from our technology. They could potentially result in shifts in treatment paradigms eroding or reducing the addressable market available to our product candidate.

We could also face competition with respect to specific targets, including the target of our ADC, MICVO, EDB+FN, by Philogen S.p.A., a Swiss based Biotechnology company, focused on generating antibody-cytokine fusions (immunocytokines) against cancers, using the L19 antibody specific to the EDB domain of Fibronectin fused to TNF, a potent inflammatory cytokine, which could pursue similar indications targeting EDB and stand out as the first non-ADC therapy pursuing EDB+FN.

There are other emerging agents in key indications of interest including R/M HNSCC. Genmab's EGFR and LGR5 targeting biclonal, petosemtamab, Bicara's EGFR/TGF-beta targeting bifunctional, ficerafusp alfa (BCA101), and Johnson and Johnson's EGFR and cMET bispecific antibody, amivantamab, are notable competitors that are targeting patient populations of interest to MICVO and pose a potentially significant threat to our clinical development strategy. Additionally, Corbus Pharmaceutical's nectin-4 targeting ADC, CRB-701 has shown preliminary efficacy data and is a direct competitor given similarity in payload (MMAE) to MICVO, and comparable patient populations and clinical development timelines in R/M HNSCC.

Other competitors may also include agents targeting specific segments such as HPV+ HNSCC, namely NeoTrail Therapeutics (formerly Hookipa)'s and PDS Biotech's vaccines and agents such as Nanobiotix's radioenhancer that may be used earlier in the treatment sequence. With the approval of pembrolizumab in the peri-operative setting based on Keynote-689, use of IO in the neoadjuvant and adjuvant settings may shift how HPV patients are treated in earlier lines of therapy. The implementation of using IO in the earlier disease settings could impact patient segmentation and treatment choices in the R/M setting.

Furthermore, ADCs such as Gilead's TROP-2 ADC, sacituzumab govitecan, Pfizer's Nectin-4 targeting ADC, enfortumab vedotin and AZ's AZD9592, a dual targeting ADC against EGFR and cMET are in clinical development in HNSCC. Enfortumab vedotin is currently pursuing a 1L HNSCC trial in combination with pembrolizumab thus adding to the crowded landscape of combo studies in the frontline setting. Additional competition may arise from other combination regimens being evaluated including but not limited to ficlatuzumab + cetuximab (2L), ivonescimab + ligufalimab (1L, CPS>1) and LN-145 + pembrolizumab (1L). 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 our product candidate is approved in oncology indications such as breast cancer, 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 candidate 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. Competitive products may make any products we develop obsolete owing to treatment paradigm shifts or noncompetitive, reducing the addressable market before we recover the expense of developing and commercializing our product candidate. Such competitors could also recruit our employees, which could negatively impact our level of expertise and our ability to execute our business plan.

We believe that our ability to successfully compete will depend on, among other things:

- our ability to develop and protect therapeutics that are more effective and safer than competing products;
- our ability to innovate with rapidly evolving technologies;
- 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 price of our product candidate and whether coverage and adequate levels of reimbursement are available under health insurance plans;
- our ability to utilize any abbreviated licensure pathways; and
- the length of time we are granted market exclusivity for any product candidate we may develop that is licensed as a biological product under a Biologics License Application (BLA).

Chemistry, Manufacturing and Controls

The manufacture of our ADCs and monoclonal antibodies requires significant scientific expertise, specialized technical capabilities, and substantial financial and operational resources. We do not own or operate any current Good Manufacturing Practice (cGMP)-compliant manufacturing facilities and currently have no plans to establish such facilities. Accordingly, we rely, and expect to continue to rely, on third-party contract development and manufacturing organizations (CDMOs) for the manufacture of our product candidates for preclinical and clinical development and, if approved, for commercial supply.

Our reliance on third-party manufacturers limits our direct control over manufacturing capacity, production schedules, costs, and compliance with cGMP and other regulatory requirements. Although we maintain quality agreements and technical oversight processes, we are dependent on the performance and compliance of our CDMOs. If any of our third-party manufacturers fail to comply with applicable regulatory requirements, experience quality or performance issues, encounter capacity constraints, or cease operations, our development timelines and potential commercialization efforts could be materially and adversely affected.

In addition, certain raw materials, components, and intermediates used in the manufacture of our product candidates may be sourced from single suppliers, and we may not maintain fully qualified alternate suppliers for all materials or manufacturing steps. Any interruption in the supply of such materials, including due to manufacturing failures, regulatory actions, business disruptions, or geopolitical events, could delay development activities or increase costs.

The manufacture of ADCs, in particular, involves complex multi-step processes, including monoclonal antibody production, linker and payload synthesis, and conjugation. Variability in process performance, including deviations in raw material specifications or process parameters, may result in reduced yields, batch failures, or the need for investigations and corrective actions. Such events could require additional manufacturing runs, process optimization, or comparability analyses and may necessitate regulatory notifications or submissions.

As part of our product development strategy, we rely on our internal scientific expertise and proprietary know-how, as well as the technical capabilities and trade secrets of our third-party manufacturing partners. We maintain agreements with our CDMOs that include customary confidentiality, intellectual property, and quality provisions designed to protect our proprietary rights and ensure compliance with applicable regulatory standards.

We believe that outsourcing manufacturing enables us to maintain a capital-efficient and flexible operating model by avoiding the significant investment required to build and operate our own manufacturing facilities and infrastructure. At the same time, we have established internal personnel and governance processes with experience in technical development, manufacturing sciences, analytical development, quality assurance, cGMP compliance, and project management to oversee our CDMOs and to manage manufacturing data and regulatory documentation in support of our development and potential commercialization activities.

Commercialization Plans

We currently retain worldwide rights to our lead product and while we intend to commercialize this asset upon FDA approval in the US, we may have opportunities to leverage partnerships to extend the reach of our products into geographies outside the US. 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 candidate. We may also pursue collaboration, co-promotion, distribution and/or other marketing arrangements with one or more third parties to commercialize our product candidate in the United States, and 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 candidate.

Licensing and Collaboration Agreements

The University of Chicago Agreement

In April 2020, we entered into a license agreement (the University License Agreement) with the University of Chicago (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 a 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. The Company assessed the milestone and royalty events under the University License Agreement as of December 31, 2025 and 2024, and determined that no such amounts were required. 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.

Pfizer Inc. Agreement

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 MICVO 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 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 in March 2021 and 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 FACT Platform technology to develop and commercialize ADC product candidates directed to certain licensed targets, including MICVO 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.

Further, pursuant to the A&R License Agreement, the Company is obligated to pay future contingent payments including development, regulatory and commercial milestones as well as running royalties on net sales of licensed products at varying rates. The Company assessed the milestone and royalty events under the A&R License Agreement as of December 31, 2025 and 2024, and determined that no such amounts were required.

We are also obligated to pay future contingent payments, including development, regulatory, and commercial milestone up to an aggregate of $665 million for the first four licensed ADCs. In addition, we are 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, 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 low-double digits to twenty percent 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 Biosion USA, Inc.

On March 28, 2022, we entered into a license agreement (the Biosion License Agreement) with Biosion USA, Inc. (Biosion) pursuant to which we obtained an exclusive, worldwide (other than Greater China (mainland China, Hong Kong, Macau and Taiwan)), license for development, manufacturing 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 us) 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 $10.0 million in March 2022 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. In December 2024, the Company paused the clinical development of PYX-106. The Company assessed the milestone and royalty events involving the Biosion License Agreement as of December 31, 2025 and 2024, and determined that no such amounts were required. 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 low-double to mid-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 generate and demonstrate the productivity and utility of our platforms and position us to receive meaningful milestone and 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.

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 monoclonal antibody molecule derived from APXiMAB technology. 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.

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. In March 2024, Simcere announced the New Drug Application (NDA) for suvemcitug for injection was accepted by the China National Medical Products Administration (NMPA).

On June 30, 2025, the National Medical Products Administration (NMPA) of China (formerly SFDA) granted final regulatory approval for suvemcitug in China. Upon suvemcitug approval by the NMPA, the Company received a $3 million regulatory approval milestone under the Simcere Agreement.

On December 2025, we entered into an amendment to the License and Collaboration Agreement (the Simcere Royalty Agreement) with Simcere, pursuant to which we relinquished our rights to future royalties on the net sales of Enzeshu® to Simcere for a one-time amount of $11.0 million and four semi-annual installments of $175,000 each. Notwithstanding the foregoing amendment, the Simcere Agreement otherwise remains in full force and effect.

T-Mab/Mabwell Agreement

In May 2008, Epitomics 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 in two therapeutic programs, each directed to a specified target for specified fields, including VEGF for the treatment of ocular diseases, in China. The Company assessed the milestone and royalty events involving Mabwell as of December 31, 2025 and determined that no such amounts were receivable. Mabwell (Shanghai) Bioscience Co., Ltd. (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, Mabwell was granted 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 after a low two-digit number of years.

Mabwell is currently in Phase 3 development of 9MW0211.

Toray Sublicense Agreement

In May 2012, Apexigen and Toray Industries, Inc. (Toray), entered into a non-exclusive sublicense agreement (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 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. The Company assessed the milestone and royalty events involving Toray as of December 31, 2025 and determined that

no such amounts were receivable. 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 U.S. and internationally for our product candidates, new therapeutic approaches, platform technologies, potential methods of use in our indications of interest 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 patents and patent applications that are wholly owned by us. Our patent portfolio includes patents and patent applications that cover our product candidates MICVO (formerly 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 for particular indications, 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. Consequently, we may not obtain or maintain adequate patent protection for any of our current or future product candidates or for our platform technologies. 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 29 different patent families, filed in various jurisdictions worldwide, including families directed to compositions of matter for antibodies and antibody-drug conjugates, families directed towards the compositions, manufacture, and use, 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.

MICVO (formerly PYX-201) Patent Families, Status, and Potential Expiration

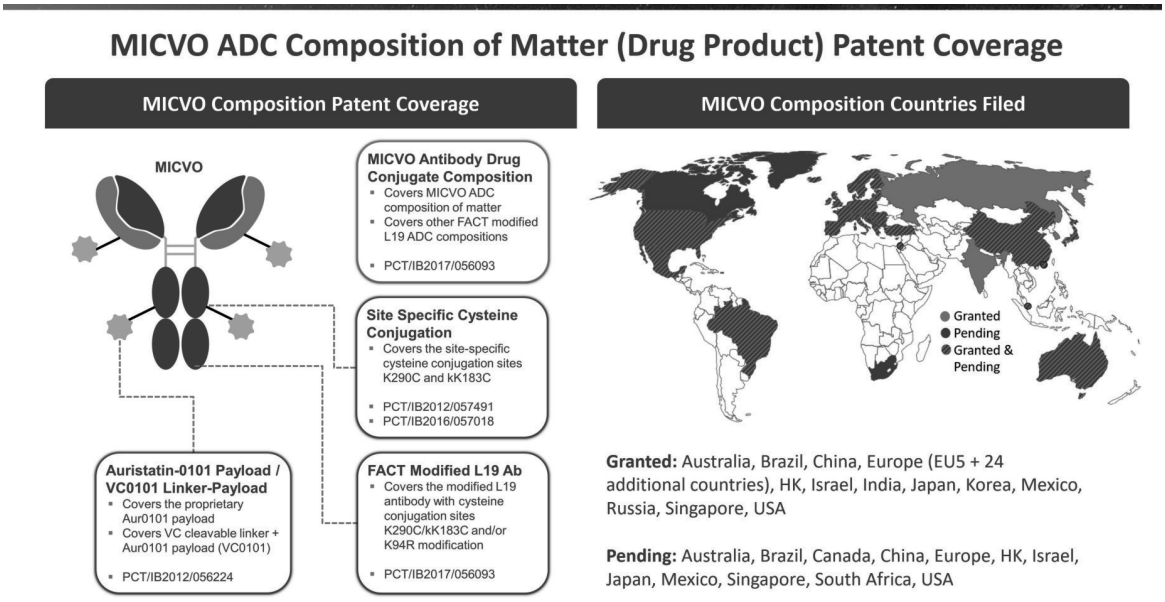
MICVO is covered by a growing portfolio of patent families, some of which are in-licensed from Pfizer, some of which we have sole ownership of, and one of which we co-own. Details, status, and potential expiration dates of MICVO patent families are summarized below:

Micvo | Patent Families, Status, and Expiration

MICVO Patent Family	Status	Next Decision Point	Likely Expiration
Composition of Matter / Drug Product	Granted and Pending	Ongoing	2037/2042+
Methods in TNBC, NSCLC, Ovarian, CRC, PDAC, Lymphoma	Pending	Ongoing	2037*
Methods in H&N, Sarcoma, HR+HER2- BC, HCC, Renal, Thyroid	PCT Pending	September 2026	2045*
Dosage and Treatment Regimens	PCT Pending	May 2027	2045*
Combination Therapies	Provisional	April 2026	2046*
Auristatin 0101 Payload	Granted	N/A	2032
FACT Cysteine Conjugation (kK183/K290C)	Granted and Pending	N/A	2033/2036

+ Assumes maximum 5 years of patent term extension, 2-3 years is more likely (depends on timing of BLA submission/approval)
* Assumes that pending patents grant, represents 20-year patent term from initial filing

MICVO Antibody-Drug Conjugate Composition of Matter (Drug Product) Patent Coverage



MICVO Related Patent Families – Constructs, Methods, and Components

MICVO Anti-EDB+FN Antibody-Drug Conjugate Composition of Matter and Methods of Using the Same. 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, including the composition of matter for MICVO and methods of using MICVO in treating certain cancer including NSCLC, colorectal cancer, PDAC and generic breast cancer, that includes granted patents in Australia, Austria, Belgium, Brazil, Bulgaria, China, Croatia, Czech Republic, Denmark, Estonia, Finland, France, Germany, Great Britian, Greece, Hong Kong, Hungary, India, Ireland, Israel, Italy, Japan, Latvia, Lithuania, Mexico, Netherlands, Norway, Poland, Portugal, Romania, Russia, Serbia, Singapore, Slovak Republic, Slovenia, South Korea, Spain, Sweden, Switzerland, Turkey, and the United States, and pending applications in Australia, Brazil, Canada, China, European Patent Organization (Europe), Hong Kong, Israel, Japan, Mexico, Singapore, South Africa, and the United States. The 20-year term of the patents in this family runs through 2037, absent any available patent term adjustments or extensions.

Methods of using MICVO - Constructs and Compositions for Treating EDB+FN Expressing Disease and Disorders in Certain Cancer Indications. We have sole ownership of a patent family for constructs, compositions, and methods of treating EDB+FN expressing diseases and disorders, including but not limited to HNSCC, sarcoma, TNBC, HR+ breast cancer, ovarian cancer, and thyroid cancer, with MICVO and similar constructs, that includes a pending PCT application. The 20-year term of this patent family runs through 2045, absent any available patent term adjustments or extensions.

Dosage and Treatment Regimens of MICVO. We have sole ownership of a patent family for dosage and treatment regimens of MICVO and similar constructs, that includes a pending PCT application. The 20-year term of this patent family runs through 2045, absent any available patent term adjustments or extensions.

Combination Therapies including MICVO. We have sole ownership of two patent families for certain drug combinations with MICVO, that include four provisional patent applications. The 20-years terms for these patent families run through 2046, absent any available patent term adjustments or extensions.

Combination of MICVO and Pembrolizumab. We have joint ownership of a patent family for the combination of MICVO and pembrolizumab in certain cancer indications at certain dose levels. The 20-year term of this patent family runs through 2046, absent any available patent term adjustments or extensions.

Cytotoxic Peptides 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 related to the FACT Platform, directed toward cytotoxic pentapeptides, including the auristatin 0101 (Aur0101) payload and MC-VC-PABC-Aur0101 linker-payload (vc0101, pelidotin) found in MICVO, and to antibody-drug conjugates thereof, that includes granted patents in Argentina, 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. The 20-year term of the patents in this family runs through 2032, 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 for compositions, methods of use, and/or methods of manufacture related to the FACT Platform, directed toward polypeptides, antibodies, and antigen-binding fragments thereof, that comprise a engineered cysteine for site-specific conjugation, including the K290C engineered cysteine found in MICVO, that includes granted patents in Australia, Canada, Colombia, India, Israel, Malaysia, Mexico, Saudi Arabia, South Africa, and Taiwan, and a pending application in Europe. 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 for compositions, methods of use, and/or methods of manufacture related to the FACT Platform, directed toward antibodies, and antigen-binding portions thereof, engineered to introduce amino acids for site-specific conjugation, including the kK183C engineered cysteine found in MICVO, that includes granted patents in Canada, EPO (Unitary Patent), France, Germany, Great Britain, Ireland, Italy, Japan, Spain, Switzerland, and the United States, and a pending application in Canada and Japan. The 20-year term of the patents in this family runs through 2032, absent any available patent term adjustments or extensions.

Composition of Matter Patents for Additional Assets (excluding MICVO)

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 Australia, Canada, China, Colombia, Hong Kong, India, Israel, Japan, Mexico, Russia, South Korea, Taiwan, and the United States, and pending applications in Brazil, China, Europe, Japan, New Zealand, 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, including PYX-106, that includes granted patents in Australia, Canada, China, Israel, Japan, Malaysia, New Zealand, Russia, Saudi Arabia, South Korea, and the United States, and pending applications in Australia, Brazil, Egypt, Europe, Hong Kong, India, Indonesia, Mexico, New Zealand, Philippines, Singapore, South Africa, United Arab Emirates, and the United States. The 20-year term of the patents 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, including PYX-107 (also known as sotigalimab) 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, Italy, Japan, Mexico, New Zealand, Russia, Singapore, South Africa, South Korea, Spain, Switzerland, and the United States, with a pending application in Israel. 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, China, Denmark, France, Germany, Great Britain, Hong Kong, India, Ireland, Italy, Japan, Netherlands, New Zealand, Norway, South Africa, South Korea, Spain, Sweden, Switzerland, and the United States, with pending applications in Canada, Europe, and the United States. The 20-year term of this second patent family runs through 2033, absent any available patent term adjustments or extension.

PYX-102 Anti-KLRG1 Antibody. We have sole ownership of a patent family for monoclonal antibodies that specifically bind human KLRG1, that includes a pending applications in Australia, Canada, China, Europe, Japan, and the United States. The 20-year term of this patent family runs through 2044, absent any available patent term adjustments or extensions.

PYX-205 Antibody-drug Conjugates and Methods of Use. We have sole ownership of a patent family for certain ADC compositions with payload optionality, that includes a pending provisional application in the United States. The 20-year term of this patent family, if converted, runs through 2047, absent any available patent term adjustments or extensions.

Certain 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 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 extensions.

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-(L)1 refractory melanomas, that includes pending applications in Europe and the United States. The 20-year term of the patents in this family runs through 2042, absent any available patent term adjustments or extensions.

PYX-002 Site Specific Ligand-Payload Conjugates. 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 pending applications in Europe and the United States. The 20-year term of the patents in this family runs through 2043, absent any available patent term adjustments or extensions.

Antibody-Drug Candidate Patent Rights

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 antibody-drug conjugate 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.

Platform Patent Rights

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 the FACT Platform, directed toward stability-modulating linker components used to make these stability-modulated antibody-drug conjugates, that includes granted patents in Australia, Brazil, Canada, China, France, Germany, Great Britain, India, Italy, Japan, Mexico, Russia, South Korea, Spain, and the United States, and a pending application in Mexico. 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 the FACT Platform, directed toward combinations of an auristatin or an auristatin-based antibody-drug conjugate 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. 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 the 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, Brazil, China, France, Germany, Great Britain, India, Ireland, Israel, Italy, Japan, Mexico, Russia, South Korea, Spain, Switzerland, and the United States, and pending applications in Canada and Europe. 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 Uncapped 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 the 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 South Korea and the United States, and no pending applications. The 20-year term of the patents in this family runs through 2038, absent any available patent term adjustments or extensions.

Bifunctional Cytotoxic Agents. 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 the FACT Platform, directed toward cytotoxic dimers comprising CBI-based and/or CPI-based sub-units, and antibody-drug conjugates comprising such dimers, that includes granted patents in Argentina, 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, the United States and Venezuela, and a pending application in Argentina. The 20-year term of the patents in this family runs through 2035, 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 for compositions, methods of use, and/or methods of manufacture related to the 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 for compositions, methods of use, and/or methods of manufacture related to the FACT Platform, directed toward transglutaminase-mediated antibody-drug conjugates with high anti-body-drug ratio, that includes granted patents in Australia, Austria, Belgium, Brazil, 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 no pending application. 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 and pending patents in the United States. The 20-year term for patents in this family runs through 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 granted patents in the United States, and no pending applications. The 20-year term for patents in this family runs through 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, and Europe, and a granted patent in the United States. The 20-year term for patents in this family runs through 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, and most countries around the world, 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 (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 is typically less, 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 candidate 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, record keeping, 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 in other countries and jurisdictions, including the EU. In the United States, the FDA regulates biological products under the Federal Food, Drug, and Cosmetic Act (FDCA) and its implementing regulations, and the Public Health Service Act (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 (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 non-clinical 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 preclinical 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 (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 Development

The FDA and comparable regulatory agencies in state and local jurisdictions and in foreign countries impose substantial requirements upon the clinical development, manufacture and marketing of pharmaceutical products. These agencies and other federal, state and local entities regulate, among other things, research and development activities and the testing, manufacture, export, import, quality control, marketing approval, safety, effectiveness, labeling, storage, record keeping, promotion, advertising, distribution and marketing and post-marketing safety reporting.

The process required by the FDA before product candidates may be marketed in the U.S. generally involves the following:

- non-clinical laboratory and animal tests, some of which must be conducted in accordance with GLP ;
- submission of an Investigational New Drug (IND) application, which contains results of non-clinical studies (e.g., laboratory evaluations of the chemistry, formulation, stability and toxicity of the product candidate), together with Investigator's Brochure, manufacturing information, analytical data, any available clinical data or literature and a proposed clinical protocol, and must become effective before human clinical trials may begin;
- approval by an independent Institutional Review Board (IRB) or ethics committee for each clinical trial site before each trial may be initiated;
- adequate and well-controlled human clinical trials conducted in accordance with the protocol and Good Clinical Practice (GCP) to establish the safety and efficacy of the product candidate for its proposed intended use;
- for drug products, submission of a New Drug Application (NDA) to the FDA for commercial marketing, or generally of a supplemental New Drug Application (sNDA), for approval of a new indication if the product is already approved for another indication;
- for biotherapeutic products, submission of a Biologics License Application (BLA) to the FDA for commercial marketing, or generally a supplemental Biologics License Application (sBLA) for approval of a new indication if the product is already approved for another indication;
- pre-approval inspection of manufacturing facilities and selected clinical investigators, clinical trial sites and/or Pyxis Oncology as the clinical trial sponsor for their compliance with cGMP and GCP, respectively;
- payment of user fees for FDA review of an NDA or BLA unless a fee waiver applies;

- agreement with the FDA on the final labeling for the product and design and implementation of any required Risk Evaluation and Mitigation Strategy;
- if the FDA convenes an advisory committee, satisfactory completion of the advisory committee review; and
- FDA approval of the NDA or sNDA, or BLA or sBLA.

Clinical Trials

Clinical trials involve the administration of the biologic product candidate to volunteers or patients under the supervision of qualified investigators in accordance with GCP requirements, which include the requirement that all research patients 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 IRB for approval covering each institution at which the clinical trial will be conducted. The IRB will consider, among other requirements, rationale for conducting the trial, clinical trial design, patient informed consent, ethical factors, the safety and rights of human patients 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 patients. The IRB may also require the clinical trial at a particular site be halted, either temporarily or permanently, or impose other conditions, for failure to comply with GCP or the IRB's requirements.

For purposes of NDA or BLA approval, human clinical trials are typically conducted in three sequential phases that may overlap or be combined:

- Phase 1 clinical trials, which involve the initial introduction of a new drug product candidate into humans, are initially conducted in a small number of volunteers or patients to assess the product candidate for early tolerability, safety, 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 provide enough data to evaluate the preliminary efficacy, optimal dosage, and common short-term side effects and risks associated with the drug. Multiple phase 2 clinical trials may be conducted to obtain information prior to beginning larger and more expensive phase 3 clinical trials.
- Phase 3 clinical trials typically are larger scale, multicenter, well-controlled trials conducted on patients with a specific disease to gather additional information about effectiveness and safety across a higher number of patients and evaluate the overall benefit-risk relationship of the product candidate following earlier phase evaluations, which will have provided preliminary evidence suggesting an effective dosage range and acceptable safety profile for the product candidate. Phase 3 trials are also intended to provide an adequate basis for the product labeling if it is approved.

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

Under the PHSA, 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 on a public registry (clinicaltrials.gov) maintained by the U.S. National Institutes of Health (the NIH). 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 NIH.

Expedited Development and Review Programs

The FDA has a number of programs intended to expedite the process for developing and reviewing promising drugs, or to provide for the approval of a drug on the basis of a surrogate endpoint. Generally, drugs that are eligible for these programs are those for serious or life-threatening conditions, those with the potential to address unmet medical needs and those that offer meaningful benefits over existing treatments. Examples of such programs include Fast Track Designation, Breakthrough Therapy Designation, Priority Review designation and Accelerated Approval, and the eligibility criteria of and benefits of each program vary:

- Fast Track is a process designed to facilitate the development and expedite the review of drugs intended to treat a serious or life-threatening conditions that demonstrate the potential to address unmet medical needs, by providing, among other things, potential actions to expedite development and review, and rolling review, which allows submission of individually completed sections of an NDA for FDA review before the entire submission is completed. The 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.
- Breakthrough Therapy Designation is a process designed to expedite the development and review of drugs intended, alone or in combination with one or more other drugs, to treat a serious or life-threatening disease or condition, and preliminary clinical evidence demonstrates that the drug may have substantial improvement on one or more clinically significant endpoints over existing therapies. Drugs designated as breakthrough therapies are also eligible for other actions to expedite review. The FDA will seek to ensure the sponsor of a Breakthrough Therapy product candidate receives intensive guidance on an efficient drug development program, intensive involvement of senior managers and experienced staff on a proactive, collaborative and cross-disciplinary review, and rolling review.
- Priority Review is designed to shorten the review period for drugs that are intended to treat a serious conditions and, if approved or licensed, would provide a significant improvement in safety or effectiveness. The FDA intends to take action on a Priority Review marketing application within six months of receipt, compared to 10 months for regular review submissions.
- Accelerated Approval provides for an earlier approval of a new drug intended to treat a serious or life-threatening disease or condition and that provides a meaningful therapeutic benefit over existing treatments and demonstrates an effect on a surrogate endpoint, or an intermediate clinical endpoint, which is considered reasonably likely to predict a clinical benefit. As a condition of approval, the FDA requires that a sponsor of a product candidate receiving Accelerated Approval perform post-marketing clinical trials or provide data on established clinical endpoints from the same trial to confirm the clinical benefit as predicted by the surrogate marker trial and may require that these studies be underway prior to approval. 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. The FDA can also withdraw an Accelerated Approval on an expedited basis provided it follows certain procedures.

Fast Track Designation, Breakthrough Therapy Designation, Priority Review and Accelerated Approval do not change the standards for licensure but may expedite the review process.

In February 2025, the FDA granted Fast Track Designation for use of MICVO for the treatment of adults with R/M HNSCC whose disease has progressed following treatment with platinum-based chemotherapy and an anti-PD-(L)1 antibody.

Additionally, with respect to oncology products, the FDA may review applications under the Real-Time Oncology Review (RTOR) program established by the FDA's Oncology Center of Excellence. The RTOR program, which allows an applicant to pre-submit components of the NDA or BLA to allow the FDA to review clinical data before the complete filing is submitted, aims to explore a more efficient review process to ensure that safe and effective treatments are available to patients as early as possible, while maintaining and improving review quality. Drugs considered for review under the RTOR program must be likely to demonstrate substantial improvements over available

therapy, which may include drugs previously granted breakthrough therapy designation for the same or other indications and must have straight-forward study designs and endpoints that can be easily interpreted.

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 disease or condition that affects fewer than 200,000 individuals in the U.S. (or for which there is no reasonable expectation that the cost of developing and making available in the U.S. for such disease or condition will be recovered from sales in the U.S.). To be eligible for orphan drug designation, the FDA must not have previously approved a drug considered the "same drug," as defined in the FDA's orphan drug regulations, for the same orphan-designated indication or the sponsor of the subsequent drug must provide a plausible hypothesis of clinical superiority over the previously approved same drug. Upon receipt of Orphan Drug Designation, the sponsor is eligible for tax credits for certain clinical trial expenses, waiver of pediatric studies, and an exemption from the BLA application fee.

In addition, upon marketing approval, an Orphan Drug Designation could be eligible for seven years of market exclusivity if no drug considered the same drug was previously approved for the same orphan condition (or if the subsequent drug is demonstrated to be clinically superior to any such previously approved same drug). Such orphan drug exclusivity, if awarded, would only block the approval of any drug considered the same drug for the same orphan indication. 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.

In May 2023, the FDA granted Orphan Drug Designation for use of MICVO in the treatment of pancreatic cancer.

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 $4,682,003 for BLAs requiring clinical data for fiscal year 2026, and the manufacturer and sponsor under an approved BLA are also subject to annual program fees, currently $442,213 (fiscal year 2026) for each prescription product. 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 cGMP 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 re-submissions 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 (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 (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.

Post-Licensure FDA Requirements

Following approval of a new product, the manufacturer and the approved product are subject to continuing regulation by the FDA, including, among other things, monitoring and record keeping activities, reporting of adverse experiences, complying with promotion and advertising requirements, which include restrictions on promoting products for unapproved uses or patient populations (known as "off-label use") and limitations on industry sponsored scientific and educational activities. Although physicians may prescribe legally available products for off-label uses, manufacturers may not market or promote such uses. Prescription drug and biologic promotional materials must be submitted to the FDA in conjunction with their first use. Further, if there are any modifications to the biologic, including changes in indications, labeling or manufacturing processes or facilities, the applicant may be required to submit and obtain FDA approval of a new BLA or sBLA, which may require the development of additional data or preclinical studies and clinical trials.

The FDA may also place other conditions on approvals including the requirement for a REMS to assure the safe use of the product. If the FDA concludes a REMS is needed, the sponsor of the BLA must submit a proposed REMS. The FDA will not approve the BLA without an approved REMS, if required. A REMS could include medication guides, physician communication plans or elements to assure safe use, such as restricted distribution methods, patient registries and other risk minimization tools. Any of these limitations on approval or marketing could restrict the commercial promotion, distribution, prescription or dispensing of products. Product approvals may be withdrawn for non-compliance with regulatory standards or if problems occur following initial marketing.

FDA regulations require that products be manufactured in specific facilities and in accordance with cGMP regulations. We rely, and expect to continue to rely, on third parties for the production of clinical and commercial quantities of our products in accordance with cGMP regulations. These manufacturers must comply with cGMP regulations that require, among other things, quality control and quality assurance, the maintenance of records and documentation and the obligation to investigate and correct any deviations from cGMP. Manufacturers and other entities involved in the manufacture and distribution of approved drugs or biologics are required to register their establishments with the FDA and certain state agencies and are subject to periodic unannounced inspections by the FDA and certain state agencies for compliance with cGMP requirements and other laws, including applicable product tracking and tracing requirements. Accordingly, manufacturers must continue to expend time, money and effort in the area of production and quality control to maintain cGMP compliance. The discovery of violations, including failure to conform to cGMP regulations, could result in enforcement actions, and the discovery of post approval problems with a product may result in restrictions on a product, manufacturer or holder of an approved BLA, including recall.

Biosimilars and Reference Product Exclusivity

The Biologics Price Competition and Innovation Act of 2009 (BPCIA) created an abbreviated approval pathway for biological product candidates shown to be highly similar ("biosimilar") to or interchangeable with an FDA licensed reference biological product. Biosimilarity, which requires 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.

The BPCIA is complex and continues to be interpreted and implemented by the FDA. In addition, government proposals have sought to 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 remains subject to significant uncertainty.

Patent Term Extension

Depending upon the timing, duration, and specifics of the FDA approval and BLA licensure of the use of product candidates, some U.S. patents may be eligible for limited patent term extension under the Drug Price Competition and Patent Term Restoration Act of 1984, commonly referred to as the Hatch-Waxman Amendments. The Hatch-Waxman Amendments permit a patent restoration term of up to five years as compensation for patent term lost during product development and the FDA regulatory review process. The patent term restoration period is typically one-half the time between the effective date of an IND and the submission date of a BLA, plus the time between the submission date and approval of that application. The total patent term after the extension may not exceed 14 years from the product date of product licensure. Only one patent applicable to a licensed biological product is eligible for extension and the application for the extension must be submitted prior to the expiration of the patent and within 60 days of the product's approval. The U.S. Patent and Trademark Office, in consultation with the FDA, reviews and approves the application for any patent term extension or restoration. 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 Regulatory Matters

Manufacturing, sales, promotion, and other activities of product candidates following product approval, where applicable, or commercialization are also subject to regulation by numerous regulatory authorities in the U.S. in addition to the FDA, which may include the Centers for Medicare & Medicaid Services (CMS), other divisions of the Department of Health and Human Services, the Department of Justice, the Drug Enforcement Administration, the Consumer Product Safety Commission, the Federal Trade Commission, the Occupational Safety & Health Administration, the Environmental Protection Agency, and state and local governments and governmental agencies.

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 (HIPAA), federal and state consumer protection laws and regulations (Section 5 of the Federal Trade Commission Act), state privacy laws, data breach notification laws, and the EU General Data Protection Regulation (GDPR).

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 candidate 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 candidate 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.

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 (EU) are addressed in a centralized way, but country-specific regulation remains essential in many respects.

Healthcare and Data Privacy Regulation

Federal and state healthcare laws and regulations, including fraud and abuse and health information privacy and security laws, also govern our business. These laws and regulations 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.

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 and their products are subject to extensive regulation and enforcement. These laws include, without limitation:

- the federal Anti-Kickback Statute, a criminal statute which prohibits, among other things, persons and entities from knowingly and willfully soliciting, offering, paying, receiving or providing any remuneration (including any kickback, bribe, or certain 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, order or recommendation of, any good or service, for which payment may be made, in whole or in part, under a federal healthcare program such as Medicare and Medicaid; a person or entity need not have actual knowledge of the federal Anti-Kickback Statute or specific intent to violate it in order to have committed a violation;
- the federal civil and criminal false claims laws, including the civil False Claims Act (the FCA), which prohibit individuals or entities from, among other things, 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;
- 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. 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. The FCA also permits a private individual acting as a "whistleblower" to bring actions on behalf of the federal government alleging violations of the FCA and to share in any monetary recovery;

- the federal civil monetary penalties laws, which impose civil fines for, among other things, the offering or transfer or remuneration to a Medicare or state healthcare program 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 services reimbursable by Medicare or a state health care program, unless an exception applies;
- the federal criminal statute enacted under HIPAA, which imposes criminal and civil liability for knowingly and willfully executing a scheme, or attempting to execute a scheme, to defraud any healthcare benefit program, including private payors, knowingly and willfully embezzling or stealing from a healthcare benefit program, willfully obstructing a criminal investigation of a healthcare offense, or 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 need not have actual knowledge of the statute or specific intent to violate it in order to have committed a violation;
- HIPAA, as amended, and the respective implementing regulations, which imposes, among other things, specified requirements on covered entities and their business associates relating to the privacy and security of individually identifiable health information including mandatory contractual terms and required implementation of technical safeguards of such information;
- the federal Physician Payments Sunshine Act, which requires manufacturers of drugs, devices, biologics, and medical supplies for which payment is available under Medicare, Medicaid, or the Children's Health Insurance Program, to monitor and report annually certain transfers of value made to U.S.-licensed physicians (defined to include doctors, dentists, optometrists, podiatrists and 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 ownership and investment interests held by U.S.-licensed physicians and their immediate family members; and
- analogous state and foreign laws and regulations, such as state anti-kickback and false claims laws, which may apply to sales or marketing arrangements and claims involving healthcare items or services reimbursed by non-governmental third party payors, including private insurers, and may be broader in scope than their federal equivalents; state and foreign laws that require pharmaceutical companies to comply with the pharmaceutical industry's voluntary compliance guidelines and the relevant compliance guidance promulgated by the federal government or otherwise restrict payments that may be made to healthcare providers; state and foreign laws that require drug manufacturers to report information related to payments and other transfers of value to physicians and other healthcare providers, and restrict marketing practices or require disclosure of marketing expenditures and pricing information; state and local laws that require the registration of pharmaceutical sales representatives; and state and foreign laws that govern the privacy and security of health information in some circumstances.

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. 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.

Healthcare Reform

The U.S. and some foreign countries are considering proposals or have enacted legislative and regulatory changes to the healthcare system that could affect our ability to sell our products profitably. Among policy makers and payers in the U.S. and elsewhere, there is significant interest in promoting changes in healthcare systems with the stated goals of containing healthcare costs, improving quality and/or expanding access.

For example, in 2010, the U.S. enacted the ACA, which among other things, increased the minimum Medicaid rebates owed by most manufacturers under the Medicaid Drug Rebate Program; extended the Medicaid Drug Rebate program to utilization of prescriptions of individuals enrolled in Medicaid managed care organizations; subjected manufacturers to new annual fees and taxes for certain branded prescription drugs; and provided incentives to programs that increase the federal government's comparative effectiveness research. Current laws, as well as other healthcare reform measures that may be adopted in the future, may result in more rigorous coverage criteria and additional downward pressure on the price for any approved products.

Since the enactment of the ACA, there have been, and continue to be, numerous legal challenges and Congressional actions to repeal and replace provisions of the law. For example, with enactment of the Tax Cuts and Jobs Act of 2017 (TCJA), Congress repealed the "individual mandate." The repeal of this provision, which requires most Americans to carry a minimal level of health insurance, became effective in 2019. Further, 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. Litigation and legislation over the ACA are likely to continue, with unpredictable and uncertain results.

In August 2022, former President Biden signed the Inflation Reduction Act of 2022 (IRA), which introduced substantial changes to drug pricing, reimbursement and access support in the U.S., including enabling CMS to establish 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 (the Medicare Drug Price Negotiation Program). The IRA contains a limited exception for small biotech drug manufacturers, which applies on a drug-specific basis, and qualifying drugs will be exempt from possible pricing negotiation through 2028 and eligible for a lower limit (i.e., a price floor) on the potential maximum fair price in 2029 and 2030, if the manufacturers of those drugs continue to qualify each year (small biotech exception). Separately, in November 2023, CMS released final guidance on another program, the Medicare Part D Manufacturer Discount Program (Part D Discount Program), which will require manufacturers to take on more of the beneficiary cost previously subsidized by the federal government through the application of increased drug discounts. The IRA also imposes additional rebates for certain Part B and Part D drugs where relevant pricing metrics associated with the products increase faster than inflation. However, it is unclear how the IRA will be effectuated or changed under the new Trump Administration and the degree of impact that the IRA will ultimately have upon our business similarly remains unclear.

At the state level, legislatures and regulatory agencies have increasingly passed legislation and implemented regulations designed to control pharmaceutical and biotherapeutic product pricing, including restrictions on pricing or reimbursement at the state government level, limitations on discounts to patients, advance notices of price increases, marketing cost disclosure and transparency measures, and, in some cases, policies to encourage importation from other countries (subject to federal approval) and bulk purchasing. These laws may affect our sales, marketing, and other promotional activities by imposing administrative and compliance burdens on us. In addition, given the lack of clarity with respect to these laws and their implementation, our reporting actions could be subject to the penalty provisions of the pertinent state and federal authorities.

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 that reward performance and leadership skills, and by offering competitive compensation and benefits programs.

Employees

As of March 20, 2026, we had 56 full-time permanent employees. Of these employees, 80% were engaged in research and development activities and 46% had advanced degrees including Ph.D., M.D., M.B.A. and J.D. More than half of our workforce is comprised of women. None of our employees are represented by a labor union or covered by a collective bargaining agreement. We consider our relationship with our employees to be good.

Culture and Employee Engagement

We place a high value in the experience and expertise of our team, 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.

Hiring & Retention Risk

We compete with biotechnology and pharmaceutical companies for qualified personnel, particularly in clinical development, regulatory affairs and technical operations. We may not be able to attract or retain personnel on acceptable terms or in a timely manner, which could affect our ability to execute our development strategy.

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 (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 (the Board) recognizes the critical importance of our team 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.

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. The Board receives periodic updates regarding workforce planning and organizational capability.

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) 453-3596. Our website address is www.pyxisoncology.com. Our common stock is listed on The Nasdaq Global Market under the ticker symbol "PYXS."

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 U.S. Securities and Exchange Commission (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 oncology company with a limited operating history and have incurred significant losses since our inception and anticipate that we will continue to incur losses over at least the next several years and may never achieve or maintain profitability.

Since our inception, we have incurred significant operating losses. We reported net losses of $79.6 million and $77.3 million for the years ended December 31, 2025 and 2024, respectively. As of December 31, 2025, we had an accumulated deficit of $443.2 million. To date, we have not generated any revenues from product sales and have financed our operations primarily through equity offerings. 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 candidate, establishing arrangements with third parties for the conduct of our clinical trials, obtaining marketing licensure for our product candidate, 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 our existing product candidate and successfully completing development of our product candidate for our collaboration partners.

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:

- continue to develop, conduct clinical trials and seek regulatory approvals for MICVO;
- scale up external manufacturing capabilities for later stage trials and to commercialize our products;
- expand, maintain and protect our intellectual property portfolio;
- ultimately establish a sales, marketing and distribution infrastructure for which we may obtain marketing licensure;
- 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 (FDA), the European Medicines Agency (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 our product candidate.

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.

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 have substantial doubt about our ability to continue as a going concern and 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 not be able to continue as a going concern or we may be forced to delay, reduce or eliminate one or more of our research and product development programs or future commercialization efforts.

Our recurring losses from operations raise substantial doubt about our ability to continue as a going concern. As a result, the financial statements accompanying this Annual Report on Form 10-K include a statement that there is substantial doubt about our ability to continue as a going concern for one year after the date the financial statements were issued, and these financial statements do not include any adjustments that might result from the outcome of this uncertainty.

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 and planned activities, particularly as we continue our clinical trials for MICVO. As of December 31, 2025, we had approximately $68.3 million in cash, cash equivalents, restricted cash and marketable debt securities. We believe that our cash, cash equivalents and marketable debt securities as of December 31, 2025, will be sufficient to fund our operations into the fourth quarter 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. Even if our product candidate 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.

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, including market volatility resulting from global economic developments, political unrest, high inflation and other factors, 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 candidate, and other general corporate purposes. Advancing the development of our product candidate will require a significant amount of capital. Our cash and cash equivalents will not be sufficient to fund our product candidate 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 cost associated with dose escalation and dose expansion mono and combo clinical trials for our product candidate;
- the manufacture of drug products and drug substance for our product candidate;
- the timing and progress of our other preclinical and clinical development activities;
- the costs and timing of future commercialization activities, including product manufacturing, marketing, sales and distribution, for our product candidate 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, enforcing and expanding patent and other intellectual property rights;
- the cost and timing of regulatory licenses; and
- insurance, legal and other regulatory compliance expenses to operate as a public company.

If we are unable to obtain funding on a timely basis or on acceptable terms, we may not be able to continue as a going concern, we may have to delay, reduce or terminate our clinical trials, 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 our product candidate that we would otherwise pursue on our own. 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.

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. In addition, changes in global macroeconomic conditions and government trade policies could further increase our operating costs and accelerate our need for additional capital. New or increased tariffs, trade restrictions, retaliatory measures, or other limitations on the movement of goods and services, whether imposed by the United States or other jurisdictions, could increase the cost of materials, equipment and services used in our research, development and manufacturing activities. Such measures could also disrupt global supply chains, increase transportation and logistics costs, and create delays in the delivery of clinical supplies. Any of these developments could materially increase our cash burn, delay development timelines, and adversely affect our ability to obtain additional financing on acceptable terms, or at all.

Risks Related to the Development of our Product Candidate

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 candidate.

Before obtaining marketing approval from regulatory authorities for the sale of our product candidate, we or our collaborators must conduct extensive trials to demonstrate the safety and efficacy of the product candidate. 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 candidate, including:

- delays in reaching, or the failure to reach, a consensus with regulators on clinical trial design;
- the supply or quality of our product candidate or other materials necessary to conduct clinical trials of our product candidate may be insufficient or inadequate, including as a result of delays in the testing, validation, manufacturing and delivery of product candidate 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 candidate may be larger than we anticipate, enrollment in these clinical trials may be slower than we anticipate, participants may fail during screening or 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 candidate 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 candidate for various reasons, including a finding that the participants are being exposed to unacceptable safety risks or that the benefit-risk ratio is negative;
- 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 candidate 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 candidate may be greater than we anticipate;
- imposition of a clinical hold by regulatory authorities as a result of a serious adverse event, concerns with the class of our product candidate 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 candidate, 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.

The FDA may modify or enhance clinical trial requirements which may affect enrollment and retention of patients and may increase costs and delay clinical programs.

If we are required to conduct additional clinical trials or other testing of our product candidate beyond those that we currently contemplate, if we are unable to successfully complete clinical trials of our product candidate 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 licensure for our product candidate;
- 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 the 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 candidate; or
- have our product removed from the market after obtaining marketing licensure.

Our product development costs also will increase if we experience delays in preclinical studies or clinical trials or in obtaining marketing licensure. 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 candidate, or could allow our competitors to bring products to market before we do and impair our ability to successfully commercialize our product candidate, 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 this product candidate 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 candidate 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.

We are heavily dependent on the success of our product candidate, MICVO, which is in the early stages of clinical development. If MICVO is not successful in clinical trials or does not receive regulatory approval or licensure or is 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 MICVO. Our future success is substantially dependent on our ability to successfully initiate and complete clinical development for, obtain regulatory licensure for, and successfully commercialize MICVO, 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 clinical development, management of clinical and manufacturing activities, regulatory licensure, establishing commercial scale manufacturing, and significant sales, marketing, and distribution efforts related to MICVO 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 MICVO receives regulatory licensure, such product 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 MICVO in the U.S. until we receive licensure of a BLA or NDA from the FDA for such product candidate, as appropriate. Further, we are not permitted to market MICVO 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 MICVO. 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 MICVO, our financial position will be materially adversely affected, and we may not be able to generate sufficient revenues to continue our business.

Evolving regulatory expectations for oncology drug development could require additional studies and delay or prevent approval of our product candidate.

Regulatory expectations for oncology drug development continue to evolve. In recent years, regulatory authorities, including the U.S. Food and Drug Administration, have placed increased emphasis on dose optimization and dose selection to balance efficacy and safety. These evolving expectations may require additional dose-ranging studies, expanded clinical trial designs, or generation of additional data beyond what we currently anticipate.

If regulatory authorities impose additional requirements on our development program, we may incur substantial additional expense, experience delays in enrollment or completion of clinical trials, or be required to modify our development plans. Any of these outcomes could delay or prevent regulatory approval and materially adversely affect our business and prospects.

Our product candidate may fail in development or suffer delays that materially and adversely affect its 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 candidate or experience significant delays in doing so, our business will be materially harmed.

Our ability to achieve and sustain profitability depends on obtaining regulatory licensure for and successfully commercializing our product candidate, either alone or with third parties. Before obtaining regulatory licensure for the commercial distribution of our product candidate, 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 candidate. 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, a product candidate, 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 candidate;
- 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, the 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 candidate 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;
- varying interpretations of data by the FDA, the EMA and other comparable foreign regulatory authorities; or
- landscape changes around market access and pricing policies that may impact reimbursement and product sales.

If any of the foregoing circumstances occur, we could experience significant delays or an inability to successfully commercialize our product candidate, 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 MICVO.

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 MICVO, which would adversely impact our financial performance. Large-scale clinical trials would require significant additional financial and management resources and heavier reliance on third party clinical research organizations (CROs) and consultants. Relying on third party CROs and consultants may cause us to encounter delays or other operational issues that are outside of our control. Although our third parties are required to comply with good laboratory practice (GLP) and good clinical practice (GCP) for any studies or trials we plan to submit to a regulatory authority, and have historically complied, 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 GLP or GCP in the future. 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 our product candidate, which would prevent or delay development, regulatory approval or licensure and commercialization.

Before obtaining regulatory licensure for the commercial sale of our product candidate we must demonstrate through lengthy, complex and expensive preclinical studies and clinical trials that our product candidate is 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 studies and clinical trial processes and, because our product candidate is 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 a similar product candidate could materially impact the success of our program. 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 candidate may not be predictive of the results of later-stage clinical trials. Although our product candidate may demonstrate promising results in preclinical studies and early clinical trials, it 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 a product candidate proceeding through preclinical studies and clinical trials. A product candidate 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 preclinical studies that were completed prior to our in-licensing or acquisition of our product candidate, which may materially and adversely affect our business, results of operations and prospects.

Additionally, our PYX-201-101 Phase 1 clinical trial is an open label study, where both the patient and investigator know whether the patient is receiving the investigational product candidate. 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. For instance, 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 candidate. 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 candidate, if we do not meet the clinical endpoints with statistical and clinically meaningful significance or if there are safety concerns associated with our product candidate, we may be prevented or delayed in obtaining marketing licensure for the product candidate. 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 candidate 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. Any of these occurrences may significantly harm our business, financial condition and prospects.

Further, our product candidate could cause undesirable side effects in clinical trials related to on-target toxicity. If an unacceptable safety profile is observed or if our product candidate has characteristics that are unexpected, we may need to abandon its 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.

Interim top-line and preliminary data from our clinical trials that we announce or publish from time to time may change as more patient data become available and are subject to audit and verification procedures that could result in material changes to the final data.

From time to time, we may publish interim top-line or preliminary data from our clinical trials. For example, in December 2025, we announced preliminary data from our dose expansion phase of Phase 1 clinical trial of MICVO. Preliminary data from clinical trials that we may complete are subject to the risk that one or more of the clinical outcomes may materially change as patient enrollment continues and more patient data become available. 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 published. Preliminary or top-line data may include, for example, data regarding a small percentage of the patients enrolled in a clinical trial, and such preliminary data should not be viewed as an indication, belief or guarantee that other patients enrolled in such clinical trial will achieve similar results or that the preliminary results from such patients will be maintained. As a result, interim and preliminary data should be viewed with caution until the final data is available. Differences between preliminary or interim data and final data could significantly harm our business prospects and may cause the trading price of our common stock to fluctuate significantly.

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 several programs that have been licensed to third parties, including larger global biopharmaceutical companies and mid-sized regional or China-focused 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. 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.

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

As a result of our limited financial and managerial resources, we must make strategic decisions as to which targets and product candidate 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 a potential product candidate could result in our focus on a product candidate with low market potential, which would harm our business, financial condition, results of operations and prospects. Our spending on current and future research, our product candidate 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.

The market may not be receptive to MICVO because it is based on our novel therapeutic modality, and we may not generate any future revenue from the sale or licensing of this product candidate.

Even if regulatory licensure is obtained for our product candidate, we may not gain sufficient market acceptance among physicians, patients, healthcare payors and others in the medical community. MICVO is based on the FACT Platform. Our future success depends on the successful development of this novel therapeutic approach. Additionally, the regulatory licensure process for a novel product candidate 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. Any development problems we experience in the future related to our program 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 candidate, 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 our product candidate we may develop on a timely or profitable basis, if at all.

Market acceptance of our product candidate 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 candidate;
- the prevalence and severity of any adverse side effects associated with our product candidate;
- 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 candidate;
- 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 candidate is 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 candidate, MICVO, is 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 Phase 1 clinical trial may make the result of this trial less predictive of the outcome of later clinical trials. Moreover, preclinical and clinical data often are susceptible to varying interpretations and analyses, and many companies that have believed their product candidate 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 MICVO. There is a high failure rate for a product candidate 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.

If we or our collaborators experience delays or difficulties in the enrollment of patients in our clinical trials, these clinical trials could be delayed or prevented.

We may not be able to continue clinical trials for our product candidate 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 other comparable foreign regulatory authorities. Our ability to identify sites who will 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 candidate 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 a high number of patients fail during screening or 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 or our collaborators inability to timely enroll a sufficient number of patients for our clinical trials, based on the above factors or others, could 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 candidate, which would cause the value of our company to decline and limit our ability to obtain additional financing.

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

Undesirable side effects caused by our product candidate 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 candidate 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 candidate may only be uncovered with a significantly larger number of patients exposed to the product candidate.

In the event that our product candidate receives regulatory licensure or approval and we or others later identify undesirable side effects, any of the following adverse events could occur, which could result in significant negative consequences:

- 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.

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 may face significant competition from other oncology-focused biotechnology and pharmaceutical entities, and our operating results will suffer if we fail to compete effectively.

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 candidate. 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 a product candidate. 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 candidate that we successfully commercialize may 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 which could negatively impact our ability to execute our business plan.

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 candidate is licensed, it 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 February 2026, there were approximately 900+ 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, Johnson & Johnson, Lyvgen Biopharma, Nextcure, Inc., Pfizer, Philogen S.p.A., Merck Sharpe & Dohme (MSD), Corbus Pharmaceuticals, and Rakuten Medical, Inc.

We could also face competition with respect to specific targets, including the target of our ADC, MICVO, EDB+FN, by Philogen S.p.A., a Swiss based Biotechnology company, focused on generating antibody-cytokine fusions (immunocytokines) against cancers, using the L19 antibody specific to the EDB domain of Fibronectin fused to TNF, a potent inflammatory cytokine, which could pursue similar indications targeting EDB and stand out as the first non-ADC therapy pursuing EDB+FN.

There are other emerging agents in key indications of interest including R/M HNSCC. Genmab's EGFR and LGR5 targeting biclonal, petosemtamab, Bicara's EGFR/TGF-beta targeting bifunctional, ficerafusp alfa (BCA101), and Johnson and Johnson's EGFR and cMET bispecific antibody, amivantamab, are notable competitors that are targeting patient populations of interest to MICVO and pose a potentially significant threat to our clinical development strategy. Additionally, Corbus Pharmaceutical's nectin-4 targeting ADC, CRB-701 has shown preliminary efficacy data and is a direct competitor given similarity in payload (MMAE) to MICVO, and comparable patient populations and clinical development timelines in R/M HNSCC.

Other competitors may also include agents targeting specific segments such as HPV+ HNSCC, namely NeoTrail Therapeutics (formerly Hookipa)'s and PDS Biotech's vaccines and agents such as Nanobiotix's radioenhancer that may be used earlier in the treatment sequence. With the approval of pembrolizumab in the peri-operative setting based on Keynote-689, use of IO in the neoadjuvant and adjuvant settings may shift how HPV patients are treated in earlier lines of therapy. The implementation of using IO in the earlier disease settings could impact patient segmentation and treatment choices in the R/M setting.

Furthermore, ADCs such as Gilead's TROP-2 ADC, sacituzumab govitecan, Pfizer's Nectin-4 targeting ADC, enfortumab vedotin and AZ's AZD9592, a dual targeting ADC against EGFR and cMET are in clinical development in HNSCC. Enfortumab vedotin is currently pursuing a 1L HNSCC trial in combination with pembrolizumab thus adding to the crowded landscape of combo studies in the frontline setting. Additional competition may arise from other combination regimens being evaluated including but not limited to ficlatuzumab + cetuximab (2L), ivonescimab + ligufalimab (1L, CPS>1) and LN-145 + pembrolizumab (1L). 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 our product candidate is approved in oncology indications such as breast cancer, 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. Competitive products may make any products we develop obsolete owing to treatment paradigm shifts or noncompetitive, reducing the addressable market before we recover the expense of developing and commercializing our product candidate. Such competitors could also recruit our employees, which could negatively impact our level of expertise and our ability to execute our business plan.

We believe that our ability to successfully compete will depend on, among other things:

- our ability to develop and protect therapeutics that are more effective and safer than competing products;
- our ability to innovate with rapidly evolving technologies;

- 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 price of our product candidate and whether coverage and adequate levels of reimbursement are available under health insurance plans;
- our ability to utilize any abbreviated licensure pathways; and
- the length of time we are granted market exclusivity for any product candidate we may develop that is licensed as a biological product under a Biologics License Application (BLA).

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 candidate 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 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 candidate 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 foreign regulatory authorities are lengthy, time-consuming and inherently unpredictable and, if we are unable to obtain marketing licensure or approval for our product candidate, our business will be substantially harmed.

The time required to obtain approval or licensure by the FDA and other comparable foreign 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 our existing product candidate, or any product candidate we may seek to develop in the future, will never obtain marketing approval or licensure.

Our product candidate could fail to receive marketing licensure in the U.S. 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 the 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 candidate may not be sufficient to support the submission of a BLA to the FDA or other submission or to obtain marketing licensure in the U.S.;
- 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 our product candidate, 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 our product candidate. Even if we believe the preliminary data collected from clinical trials of our product candidate is promising, such preliminary data may not be sufficient to support licensure by the FDA.

In addition, even if we were to obtain licensure, regulatory authorities may approve our product candidate for fewer or more limited indications than we request, 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 candidate.

Even if we receive regulatory licensure of our product candidate, 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 candidate.

If our product candidate is 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.

The FDA and foreign regulatory authorities will continue to monitor closely the safety profile of any product even after approval. If the FDA or foreign regulatory authorities become aware of new safety information after approval of a product candidate, they may require labeling changes or establishment of a Risk Evaluation and Mitigation Strategies (REMS), if not already established in pre-approval, or similar strategy, impose significant restrictions on its indicated uses or marketing, or impose ongoing requirements for potentially costly post approval studies or post-market surveillance.

The FDA and comparable foreign regulatory authorities may conduct periodic inspections for compliance with regulatory requirements and standards. Later discovery of previously unknown problems with our product candidate, may result in consequences including, among other things:

- restrictions and warnings on the labeling of a product;
- restrictions on product distribution or use;
- requirements to conduct post-marketing studies or clinical trials;
- damage to relationships with any potential collaborators;
- unfavorable press coverage and damage to our reputation;
- 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 comparable foreign regulatory 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 candidate; and
- injunctions or the imposition of civil or criminal penalties.

We, and any collaborators, must comply with requirements concerning advertising and promotion for our product candidate 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 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.

If we decide to seek additional Breakthrough Therapy Designation and/or Fast Track Designation by the FDA, even if granted for any of our product candidate, may not lead to a faster development or regulatory review or licensure process and it does not increase the likelihood that our product candidate will receive marketing licensure.

We may seek additional Breakthrough Therapy Designation and/or Fast Track Designation for our product candidate. For example, in February 2025, the FDA granted Fast Track Designation for use of MICVO in the treatment of adult patients with R/M HNSCC whose disease has progressed following treatment with platinum-based chemotherapy and an anti-PD-(L)1 antibody. The FDA may withdraw the Fast Track Designation if the clinical development program no longer meets the criteria for Fast Track Designation. There is no assurance that the FDA will grant these designations to any of our current or 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, increased 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 and Priority Review, if they meet regulatory requirements for those other programs.

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. The FDA may withdraw any Fast Track Designation at any time.

In any event, the receipt of a Breakthrough Therapy Designation and/or Fast Track Designation for a product candidate may not result in a faster development process, review or licensure compared to standard review and do not assure ultimate licensure by the FDA. In addition, even if our product candidate qualifies as a Breakthrough Therapy, the FDA may later decide that the product no longer meets the conditions for qualification. Additionally, 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 for MICVO in pancreatic cancer. Regulatory authorities in some jurisdictions, including the U.S. 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 U.S., or a patient population greater than 200,000 in the U.S. when there is no reasonable expectation that the cost of developing and making available the drug in the U.S. will be recovered from sales in the U.S. for that drug or biological product. In the U.S., 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 our product candidate 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 candidate in additional orphan indications in which there is a medically plausible basis for the use of this product candidate. Even if we obtain Orphan Drug Designation, exclusive marketing rights in the U.S. 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.

It is also possible that current or future litigation or action by Congress could change the scope of available orphan exclusivity. 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 candidate will receive marketing licensure. If not granted, we may be required to conduct additional non-clinical and clinical studies and trials beyond those that we currently contemplate. Even if we receive Accelerated Approval, 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 MICVO and may seek approval of future product candidates through the FDA's Accelerated Approval Program. For any licensure to market a biological product, we must provide the FDA and comparable foreign regulatory authorities 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 underway prior to Accelerated Approval, pursuant to the Food and Drug Omnibus Reform Act of 2022 (FDORA) enacted in 2022 and under FDA's draft guidance on "Accelerated Approval and Considerations for Determining Whether a Confirmatory Trial is Underway" made available in January 2025. In addition, Section 506(c) of the FDCA provides FDA authority to impose specific conditions on Accelerated Approval, including requiring post-approval study(ies) to verify and describe clinical benefit, and requiring submission of promotional materials during the pre-approval review period and, following approval and for such period thereafter as FDA determines appropriate, at least 30 days prior to dissemination. The statute also requires FDA, by no later than the date of Accelerated Approval, to specify conditions for required post-approval studies, which may include enrolment targets, protocol, and milestones (including a target completion date), and FDA may require such studies to be underway prior to approval or within a specified time period after approval. If such confirmatory post-marketing trials fail to confirm the product's clinical profile or risks and benefits, or if we fail to conduct any required confirmatory trial with due diligence, or other evidence shows the product is not safe and effective under the conditions of use, 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 to 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 post-marketing requirement to verify clinical benefit. The draft guidance, while not finalized, included statements where 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. Further description of the expedited withdrawal process was released by the FDA in the recent draft guidance *Expedited Program for Serious Conditions – Accelerated Approval of Drugs and Biologics* (December 2024).

Moreover, Congress is considering potential changes to the Accelerated Approval Program that could impact our ability to obtain Accelerated Approval, or increase the burdens associated with post-marketing requirements in the event we do obtain Accelerated Approval. In particular, the FDA must specify certain conditions for required post approval studies for products that receive Accelerated Approval, which may include enrollment targets and milestones, including the target date for study completion, by the time the drug is approved. The FDA may also require post approval studies to be underway at the time of Accelerated Approval or within a specified time period following Accelerated Approval for such drugs, and must explain any instances where it does not require such studies. FDA's January 2025 draft guidance on *Accelerated Approval and Considerations for Determining Whether a Confirmatory Trial is Underway*, while not finalized, suggests that FDA generally intends to consider a confirmatory trial to be "underway" prior to Accelerated Approval if (1) the trial has a target completion date that is consistent with diligent and timely conduct of the trial, considering the nature of the trial's design and objectives, (2) the sponsor's progress and plans for post approval conduct of the trial provide sufficient assurance to expect timely completion of the trial, and (3) enrollment of the confirmatory trial has been initiated.

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 our product candidate that receive marketing approval, or such authorities do not grant our product candidate appropriate periods of data or market exclusivity before approving generic versions of our product candidate, the sales of our product candidate 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.

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 (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 candidate 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, the criteria for designating an "orphan medicinal product" are similar in principle to those in the U.S. 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. 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 candidate may face from biosimilar versions of our product candidate 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 the product candidate. 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 this product candidate may be substantially limited if our product candidate, if and when approved, are not afforded the appropriate period of non-patent exclusivity.

Our failure to obtain regulatory approval in international jurisdictions would prevent us from marketing our product candidate outside the U.S. and the sales of our product candidate could be adversely affected.

In order to market and sell our product candidate in other jurisdictions, we must obtain separate marketing approvals for those jurisdictions and comply with their numerous and varying regulatory requirements. We may not obtain foreign regulatory approvals on a timely basis, or at all. The approval procedure varies among countries and can involve additional testing. The time required to obtain approval may differ substantially from that required to obtain FDA approval. The regulatory approval process outside the U.S. generally includes all of the risks associated with obtaining FDA approval. In addition, in many countries outside the U.S., product reimbursement approvals must be secured before regulatory authorities will approve the product for sale in that country. Obtaining foreign regulatory approvals and compliance with foreign regulatory requirements could result in significant delays, difficulties and costs for us and could delay or prevent the introduction of our product candidate in certain countries. Further, clinical trials conducted in one country may not be accepted by regulatory authorities in other countries and regulatory approval in one country does not ensure approval in any other country. Our failure to obtain approval of our product candidate by foreign regulatory authorities may negatively impact the commercial prospects of such product candidate and our business prospects could decline.

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

We may seek to identify patient subsets within a disease category that may derive selective and meaningful benefit from the product candidate we are developing. Through collaborations or license agreements, companion diagnostics may help us to more accurately identify patients within a particular subset, both during our clinical trials and in connection with the commercialization of our product candidate, if approved. In connection with the clinical development of our product candidate for certain indications, we may work with collaborators to develop or obtain access to companion diagnostic tests to identify appropriate patients for our product candidate. 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. Companion diagnostics are subject to regulation by the FDA and comparable foreign regulatory authorities as a medical device and may require separate regulatory authorization prior to commercialization. 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 a product candidate, 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 (IDE). In the case of a companion diagnostic that is designated as "significant risk device," approval of an IDE by the FDA and an 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 candidate. In addition, the commercial success of our product candidate 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.

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 U.S. and elsewhere will play a primary role in the recommendation and prescription of any product candidate 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 candidate, if we obtain marketing licensure. In particular, the research of our product candidate, 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; 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.

Even if we commercialize our product candidate, it or any other product candidate that we develop, may become subject to unfavorable pricing regulations or third party coverage or reimbursement practices, which could harm our business.

Significant uncertainty exists as to the coverage and reimbursement status of any products for which we may obtain regulatory licensure. Our ability to successfully commercialize our product candidate 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, including government health care programs, managed care providers, private health insurers, health maintenance organizations and other organizations. In the U.S., no uniform policy for coverage and reimbursement for pharmaceutical products exists among third party payors. Third party payors decide which medications they will pay for and establish reimbursement levels; therefore, coverage and reimbursement for our product candidate 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 if they are granted Accelerated Approval. Failure to obtain or maintain coverage and adequate reimbursement for our product candidate, if approved, could limit our ability to market the products and decrease our ability to generate revenue.

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. We cannot be sure that coverage and reimbursement will be available for any product that we commercialize and, if reimbursement is available, what the level of reimbursement will be. Limitation on coverage and reimbursement may impact the demand for, or the price of, and our ability to successfully commercialize any product candidate that we develop. 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 U.S. 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 candidate. 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 candidate 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 our product candidate.

The regulations that govern marketing approvals, coverage and reimbursement for new drug products vary widely from country to country. Current and future legislation may significantly change the approval requirements in ways that could involve additional costs and cause delays in obtaining approvals. In some countries, the pricing for a drug must be approved before the drug may be marketed. In many countries, the pricing review period begins after marketing or product licensing approval is granted. There can be no assurance that any country will allow reimbursement and pricing arrangements for our product candidate that are sufficient to recoup our investment.

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 candidate and may affect the prices we may set.

In the U.S. 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. 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 – Healthcare and Data Privacy Regulation – 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 U.S., 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 U.S. can have a significant impact on the profitability of a given market, and further uncertainty is introduced if and when these laws change.

We cannot predict the likelihood, nature or extent of government regulation that may arise from future legislation or administrative action in the U.S. 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 candidate may lose any regulatory licensure or approval that may have been obtained and we may not achieve or sustain profitability.

Our operations are subject to trade controls, sanctions and anti-corruption laws, and noncompliance could result in significant penalties and operational disruption.

We engage third parties and vendors and may conduct activities across multiple jurisdictions. As a result, our operations may be subject to import and export controls, economic sanctions, customs requirements, and anti-corruption and anti-bribery laws administered by the United States and foreign authorities. These regulatory regimes are complex, change frequently, and may be subject to differing interpretations.

Any failure, or alleged failure, by us or by third parties acting on our behalf to comply with these requirements could result in investigations, civil or criminal penalties, fines, loss of export privileges, contract termination, reputational harm, or increased compliance costs. Even allegations of noncompliance could divert management attention and materially adversely affect our business, financial condition and results of operations.

The biopharmaceutical industry is subject to extensive regulatory obligations and policies that may be subject to significant and abrupt change, including due to judicial challenges, election cycles, and resulting regulatory updates and changes in policy priorities.

On June 28, 2024, the U.S. Supreme Court issued an opinion holding that courts reviewing agency action pursuant to the Administrative Procedure Act (APA) "must exercise their independent judgment" and "may not defer to an agency interpretation of the law simply because a statute is ambiguous." The decision will have a significant impact on how lower courts evaluate challenges to agency interpretations of law, including those by the Department of Health and Human Services (HHS), CMS, FDA and other agencies with significant oversight of the biopharmaceutical industry. The new framework is likely to increase both the frequency of such challenges and their odds of success by eliminating one way in which the government previously prevailed in such cases. As a result, significant regulatory policies will be subject to increased litigation and judicial scrutiny.

In addition, federal agency priorities, leadership, policies, rulemaking, communications, spending, and staffing may be significantly impacted by election cycles and legislative developments. For example, the current presidential administration's commitment to significantly reduce government spending through cuts to federal healthcare programs and reductions in the workforces of key government agencies, such as HHS, FDA and CMS. Efforts by the current administration to limit federal agency budgets or personnel may result in reductions to agency budgets, employees, and operations. The administration and agencies have also made abrupt announcements about new or changed regulatory policies, such as policies related to the use of artificial intelligence to review product applications. And, the recent federal government shutdown may prevent the FDA or other regulatory authorities from conducting their regular inspections, reviews or other regulatory activities, and may significantly impact the ability of the FDA to timely review and process our regulatory submissions. These developments may lead to greater uncertainty regarding FDA policies, slower response times and longer review periods, potentially affecting our ability to progress development of our product candidate or obtain regulatory approval for our product candidate.

Any resulting changes in regulation may result in unexpected delays, increased costs, or other negative impacts on our business that are difficult to predict.

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.

In the ordinary course of business, we collect, receive, store, process, generate, use, transfer, disclose, make accessible, protect, secure, dispose of, transmit, and share, or collectively, process, personal data and other sensitive information, including proprietary and confidential business data, trade secrets, intellectual property, sensitive third party data, business plans, transactions, clinical trial data and financial information or collectively, sensitive data. 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.

In the U.S., federal, state, and local governments have enacted numerous data privacy and security laws, including data breach notification laws, personal data privacy laws, consumer protection laws (e.g., Section 5 of the Federal Trade Commission Act), and other similar laws (e.g., wiretapping laws). 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 (HIPPA), as amended by the Health Information Technology for Economic and Clinical Health Act (HITECH). We are not currently acting as a covered entity (health plans, health care clearinghouses and certain health care providers) or business associate (individuals or entities that create, receive, maintain or transmit individually identifiable health information in connection with providing a service for or on behalf of a covered entity, as well as their covered subcontractors) 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.

In the past few years, numerous U.S. states have enacted health-specific or comprehensive privacy laws that impose certain obligations on covered businesses, including providing specific disclosures in privacy notices and affording residents with certain rights concerning their personal data. For example, Washington's My Health My Data Act regulates consumer health data, which includes personal information identifies a consumer's past, present, or future physical or mental health. However, 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. Another example, the California Consumer Privacy Act of 2018 (CCPA), as amended by the California Privacy Rights Act of 2020 (CPRA), collectively CCPA, 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; 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. 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, private right of action for data breaches, and created a new California data protection agency authorized to issue substantive regulations and could result in increased privacy and information security enforcement and litigation. Similar laws have been adopted 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 laws generally 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 we are subject to or affected by HIPAA, the CCPA, 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.

Additionally, the FTC and many state attorneys general 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 and in particular health information. Courts may also adopt the standards for fair information practices promulgated by the FTC, which concern consumer notice, choice, security and access. Consumer protection 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. If such information that we publish is considered untrue, we may be subject to government claims of unfair or deceptive trade practices, which could lead to significant liabilities and consequences. Furthermore, according to the FTC, violating consumers' privacy rights or failing to take appropriate steps to keep consumers' personal information secure may constitute unfair acts or practices in or affecting commerce in violation of Section 5 of the FTC Act. The FTC has also been active with respect to enforcement of its Health Breach Notification Rule and in scrutinizing the use and disclosure of sensitive personal information. The FTC finalized changes to the Health Breach Notification Rule in April 2024. Additionally, the FTC published an advance notice of proposed rulemaking in 2022 on commercial surveillance and data security, and may implement new trade regulation rules or other regulatory alternatives concerning the ways in which companies (1) 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 in the coming years.

Outside the U.S., an increasing number of laws, regulations, and industry standards govern data privacy and security. For example, the European Union General Data Protection Regulation (EU GDPR) and the United Kingdom's GDPR (UK GDPR), collectively GDPR, impose strict requirements for the processing of personal data. The GDPR imposes a number of compliance obligations including accountability and transparency requirements, requirements to process personal data lawfully, obligations to consider data protection as any new products or services are developed and designed, obligations to implement appropriate technical and organizational security measures to safeguard personal data and to report certain personal data breaches, obligations to comply with data protection rights of data subjects and additional requirements around the processing of special categories of personal data, including health and genetic data. The GDPR have restrictions on transfers of personal data from their jurisdiction to other jurisdictions. Companies 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 up to 4% of the annual global turnover of the preceding year for the noncompliant company, whichever is greater.

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 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/or liabilities under applicable laws and regulations. We generally contract with third parties for the disposal of these materials and wastes and cannot eliminate the risk of accidental contamination or injury. Upon an event of this nature, we may be held liable for any resulting damages and such liability could exceed our resources and federal, state or other applicable authorities may curtail our use of certain materials and/or interrupt our business operations. Environmental laws and regulations are complex, change frequently and have tended to become more stringent and we may incur substantial costs to comply. Current or future laws and regulations may impair our research, development or production efforts. Failure to comply with these laws and regulations 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 are subject to U.S. and certain foreign export and import controls, anti-corruption laws and anti-money laundering laws and regulations. We can face criminal liability and other serious consequences for violations, which can harm our business.

We are subject to various federal, state, and foreign government export and import laws and regulations, anti-bribery and anti-money laundering laws in the U.S. and 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 U.S., 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 and medical 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, clinical, and scientific personnel. We are highly dependent upon members of our senior management, including Thomas Civik, currently serving as Interim Chief Executive Officer of the Company, Jitendra Wadhane, who serves as Principal Financial and Accounting Officer, as well as our senior scientists, senior medical personnel and other members of our senior management team. The loss of one or more of our executive officers, senior scientists, senior medical personnel and other members of our senior management team could delay or prevent the successful development of our product pipeline, the initiation and completion of our clinical trials or the commercialization of our product candidate or any future product candidate.

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 may 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.

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

We are exposed to the risk that our employees, consultants, distributors, and collaborators may engage in fraudulent or illegal activity. Misconduct by these parties could include intentional, reckless or negligent conduct or disclosure of unauthorized activities to us that violates the regulations of the FDA, U.S. regulators and non-U.S. regulators, including those laws requiring the reporting of true, complete and accurate information to such regulators.

We have adopted a code of conduct applicable to all of our employees, officers, directors, including consultants, but it is not always possible to identify and deter misconduct by our employees and other third parties, and the precautions we take to detect and prevent this activity may not be effective in controlling unknown or unmanaged risks or losses or in protecting us from governmental investigations or other actions or lawsuits stemming from a failure to comply with these laws or regulations. If any such actions are instituted against us and we are not successful in defending ourselves or asserting our rights, those actions could result in the imposition of significant fines or other sanctions, including the imposition of civil, criminal and administrative penalties, damages, monetary fines, contractual damages, reputational harm, any of which could adversely affect our ability to operate our business and our results of operations. Whether or not we are successful in defending against such actions or investigations, we could incur substantial costs, including legal fees, and divert the attention of management in defending ourselves against any of these claims or investigations.

We currently have no marketing, sales, or distribution infrastructure and both establishing this infrastructure or outsourcing this function to a third party carries substantial risks to us.

We currently have no marketing, sales, or distribution capabilities because our product candidate is still in clinical development. If our product candidate completes clinical development and is approved, we intend to either establish a sales and marketing organization with technical expertise and supporting distribution capabilities to commercialize our product candidate 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 information technology systems, or those of any of our existing or future CROs, manufacturers, other contractors, consultants, or collaborators, may be compromised, 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 information technology systems and infrastructure, 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, errors, malfeasance, 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.

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.

If such an event were to occur and cause interruptions in our operations, it could result in a material disruption of our product candidate development program 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 candidate 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.

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 candidate 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, may not cover all claims made against us and could have high deductibles. Defending a suit, regardless of its merit, could be costly and divert management attention. In addition, such insurance may not be available to us in the future on economically reasonable terms, or at all.

Our use of emerging technologies, including artificial intelligence, may introduce operational, legal and reputational risks.

We and our third-party vendors may use emerging technologies, including artificial intelligence and machine-learning tools, in connection with research, data analysis, clinical operations or other business processes. These technologies may produce inaccurate, incomplete or misleading outputs, and errors may not be readily detectable. Their use may also raise novel issues relating to data privacy, intellectual property ownership, regulatory compliance and evolving industry standards.

The legal and regulatory framework governing these technologies is rapidly evolving. If we fail to appropriately govern their use, or if regulators impose new restrictions or requirements, we could experience delays, increased costs, regulatory scrutiny, litigation exposure or reputational harm, any of which could materially adversely affect our business.

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 candidate 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, but not limited to:

- 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 currency fluctuations, which could result in increased operating expenses and reduced revenue, and other obligations incident to doing business in another country;
- 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 U.S.;
- 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.

Changes in U.S. or international social, political, regulatory and economic conditions or in laws and policies governing trade, manufacturing, development and investment in the countries where we currently conduct our business could adversely affect our business, reputation, financial condition and results of operations. Changes or proposed changes in U.S. or other countries' trade policies may result in restrictions and economic disincentives on international trade. The U.S. government has recently imposed, or is currently considering imposing, tariffs on certain trade partners, including China. Tariffs, economic sanctions and other changes in U.S. trade policy have in the past and could in the future trigger retaliatory actions by affected countries, and certain foreign governments have instituted or are considering imposing retaliatory measures on certain U.S. goods. Further, any emerging protectionist or nationalist trends (whether regulatory- or consumer-driven) either in the United States or in other countries could affect the trade environment. Our business, like many other corporations, would be impacted by changes to the trade policies of the United States and foreign countries (including governmental action related to tariffs, international trade agreements, or economic sanctions). Such changes have the potential to adversely impact the U.S. economy or certain sectors thereof, the global economy, and our industry, and as a result, could have a material adverse effect on our business, financial condition and results of operations.

Our research and development activities involve hazardous materials, and noncompliance with environmental, health and safety laws could result in significant liability.

Our research and development activities, and those of our third-party vendors, may involve the use, storage, transportation and disposal of biological materials, chemicals and other hazardous substances. These activities are subject to extensive environmental, health and safety laws and regulations. Accidental contamination, spills, exposures or other incidents could occur.

If such events occur, we could incur significant costs for investigation, remediation, fines or penalties, third-party claims and reputational harm. In addition, any material failure to comply with applicable environmental, health and safety requirements could disrupt our operations or delay development activities, which could materially adversely affect our business and prospects.

Disruptions at the FDA, the SEC and other government agencies could hinder their ability to perform 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 funding, 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 U.S. Securities and Exchange Commission (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 October 2025, 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 were to occur, 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 candidate 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 candidate, pursuant to which we may license patents and technology for future product candidate. 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 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 licensing arrangements are not successful, we may not be able to capitalize on the market potential of the product candidate.

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 current or future product candidate. 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.

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 candidate 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 candidate 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 candidate, 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 candidate could delay the development and commercialization of our product candidate 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 candidate. Any failure by a third party manufacturer to produce acceptable raw materials or product candidate 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 do not currently have, nor do we plan to acquire, the infrastructure or capability to manufacture or distribute preclinical, clinical or commercial quantities of drug substance or drug product, including our existing product candidate. We rely on third party contract manufacturers to manufacture our preclinical and clinical trial product supplies. We expect to continue to rely on third party manufacturers if we receive regulatory licensure for our product candidate. We do not have complete control over the ability of our third party manufacturers to maintain adequate manufacturing capacity and capabilities to serve our needs, including quality control, quality assurance and qualified personnel. 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 Current Good Manufacturing Practice (cGMP). 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 candidate 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 candidate. 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 our product candidate in a timely manner or within budget.

We expect to continue to rely on third party manufacturers if we receive regulatory licensure for our 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 our product candidate, or to do so on commercially reasonable terms, we may not be able to develop and commercialize our product candidate 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 the product candidate under development;
- delay in submitting regulatory applications, or receiving regulatory licenses, for the product candidate;
- 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 candidate; 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 non-renewal 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 candidate, 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 candidate and other materials. If we receive marketing licensure for our product candidate, 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 comparable foreign regulatory requirements. 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 our product candidate 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 candidate 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 comparable foreign regulatory requirements. 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 candidate 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 candidate, 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 our product candidate, operating restrictions and criminal prosecutions, any of which could significantly and adversely affect supplies of our product candidate and harm our business and results of operations. Our product candidate 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 candidate, 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 candidate 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.

Legislative or regulatory restrictions on the use of certain foreign biotechnology or manufacturing service providers could materially disrupt our operations.

We rely on third-party manufacturers, suppliers and service providers for the development, manufacture and supply of our product candidate and related materials. Some of these third parties, or their subcontractors, may be located outside the United States. From time to time, legislative or regulatory proposals are introduced that could restrict, condition or prohibit U.S. companies from contracting with, or sourcing from, certain foreign biotechnology or manufacturing service providers, including providers located in China.

If such restrictions are enacted or expanded, we or our vendors may be required to discontinue relationships with affected counterparties, even if those counterparties provide specialized capabilities, capacity, or cost advantages. Transitioning to alternative providers could require significant time and expense, including technology transfer, qualification and validation activities, additional audits, and potential regulatory engagement. We may be unable to identify acceptable alternatives on reasonable timelines or terms, which could delay clinical trials, interrupt manufacturing, increase development costs, and materially adversely affect our business and prospects.

A portion of our manufacturing of our product candidate 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 candidate is 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 candidate. Foreign and certain Chinese biotechnology companies and CDMOs, may become subject to U.S. legislation, including the legislation pending in Congress called the BIOSECURE Act. The Act could impose trade restrictions, sanctions, and other regulatory requirements by the U.S. government, which could restrict or even prohibit our ability to work with such entities. If we are restricted or prohibited from working with our current CDMOs, we may incur added costs or reduction of the supply of material available to us, delays in the procurement or supply of such material or adverse effects on our ability to manufacture our product candidate. Additionally, changes in U.S. trade policy, sanctions, export controls, import restrictions, tariffs, or other measures targeting certain foreign jurisdictions or entities could increase our costs, delay clinical supply, limit access to manufacturing capacity or materials, or require us to transition to alternative vendors, which could require significant time, expense, and regulatory effort. Any such disruptions could accelerate our cash burn and increase our need for additional capital. 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 candidate 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. . In addition, supply chain disruptions and delays may also occur as a result of any new tariff policies or trade restrictions, which could also negatively impact third party manufacturing. For example, on April 2, 2025, the United States government announced a baseline 10% tariff on all foreign goods, with goods imported from specified nations, including China and those in the European Union, taxed at higher rates. Any of these matters could materially and adversely affect our business and results of operations. Recent U.S. biosecurity-related legislation and related regulatory actions could restrict or complicate the ability of life sciences companies to use certain third-party biotechnology service providers, including for manufacturing, testing, or research services, particularly where federal funding, grants, or contracts are implicated. To the extent we or our collaborators rely on affected providers (including providers with operations in China), we may need to transition to alternative vendors, which could increase costs, delay development timelines, and disrupt supply chains.

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

In order to conduct clinical trials of our product candidate, we will need to manufacture it 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 candidate, cause us to incur higher costs and prevent us from commercializing our product candidate 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 our 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 our product candidate 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 candidate 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 candidate. 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 candidate and will not be able to, or may be delayed in our efforts to, successfully commercialize our product candidate.

Risks Related to Our Intellectual Property

If we are unable to obtain or protect our intellectual property in and to our product candidate, 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 candidate and discovery programs. Our success depends in large part on our ability to obtain and maintain patent and other intellectual property rights in the U.S. and other countries. We and or licensors have filed patent applications in the U.S. and abroad directed to our product candidate in an effort to establish intellectual property positions for their compositions of matter as well as uses in the treatment of diseases. Our intellectual property includes patents and patent applications that we own, as well as those we in-license, including in-licensed patents that we manage directly and those that remain managed by our licensors.

We or our licensors have not pursued or maintained, and may not pursue or maintain in the future, patent protection for our product candidate in every country or territory in which we may sell our products, if approved. 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. In addition, we cannot be sure that any of our pending patent applications will issue, or that if issued, will be in a form advantageous to us. The United States Patent and Trademark Office (USPTO), international patent offices, or judicial bodies may deny, or significantly narrow claims made under our patent applications and our 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. We may be subject to a third party submission of prior art to the USPTO, or other patent offices, in our pending patent applications. 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. In addition to the above, patent prosecution is a lengthy process, during which the scope of the claims initially submitted for examination by the USPTO may be significantly narrowed or may not issue at all. The claims of our issued patents or patent applications when issued may not cover our current or future product candidate, 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 future product candidate in the U.S. or in other foreign countries, or we may be required to disclaim all or a portion of the remaining patent term to secure issuance. Even if patents do successfully issue, 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 current and future product candidate. 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 candidate 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 candidate, it could dissuade companies from collaborating with us to develop and commercialize product candidate 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 U.S. For example, European patent law restricts the patentability of methods of treatment of the human body more than U.S. 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 U.S. 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. It is also possible that in our evaluation of third party intellectual property, we failed to identify relevant patents or applications. We cannot guarantee that any of our patent searches or analyses, including but not limited to the identification of relevant patents, the scope of patent claims or the expiration of relevant patents, are complete or thorough, nor can we be certain that we have identified each and every third party patent and pending application in the U.S. and abroad that is relevant to or necessary for the commercialization of our current and future products. 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 U.S. and other countries may diminish the value of our patents or narrow the scope of our patent protection.

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 U.S. 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 candidate.

Moreover, patents have a limited lifespan. In the U.S. and internationally, a patent generally expires 20 years after the earliest filing date of a non-provisional patent application. Various extensions may or may not be available; however, the life of a patent, and the protection it affords, is limited. Without patent protection for our current or future product candidate, 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 candidate, patents protecting such candidate 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. We may also rely on trade secrets, know-how and continuing technological innovation to develop and maintain our proprietary and intellectual property position. 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 candidate could be negatively affected, which would harm our business.

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 U.S. 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, reputable law firms, service providers, and our licensors to pay these fees and to help us comply with these requirements. 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.

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.

Third parties may initiate legal proceedings against us or our licensors or collaborators alleging that we or our licensors or collaborators are infringing their intellectual property rights or to challenge the validity or scope of our intellectual property rights, including in oppositions, interferences, reexaminations, inter partes reviews, derivation or other similar proceedings before the U.S. or other domestic or foreign jurisdictions. These proceedings can be expensive and time-consuming and adversaries in these proceedings may have the ability to dedicate substantially greater resources to prosecuting these legal actions than we or our licensors or collaborators can.

An unfavorable outcome could require us or our licensors or collaborators to cease using the related technology or developing or commercializing our product candidates, or to attempt to license rights to it from the prevailing party. Our business could be harmed if the prevailing party does not offer us or our licensors or collaborators a license on commercially reasonable terms or at all. Even if we or our licensors or collaborators obtain a license, it may be non-exclusive, thereby giving our competitors access to the same technologies licensed to us or our licensors or collaborators. In addition, we could be found liable for monetary damages, including treble damages and attorneys' fees. A finding of infringement could prevent us from commercializing our product candidates or force us to cease some of our business operations, which could materially harm our business.

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.

Many of our employees, consultants or advisors were previously, or are currently, 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 confidential information or 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 distract management.

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 Pfizer license agreement 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 may enter into additional such agreements in the future. In particular, the rights to the intellectual property covering MICVO are in-licensed from Pfizer. 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, 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 become 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, 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 such 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 U.S., 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 party reexaminations, inter parties review, or post-grant review, or oppositions or similar proceedings outside the U.S., 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 U.S. 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 U.S. 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 or weakening the rights of patent owners in certain circumstances or situations. In addition to increasing uncertainty regarding 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. For example, many foreign countries have compulsory licensing laws under which a patent owner must grant licenses to third parties, or limit the enforceability of patents against third parties, including government agencies or government contractors.

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 the U.S. 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. Additionally, some foreign countries do not protect intellectual property rights to the same extent as the federal laws of the U.S. and we may encounter problem protecting and defending our intellectual properties rights in such countries, which could negatively affect our business. For example, many foreign countries have compulsory licensing laws under which a patent owner must grant licenses to third parties, or limit the enforceability of patents against third parties, including government agencies or government contractors.

If we are unable to protect the confidentiality of our trade secrets, our business and competitive position may 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 U.S. 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, 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 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 U.S. are sometimes less willing to protect trade secrets.

Risks Related to Our Common Stock

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" and the following:

- results of our preclinical studies, IND submissions and clinical trials, of our product candidate, or those of our competitors or our existing or future collaborators;
- regulatory or legal developments in the U.S. and other countries;
- 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;
- regulatory actions with respect to our products, product candidate, preclinical studies, clinical trials, manufacturing process or sales and marketing terms or that of our competitors;
- actual or anticipated variations in our financial results or those of companies that are perceived to be similar to us;
- 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, including announcement and expectation of additional financing efforts;

- 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;
- 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; and
- general economic, industry and market conditions, including, but not limited to, terrorist acts, acts of war, periods of widespread civil unrest, natural disasters, public health emergencies and other calamities.

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 candidate, 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.

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

The global economy, including credit and financial markets, has experienced extreme volatility and disruptions, including severely diminished liquidity and credit availability, bank failures, increases in inflation rates and uncertainty about economic stability. Any such volatility and disruptions may have adverse consequences for us or the third parties on whom we rely. If the equity and credit markets deteriorate, including as a result of political unrest or war, it may make any necessary debt or equity financing more difficult to obtain in a timely manner or on favorable terms, more costly or more dilutive. Inflation can adversely affect us by increasing our costs, including personnel costs. Any significant increases in inflation and related increases in interest rates could have a material adverse effect on our business, results of operations and financial condition.

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, 2026, 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 39.9% 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.

We are an "emerging growth company" and a "smaller reporting company," and the reduced disclosure requirements applicable to us 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 (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 U.S Securities and Exchange Commission. 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 U.S. 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, 2025, our federal and state net operating losses (NOLs) in the United States were $82.1 million ($390.9 million before tax) and $14.3 million ($218.2 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 through Apexigen, begin to expire in 2033. The state net operating loss carryforwards begin expiring in 2035. In addition, as of December 31, 2025, we had $10.0 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 appropriate 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 IT 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 information technology systems, or those of any of our existing or future CROs, manufacturers, other contractors, consultants, or collaborators, may be compromised, 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 Principal Financial and Accounting Officer (PF & AO) 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 PF & AO 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 PF & AO 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 May 23, 2026. 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, 2026, there were approximately 56 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

None.

Use of Proceeds from Initial Public Offering

Not Applicable.

Securities Authorized for Issuance under Equity Incentive Plans

The information required by this Item will be included in our definitive proxy statement to be filed with the SEC for the 2026 Annual Meeting of Stockholders and is incorporated herein by reference.

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

Pyxis Oncology is a clinical-stage oncology company advancing a development strategy focused on addressing unmet medical needs in patients with solid tumors with an immediate focus on head and neck squamous cell carcinoma (HNSCC).

Our lead product candidate, micvotabart pelidotin (MICVO, formerly PYX-201), is an investigational novel antibody-drug conjugate (ADC) that uniquely targets the splice variant of fibronectin, extradomain-B of fibronectin (EDB+FN), a non-cellular structural component of the extracellular matrix (ECM) in the tumor microenvironment (TME). EDB+FN is an isoform of fibronectin present in tumors that is negligibly expressed in normal adult tissues and facilitates cancer progression by playing multiple roles including promoting cell proliferation, adhesion, and migration, activating the integrin signaling pathway, stimulating angiogenesis and vascular remodeling, driving epithelial-mesenchymal transition (EMT), and establishing the pre-metastatic niche. We believe EDB+FN is a compelling target for cancer therapeutics as the physiological expression of EDB+FN is very low in healthy adult tissues, yet it is found to be highly expressed in a variety of solid tumors.

Our ADC, MICVO, consists of a fully human IgG1 monoclonal antibody that is site-specifically conjugated to a cleavable linker with an optimized auristatin (Aur0101) microtubule inhibitor payload. Unlike conventional ADCs which bind to an antigen on the surface of a cancer cell, MICVO is designed to bind to EDB+FN in the tumor ECM, where extracellular proteases under acidic conditions cleave the linker to release the Aur0101 payload. The payload diffuses through the membrane of cancer cells to kill them directly, which is the first component of MICVO's three-pronged mechanism of action (MOA). The dying cancer cells release the payload which diffuses into nearby cancer cells and kills them via the bystander effect, representing the second component of MICVO's MOA. The dying cancer cells also release neoantigens which trigger immunogenic cell death (ICD), the final component of its MOA. Together with its purpose-built design and postulated three-pronged MOA, MICVO has the potential for improved stability and anti-tumor activity compared to conventional ADCs.

MICVO is currently being studied as monotherapy in recurrent and metastatic head and neck squamous cell carcinoma (R/M HNSCC) and in combination with KEYTRUDA® (pembrolizumab) in 1L/2L+ R/M HNSCC and other solid tumors.

MICVO Monotherapy

PYX-201-101 Phase 1 (Part 1) Monotherapy Dose Escalation Study

As part of our Phase 1 monotherapy study, referred to as PYX-201-101, we conducted a dose escalation study to evaluate MICVO monotherapy in patients with advanced solid tumors known to express EDB+FN. In November 2024, we reported positive preliminary results from the dose escalation study, which included a total of 80 patients dosed across nine solid tumor types at doses ranging from 0.3 mg/kg to 8 mg/kg, with a data cut-off of October 4, 2024. Of the nine solid tumor types included in the study, the strongest tumor regression response was observed in R/M HNSCC. Among the six efficacy evaluable heavily pre-treated patients with R/M HNSCC, the confirmed objective response rate (ORR) was 50% per RECIST v1.1 at the therapeutically active dose response range of 3.6 mg/kg – 5.4 mg/kg administered intravenously every three weeks (IV Q3W), including one confirmed complete response (CR) and two confirmed partial responses (PRs), with a disease control rate (DCR) of 100%. Based on observations from the dose-escalation study, 5.4 mg/kg IV Q3W presented an optimal benefit-risk profile within the efficacious dose range and was selected for dose expansion. Subsequent translational data indicated reduction in ctDNA TF after treatment with MICVO, particularly at the 5.4 mg/kg dose, supported a positive molecular response to MICVO, providing further validation of the dose selection strategy for dose expansion.

PYX-201-101 Phase 1 (Part 2) Monotherapy Dose Expansion in R/M HNSCC

In January 2025, we initiated the dose expansion portion (Part 2) of the Phase 1 PYX-201-101 monotherapy study to further evaluate MICVO as a monotherapy at a dose of 5.4 mg/kg IV Q3W and to assess preliminary efficacy in R/M HNSCC. The Part 2 dose-expansion phase includes the following two cohorts:

- Arm 1: MICVO monotherapy for second line (2L) and third line (3L) R/M HNSCC patients who have received prior platinum-based chemotherapy and prior PD-(L)1 inhibitor therapy; and
- Arm 2: MICVO monotherapy for 2L and 3L R/M HNSCC patients who have received prior epidermal growth factor receptor (EGFR) directed therapy and prior PD-(L)1 inhibitor therapy.

In December 2025, we reported positive preliminary data from our ongoing Phase 1 monotherapy study evaluating MICVO in patients with 2L+ R/M HNSCC, based on a data cut-off date of November 3, 2025, which included all R/M HNSCC patients dosed at 5.4 mg/kg total body weight (TBW) in Part 1 and in Part 2. As of the data cut-off, 18 R/M HNSCC patients had been treated and 13 patients were efficacy evaluable. All treated patients had received prior systemic therapy, with a median of three prior lines of therapy. All treated patients had received prior platinum-based and checkpoint inhibitor therapies while 67% of treated patients had received prior taxanes and 50% of treated patients had received prior EGFR-targeted therapies, specifically cetuximab. Among the 13 efficacy evaluable patients, the confirmed ORR was 46% (6/13, one patient confirmed response after November 3, 2025 data cut-off) per RECIST v1.1, including one confirmed complete response. Confirmed responses were observed in both dose-expansion cohorts, including patients previously treated with platinum-based therapy and anti-PD(L)1 therapy (Arm 1) and patients previously treated with an EGFR inhibitor and/or anti-PD(L)1 therapy (Arm 2), and were observed in patients regardless of HPV status. The preliminary data also showed a DCR of 92%, with 12 of 13 efficacy evaluable patients demonstrating significant tumor regression or tumor control.

Preliminary data reported in December 2025 indicated that MICVO was generally well tolerated. No Grade 4 ADC payload treatment-related adverse events (TRAEs) of interest were observed, and no Grade 5 events occurred. TRAEs were reported in 89% (16/18) of patients, with Grade ≥3 TRAEs reported in 56% (10/18) of patients. TRAEs leading to treatment discontinuation occurred in 28% (5/18) of patients. We observed a higher discontinuation rate and incidence of Grade ≥3 TRAEs in high body weight patients (defined as at least 10% above adjusted ideal body weight, or AIBW). In the preliminary dataset, all patients (5/5) who experienced TRAEs leading to treatment discontinuation had high body weight. Several approved ADCs have demonstrated comparable associations among patient body weight, systematic drug exposure, and tolerability profiles. Many of these ADCs, such as Padcev, Adcetris, and Elahere, have addressed such observations through dosing modifications that resulted in an improved tolerability profile while sustaining efficacy, including through capping the maximum allowable dose or employing AIBW dosing. We are actively evaluating both of these approaches to optimize MICVO's benefit-risk profile.

MICVO Combination Therapy

In November 2024, we announced a Clinical Trial Collaboration and Supply Agreement with Merck & Co, Inc. or Merck (known as MSD outside of the United States and Canada), for a Pyxis Oncology-sponsored study of MICVO in combination with Merck's anti-PD-1 therapy, KEYTRUDA® (pembrolizumab). In January 2025, we initiated the Phase 1/2 combination study with KEYTRUDA®, PYX-201-102, and are actively enrolling and dosing patients in this study. PYX-201-102 is a Phase 1/2 open label, global, multicenter dose escalation and dose expansion study designed to evaluate the safety, tolerability, pharmacokinetics (PK), pharmacodynamics (PD) and preliminary efficacy of MICVO in combination with pembrolizumab in patients with advanced solid tumors. Patients with histologically or cytologically confirmed advanced solid tumors, including 1L R/M HNSCC, 2L+ R/M HNSCC, cervical cancer, gastric cancer, HR+/HER2- breast cancer, and locally advanced or metastatic triple-negative breast cancer (TNBC), are eligible to enroll.

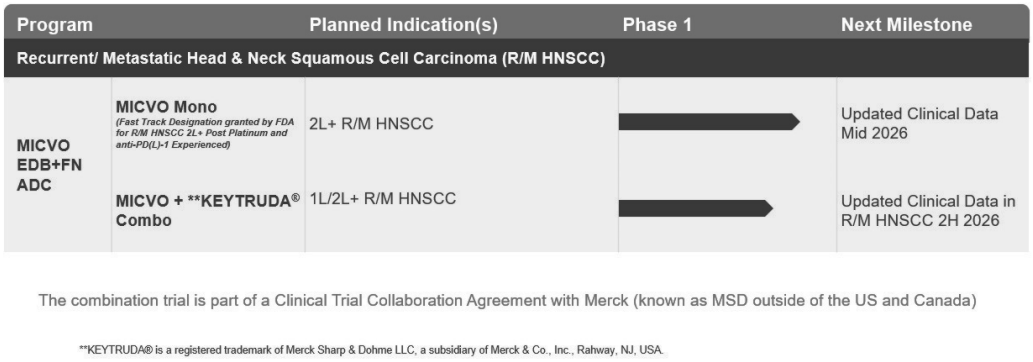
PYX-201-102 Phase 1/2 Preliminary Combination Data in R/M HNSCC

In December 2025, we reported positive preliminary data from this study, evaluating MICVO at 3.6 mg/kg and 4.4 mg/kg IV Q3W, each administered in combination with a fixed 200 mg dose of pembrolizumab Q3W, in patients with 1L/2L+ R/M HNSCC. As of the data cut-off date of November 3, 2025, seven patients had been treated, including four patients at 3.6 mg/kg and three patients at 4.4 mg/kg of MICVO, each in combination with pembrolizumab. All treated patients had received prior systemic therapy, including four patients with 1L R/M HNSCC (median of one prior systemic therapy administered in the neoadjuvant or adjuvant setting) and three patients with 2L+ R/M HNSCC (median of three prior lines of therapy, some of which were administered prior to the R/M setting). Among the seven efficacy-evaluable patients, the confirmed ORR was 71% (5/7, one patient confirmed response after November 3, 2025 data cut-off) and the DCR was 100% (7/7), with all seven patients demonstrating meaningful tumor regression. Responses were observed across a range of PD-L1 combined positive scores (CPS), from CPS≥1 to CPS>20, and included responses in patients who had previously received checkpoint inhibitor treatment and had experienced disease progression while receiving checkpoint inhibitor treatment. Preliminary safety data indicated that MICVO in combination with pembrolizumab was generally well tolerated, with no Grade 3 or Grade 4 ADC payload TRAEs of interest and no Grade 5 events reported. TRAEs were reported in 86% (6/7) of patients. No TRAEs led to treatment discontinuation, and, as of the data cut-off date, no overlapping toxicities between MICVO and pembrolizumab (KEYTRUDA®) had been observed.

We believe the totality of our preliminary data supports continued clinical development of both MICVO monotherapy expansion and combination therapy trials.

Our Clinical Pipeline

The following table summarizes our clinical pipeline:



MICVO Monotherapy Pipeline

The dose expansion phase of our PYX-201-101 monotherapy study is ongoing with the objective of further evaluating the preliminary safety, efficacy and durability signals observed with MICVO in R/M HNSCC at the 5.4mg/kg dose. We completed target enrollment of approximately 40 patients in the Phase 1 monotherapy dose expansion study of MICVO in 2L+ R/M HNSCC in the first quarter of 2026 and are actively treating patients in two monotherapy R/M HNSCC cohorts at the 5.4 mg/kg IV Q3W dose. The dose expansion phase includes the following R/M HNSCC cohorts across sites in the United States (US), European Union (EU) and other countries:

- MICVO monotherapy for 2L and 3L R/M HNSCC patients who have received prior platinum-based chemotherapy and prior PD-(L)1 inhibitor therapy. We expect to enroll approximately 20 patients in this expansion cohort at the 5.4 mg/kg IV Q3W dose and anticipate reporting updated clinical data from this cohort in mid-2026; and
- MICVO monotherapy for 2L and 3L R/M HNSCC patients who have received prior epidermal growth factor receptor (EGFR) directed therapy and prior PD-(L)1 inhibitor therapy. We expect to enroll approximately 20 patients in this expansion cohort at the 5.4 mg/kg IV Q3W dose and anticipate reporting updated clinical data from this cohort in mid-2026.

MICVO Phase 1 monotherapy data in 2L+ R/M HNSCC expected in mid-year 2026 will include patients dosed at 5.4 mg/kg IV Q3W with a dose cap for patients with higher body weight, as well as patients previously dosed at 5.4 mg/kg IV Q3W based on total body weight. The results are expected to include detailed analyses of the effect of the modified weight-based dosing strategy on safety and efficacy. AIBW dosing, which has demonstrated improved tolerability without apparent loss of activity in clinical studies of other antibody-drug conjugates, is being implemented in ongoing clinical studies as well.

During the fourth quarter of 2025, we obtained feedback and alignment from the U.S. Food and Drug Administration (FDA) regarding the clinical trial design for a planned pivotal monotherapy study in 2L+ R/M HNSCC.

MICVO Combination Therapy Pipeline

Our Phase 1/2 combination study with KEYTRUDA® (PYX-201-102) is ongoing and we are conducting the dose escalation phase of PYX-201-102 across multiple tumor types with the objective of identifying the Recommended Phase 2 Dose (RP2D) of MICVO in combination with pembrolizumab. We are currently enrolling and dosing patients across several dose levels between 3.6 mg/kg and 5.4 mg/kg of MICVO, in combination with pembrolizumab at the fixed dose of 200 mg IV Q3W, in order to accurately characterize the RP2D for MICVO in combination with pembrolizumab, subject to ongoing safety review, enrollment progress, and clinical data evaluation.

We expect to report updated data from the PYX-201-102 study in patients with 1L/2L+ R/M HNSCC in the second half of 2026.

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. We have incurred significant operating losses since our inception. We reported net losses of $79.6 million and $77.3 million for the years ended December 31, 2025 and 2024, respectively. As of December 31, 2025, we had an accumulated deficit of $443.2 million, net equity of $53.4 million, and cash, cash equivalents and marketable debt securities of $66.9 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 will be necessary to fund future clinical and preclinical activities.

Components of Our Results of Operations

Revenues

To date, we have not generated any revenues from product sales and do not expect to generate any revenues from product sales in the foreseeable future. We record revenues from research and development agreements, including amounts related to upfront receipt for license fees, royalties, sale of royalty rights, milestones and other contingent receipts and fees for research and development services.

Our ability to generate product revenues will depend upon our ability to successfully develop, obtain regulatory approval and commercialize our product candidate. Due to the numerous risks and uncertainties associated with product development and regulatory approval, we are unable to predict the amount, timing or whether we will be able to obtain product revenues.

Costs and Operating Expenses

Cost of Revenues

The components of our cost of revenues are expenses directly attributable to earn revenues. For the years ended December 31, 2025 and 2024, cost of revenues consists of the expensing of the remaining carrying value of the definite‑lived intangible asset associated with certain royalty rights.

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 separated into program-specific costs and unallocated costs.

Program-specific costs include:

- direct third party costs, which include expenses incurred under agreements with contract research organizations (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, manufacturing and testing clinical and preclinical materials, including costs incurred under agreements with contract development and manufacturing organizations (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 and clinical 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; and
- 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 clinical development activities related to our product candidate in the near term and in the future. The successful development of our product candidate 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 our product candidate and we may never succeed in obtaining regulatory approval for our product candidate.

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 rental income under our sublease.

Results of Operations

Comparison of the Years Ended December 31, 2025 and 2024

Our results of operations were as follows (in thousands):

	Year Ended December 31,		
	2025	2024	Change
Revenues			
Sale of royalty rights	$ 11,038	$ 8,000	$ 3,038
Milestone revenue	2,820	—	2,820
Royalty revenues	—	8,146	(8,146)
Total revenues	13,858	16,146	(2,288)
Costs and operating expenses			
Cost of revenues	2,388	475	1,913
Research and development	73,696	58,747	14,949
General and administrative	22,194	25,420	(3,226)
Impairment of in-process research and development intangible asset	—	20,964	(20,964)
Total costs and operating expenses	98,278	105,606	(7,328)
Loss from operations	(84,420)	(89,460)	5,040
Other income, net			
Interest and investment income, net	3,610	7,039	(3,429)
Sublease income	2,575	2,926	(351)
Total other income, net	6,185	9,965	(3,780)
Loss before income taxes	(78,235)	(79,495)	1,260
Income tax expense (benefit)	1,386	(2,164)	3,550
Net loss	**$ (79,621)**	**$ (77,331)**	**$ (2,290)**

Revenues

Revenues decreased by $2.3 million, from $16.1 million for the year ended December 31, 2024, to $13.9 million for the year ended December 31, 2025.

For the year ended December 31, 2025, we recognized revenue primarily in connection with the Simcere Agreement. Such revenue included a $2.8 million regulatory milestone earned upon approval of suvemcitug in China. In addition, we recognized consideration related to the sale of royalty rights for Enzeshu® under the amended License and Collaboration Agreement between Simcere and Apexigen, which included a one-time payment of $11.0 million and four semi-annual installment payments of $175,000 each.

For the year ended December 31, 2024, revenues consisted of amounts recognized for the Settlement Agreement with Novartis. Pursuant to the Settlement Agreement, we transferred our rights to future royalties on net sales of Beovu® to Novartis in exchange for a one-time payment of $8.0 million. In addition, Novartis agreed to waive its right to recoup $8.1 million of royalties previously paid to us and Apexigen.

Costs and Operating Expenses

Cost of Revenues

Cost of revenues was $2.4 million for the year ended December 31, 2025, compared to $0.5 million for the year ended December 31, 2024. Cost of revenues in each period consisted of the write-off of the remaining carrying value of the definite-lived intangible asset associated with royalty rights sold to Simcere pursuant to the Simcere Agreement in 2025 and to Novartis pursuant to the Settlement Agreement in 2024.

Research and Development Expenses

Research and development expenses were as follows (in thousands):

	Year Ended December 31,		
	2025	2024	Change
Program-specific costs:			
MICVO	$ 41,042	$ 26,901	$ 14,141
PYX-106	3,130	7,462	(4,332)
Other program costs	1,423	1,293	130
Total program costs	**45,595**	**35,656**	**9,939**
Unallocated costs:			
Personnel-related expenses including stock-based compensation	18,867	17,295	1,572
Other costs	9,234	5,796	3,438
Total research and development expenses	**$ 73,696**	**$ 58,747**	**$ 14,949**

Research and development expenses increased by $15.0 million, from $58.7 million for the year ended December 31, 2024, to $73.7 million for the year ended December 31, 2025.

MICVO program-specific research and development costs increased by $14.1 million, primarily reflecting a $6.1 million increase in contract manufacturing costs due to the timing of MICVO manufacturing runs and a $7.5 million increase in clinical trial-related expenses associated with the MICVO monotherapy and combination therapy trials, as a result of a higher number of patients dosed and site activations.

PYX-106 program-specific research and development costs decreased by $4.3 million, primarily reflecting lower program-related expenses following the pause in clinical development of PYX-106-101 in December 2024.

Unallocated research and development costs increased by $5.0 million primarily due to severance cost of $0.9 million and an increase in other business expenses.

General and Administrative Expenses

General and administrative expenses were as follows (in thousands):

	Year Ended December 31,		
	2025	2024	Change
Personnel-related expenses including stock-based compensation	$ 13,880	$ 15,780	$ (1,900)
Professional and consultant fees	4,179	4,491	(312)
Facilities, insurance and other costs	4,135	5,149	(1,014)
Total general and administrative expenses	**$ 22,194**	**$ 25,420**	**$ (3,226)**

General and administrative expenses decreased by $3.2 million, from $25.4 million for the year ended December 31, 2024, to $22.2 million for the year ended December 31, 2025. This decrease was primarily attributable to a $1.9 million reduction in personnel-related expenses, including $0.6 million of lower employee-related costs and $1.3 million of lower stock-based compensation. In addition, facilities, insurance and other costs decreased by $1.0 million, and professional and consultant fees decreased by $0.3 million, primarily reflecting lower legal costs in 2025 as compared to 2024.

Impairment of In-Process Research and Development Intangible Asset

In December 2024, we announced a strategic realignment plan to prioritize resources toward clinical development of MICVO and continue to defer further clinical development of PYX-107. As a result of the uncertain timing of the future clinical development of PYX-107, we recognized an impairment loss of $21.0 million during the year ended December 31, 2024. No impairment loss was recorded during the year ended December 31, 2025.

Other Income, net

Other income, net for the years ended December 31, 2025 and 2024 was $6.2 million and $10.0 million, respectively. The decrease was primarily due to a decrease in interest and investment income as compared to the previous year.

Income Taxes

Income tax expense was $1.4 million for the year ended December 31, 2025, as compared to an income tax benefit of $2.2 million for the year ended December 31, 2024. Income tax expense for 2025 was primarily related to corporate income taxes in China associated with revenue recognized from the regulatory approval milestone payment and sale of royalty rights under the Simcere Agreement. The 2024 income tax benefit resulted from the reversal of the deferred tax liability associated with the impairment of the PYX-107 IPR&D intangible asset.

Liquidity and Capital Resources

We had cash, cash equivalents and marketable debt securities of $66.9 million as of December 31, 2025. For the years ended December 31, 2025 and 2024, we had net losses of $79.6 million and $77.3 million, respectively. As of December 31, 2025, we had an accumulated deficit of $443.2 million.

On November 26, 2025, 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 $350.0 million. On December 9, 2025, the registration statement was declared effective by the SEC. The registration statement includes an at-the-market (ATM) offering program for the sale of up to $150.0 million of shares of our common stock. During the year ended December 31, 2025, we did not sell any shares under the ATM program. As of December 31, 2025, we had $150.0 million of remaining capacity available under the ATM facility.

We expect our expenses to increase substantially in connection with our ongoing activities, particularly as we advance further clinical trials for MICVO. The timing and amount of our funding requirements will depend on many factors, including:

- the cost associated with monotherapy and combination therapy clinical trials for MICVO;
- the manufacture of drug products and drug substance for MICVO;
- the timing and progress of our other preclinical and clinical development activities;
- 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 our product candidate 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 cost and timing of regulatory licenses; and
- insurance, legal and other regulatory compliance expenses to operate as a public company.

Until such time, if ever, we can generate substantial product revenues, 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 candidate, 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 candidate 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, 2025 and 2024 (in thousands):

	Year Ended December 31,	
	2025	**2024**
Net cash used in operating activities	$ (63,502)	$ (57,672)
Net cash provided by investing activities	58,857	8,155
Net cash provided by financing activities	594	59,326
Net (decrease) increase in cash, cash equivalents and restricted cash	**$ (4,051)**	**$ 9,809**

Operating Activities

Net cash used in operating activities for the year ended December 31, 2025 was $63.5 million, which consisted of our net loss of $79.6 million, a net increase in our operating assets and liabilities of $1.9 million partially offset by non-cash charges of $14.2 million. The non-cash charges were primarily due to $11.8 million in stock-based compensation, $4.5 million of depreciation and amortization expense and $0.8 million of operating lease expense, offset by $3.0 million of accretion of discounts on marketable debt securities. The net change in our operating assets and liabilities was primarily due to a $6.0 million increase in accounts payable related to timing of vendor payment, a $0.3 million decrease in prepaid expenses and other current assets, a reduction of $2.8 million in accrued expenses and other current liabilities and a decrease in operating lease liabilities of $1.5 million.

Net cash used in operating activities for the year ended December 31, 2024 was $57.7 million, which consisted of our net loss of $77.3 million and a net change in our operating assets and liabilities of $11.8 million, offset by non-cash charges of $31.5 million. The non-cash charges were primarily due to a $21.0 impairment of an intangible asset, $12.9 million in stock-based compensation and $3.0 million of depreciation and amortization expense, offset by $6.1 million of accretion of discounts on marketable debt securities. The net change in our operating assets and liabilities was primarily due to reversal of $7.7 million in deferred revenue related to the Settlement Agreement with Novartis, a reduction of $1.7 million in accrued expenses and other current liabilities and a decrease in operating lease payments of $1.2 million. These decreases were partially offset by a $1.2 million increase in accounts payable related to timing of vendor payments.

Investing Activities

Net cash provided by investing activities for the year ended December 31, 2025 was $58.9 million, which consisted of the redemption of marketable debt securities of $165.9 million, offset by purchases of marketable debt securities of $107.0 million.

Net cash used in investing activities for the year ended December 31, 2024 was $8.2 million, which consisted of the redemption of marketable debt securities of $168.5 million, offset by purchases of marketable debt securities of $160.1 million.

Financing Activities

Net cash provided by financing activities for the year ended December 31, 2025 was $0.6 million, which consisted primarily of $0.7 million in net proceeds from exercise of stock options and proceeds from issuance of common stock under the ESPP, partially offset by tax withholding payments related to the net settlement of restricted common stock of $0.1 million.

Net cash provided by financing activities for the year ended December 31, 2024 was $59.3 million, which consisted primarily of net proceeds from the issuance of common stock and pre-funded warrants in private placements and our ATM offering program.

Outlook and Going Concern

As of December 31, 2025, we had approximately $66.9 million in cash, cash equivalents and marketable debt securities. We believe that our cash, cash equivalents and marketable debt securities as of December 31, 2025 will be sufficient to fund our operations into the fourth quarter 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.

Our future cash flows are dependent on key variables such as its ability to secure additional sources of funding in the form of public or private financing of equity or debt or collaboration agreements or a combination of these. While we remain optimistic to obtain additional

funding, the current available cash, cash equivalents and marketable debt securities, will not be sufficient to fund our operations over the next 12 months from the date of this Annual Report on Form 10-K. This condition raises substantial doubt about our ability to continue as a going concern for one year from the date the audited consolidated financial statements are issued.

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 $25.1 million. The operating lease obligation is discussed in Note 12, *Operating Leases*, in our Notes to Consolidated 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 3, *Licensing Agreements*, in our Notes to Consolidated 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 (GAAP). 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, *Summary of Significant Accounting Policies*, in our Notes to Consolidated Financial Statements included in Part II, Item 8 of 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. Research and development costs are expensed as incurred and consist primarily of license fees to acquire intellectual property that do 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 our behalf. 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. Payments under some of these contracts depend on preclinical and/or clinical trial milestones. 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 pursuant to the terms of the contractual arrangements 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. There may be instances in which payments made to our vendors exceed the level of services provided and result in a prepayment of expenses. 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.

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 Notes to Consolidated Financial Statements included in Part II, Item 8 of this Annual Report on Form 10-K.

Jumpstart Our Business Startups Act

We are an "emerging growth company," as defined in the Jumpstart Our Business Startups Act of 2012, or the JOBS Act. 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 revenues were 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 revenues, 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 Principal Executive Officer and Principal Financial and Accounting Officer, as appropriate, to allow for timely decisions regarding required disclosure.

Our management, with the participation of our Principal Executive Officer and our Principal Financial and Accounting Officer, evaluated the effectiveness of our disclosure controls and procedures as of December 31, 2025, the end of the period covered by this Annual Report. Based on this evaluation, our Principal Executive Officer and our Principal Financial and Accounting Officer concluded that our disclosure controls and procedures were effective as of December 31, 2025 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 and Accounting 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 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 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, 2025. 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, 2025, 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, 2025, 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 Principal Executive Officer and Principal Financial and Accounting Officer, does not expect that our disclosure controls and procedures, or our internal controls, will prevent all errors 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.

Trading arrangement

During the quarter ended December 31, 2025, none of our directors or officers (as defined in Rule 16a-1(f) under the Exchange Act) adopted or terminated any "Rule 10b5-1 trading arrangement" or "non-Rule 10b5-1 trading arrangement," as each term is defined in Item 408 of Regulation S-K for the purchase or sale of our securities, except as set forth below:

Name and Title	Type of Plan	Adoption or Termination Date	Plan Start Date	Plan End Date	Aggregate Number of Securities to be Sold	Description of Trading Arrangement
Lara Sullivan, M.D., Former President, Chief Executive Officer and Chief Medical Officer and Current Director	Rule 10b5-1 trading arrangement	Adopted on December 22, 2025	December 22, 2025	March 31, 2027	411,845	Sales of shares intended to satisfy the affirmative defense of Rule 10b5–1(c)

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

Not Applicable.

PART III

Item 10. Directors, Executive Officers and Corporate Governance.

We have an Insider Trading Policy governing the purchase, sale and other dispositions of its securities by employees, directors and consultants that is reasonably designed to promote compliance with insider trading laws, rules and regulations and the Nasdaq Stock Market LLC listing standards. Our Insider Trading Policy is filed as Exhibit 19.1 to this Annual Report on Form 10-K.

The remaining information required by this item will be included in our definitive proxy statement to be filed with the SEC for the 2026 Annual Meeting of Stockholders and is incorporated herein by reference.

Item 11. Executive Compensation.

The information required by this Item will be included in our definitive proxy statement to be filed with the SEC for the 2026 Annual Meeting of Stockholders and is incorporated herein by reference.

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

The information required by this Item will be included in our definitive proxy statement to be filed with the SEC for the 2026 Annual Meeting of Stockholders and is incorporated herein by reference.

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

The information required by this Item will be included in our definitive proxy statement to be filed with the SEC for the 2026 Annual Meeting of Stockholders and is incorporated herein by reference.

Item 14. Principal Accounting Fees and Services.

The information required by this Item will be included in our definitive proxy statement to be filed with the SEC for the 2026 Annual Meeting of Stockholders and is incorporated herein by reference.

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 Here with
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	
10.3+	Pyxis Oncology, Inc. 2019 Equity Incentive Plan	S-8	333-260441	4.3	October 22, 2021	
10.4+	Pyxis Oncology, Inc. 2021 Equity Incentive Plan	S-8	333-260441	4.4	October 22, 2021	
10.5+	Pyxis Oncology, Inc. Employee Stock Purchase Plan	S-8	333-260441	4.5	October 22, 2021	
10.6†	License Agreement by and between Pyxis Oncology, Inc. and Pfizer Inc., dated December 8, 2020	S-1	333-259627	10.7	September 17, 2021	
10.7†	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	
10.8†	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	
10.13	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	
10.14†	License Agreement, dated March 28, 2022 between the registrant and Biosion USA, Inc.	10-Q	001-40881	10.1	May 13, 2022	
10.15†	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	
10.16†	Letter Agreement by and between Pyxis Oncology, Inc. and Pfizer Inc., dated October 14, 2022	10-Q	001-40881	10.2	November 1, 2022	
10.17+	Amended Employment Agreement between Pyxis Oncology, Inc. and Lara Sullivan, M.D.	10-K	001-40881	10.21	March 22, 2023	

10.18+	Amended Employment Agreement between Pyxis Oncology, Inc. and Pamela Connealy	10-K	001-40881	10.22	March 22, 2023	
10.19+	Amended Employment Agreement between Pyxis Oncology, Inc. and Jitu Wadhane	10-K	001-40881	10.23	March 22, 2023	
10.20	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	
10.21†	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	
10.22†	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	
10.23†	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	
10.24†	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	
10.25+	Apexigen, Inc. 2010 Equity Incentive Plan.	S-8 POS	333-272510	4.3	August 23, 2023	
10.26+	Apexigen, Inc. 2020 Equity Incentive Plan.	S-8 POS	333-272510	4.4	August 23, 2023	
10.27+	Apexigen, Inc. 2022 Equity Incentive Plan.	S-8 POS	333-272510	4.5	August 23, 2023	
10.30+†	Amended Employment Agreement between Pyxis Oncology, Inc. and Ken Kobayashi, M.D.	10-K	001-40881	10.34	March 21, 2024	
10.32	Pyxis Oncology, Inc. Deferred Compensation Plan	10-Q	001-40881	10.1	August 14, 2024	
10.33	First Amendment to Pyxis Oncology, Inc. 2021 Equity and Incentive Plan	14A	001-40881	A-1	September 25, 2024	
10.34	Separation Agreement and General Release of Ken Kobayashi	10-Q	001-40881	10.1	May 15, 2025	
10.35	Separation Agreement and General Release of Pamela Connealy	10-Q	001-40881	10.1	August 14, 2025	
10.36	Amended Employment Agreement between Pyxis Oncology, Inc. and Thomas Civik					X
19.1	Insider Trading Policy dated November 14, 2023	10-K	001-40881	19.1	March 18, 2025	
21.1	List of Subsidiaries	10-K	001-40881	21.1	March 21, 2024	
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	10-K	001-40881	97	March 22, 2024	
101.INS	Inline XBRL Instance Document – the instance document does not appear in the Interactive Data File because XBRL tags are embedded within the Inline XBRL document.					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 23, 2026

By: /s/ Thomas Civik
Thomas Civik
Interim Chief Executive Officer
(Principal Executive Officer)

POWER OF ATTORNEY

KNOW ALL PERSONS BY THESE PRESENTS, that each person whose signature appears below constitutes and appoints Thomas Civik and Jitendra Wadhane 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/ Thomas Civik **Thomas Civik**	Interim Chief Executive Officer, Director *(Principal Executive Officer)*	March 23, 2026
/s/ Jitendra Wadhane **Jitendra Wadhane**	Principal Financial and Accounting Officer *(Principal Financial and Accounting Officer)*	March 23, 2026
/s/ John Flavin **John Flavin**	Chairman of the Board of Directors	March 23, 2026
/s/ Darren Cline **Darren Cline**	Director	March 23, 2026
/s/ Freda Lewis-Hall, M.D. **Freda Lewis-Hall, M.D.**	Director	March 23, 2026
/s/ Rachel Humphrey, M.D. **Rachel Humphrey, M.D.**	Director	March 23, 2026
/s/ Jakob Dupont, M.D. **Jakob Dupont, M.D.**	Director	March 23, 2026
/s/ Santhosh Palani, Ph.D., CFA **Santhosh Palani, Ph.D., CFA**	Director	March 23, 2026
/s/ Michael A. Metzger **Michael A. Metzger**	Director	March 23, 2026
/s/ Lara Sullivan, M.D. **Lara Sullivan, M.D.**	Director	March 23, 2026

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, 2025 and 2024, 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, 2025, 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, 2025 and 2024, and the results of its operations and its cash flows for each of the two years in the period ended December 31, 2025, in conformity with U.S. generally accepted accounting principles.

The Company's Ability to Continue as a Going Concern

The accompanying consolidated financial statements have been prepared assuming that the Company will continue as a going concern. As discussed in Note 2 to the financial statements, the Company has suffered recurring losses from operations and has stated that substantial doubt exists about the Company's ability to continue as a going concern. Management's evaluation of the events and conditions and management's plans regarding these matters are also described in Note 2. The consolidated financial statements do not include any adjustments that might result from the outcome of this uncertainty.

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 23, 2026

PYXIS ONCOLOGY, INC.

Consolidated Balance Sheets
(In thousands, except share and per share amounts)

	December 31, 2025	December 31, 2024
Assets		
Current assets:		
Cash and cash equivalents	$ 15,422	$ 19,473
Marketable debt securities	51,435	107,458
Restricted cash	1,472	1,472
Prepaid expenses and other current assets	3,776	4,037
Total current assets	72,105	132,440
Property and equipment, net	7,997	9,899
Intangible assets, net	—	2,600
Operating lease right-of-use asset	11,418	12,242
Total assets	**$ 91,520**	**$ 157,181**
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable	$ 10,885	$ 4,859
Accrued expenses and other current liabilities	8,554	11,371
Operating lease liabilities, current portion	1,692	1,450
Total current liabilities	21,131	17,680
Operating lease liabilities, net of current portion	16,958	18,650
Financing lease liabilities, net of current portion	23	100
Total liabilities	38,112	36,430
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, par value $0.001 per share; 190,000,000 shares authorized; 62,690,229 and 59,967,814 shares issued and outstanding as of December 31, 2025 and December 31, 2024, respectively	63	60
Additional paid-in capital	496,469	484,077
Accumulated other comprehensive income	53	170
Accumulated deficit	(443,177)	(363,556)
Total stockholders' equity	53,408	120,751
Total liabilities and stockholders' equity	**$ 91,520**	**$ 157,181**

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,	
	2025	**2024**
Revenues		
Sale of royalty rights (See Note 4)	$ 11,038	$ 8,000
Milestone revenue (See Note 3)	2,820	—
Royalty revenues	—	8,146
Total revenues	13,858	16,146
Costs and operating expenses		
Cost of revenues	2,388	475
Research and development	73,696	58,747
General and administrative	22,194	25,420
Impairment of in-process research and development intangible asset (See Note 10)	—	20,964
Total costs and operating expenses	98,278	105,606
Loss from operations	(84,420)	(89,460)
Other income, net		
Interest and investment income, net	3,610	7,039
Sublease income	2,575	2,926
Total other income, net	6,185	9,965
Loss before income taxes	(78,235)	(79,495)
Income tax expense (benefit)	1,386	(2,164)
Net loss	**$ (79,621)**	**$ (77,331)**
Net loss per common share - basic and diluted	$ (1.28)	$ (1.32)
Weighted average shares of common stock outstanding - basic and diluted	62,143,166	58,445,765
Other comprehensive (loss) income		
Net unrealized (loss) gain on marketable debt securities	(117)	107
Other comprehensive (loss) income	(117)	107
Comprehensive loss	**$ (79,738)**	**$ (77,224)**

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 (Loss)	Accumulated Deficit	Total Stockholders' Equity
	Shares	Amount				
Balance at December 31, 2024	**59,967,814**	**$ 60**	**$ 484,077**	**$ 170**	**$ (363,556)**	**$ 120,751**
Exercise of pre-funded warrants	1,611,215	2	—	—	—	2
Stock options exercised	345,435	—	632	—	—	632
Issuance of restricted common stock, net of tax withholdings	687,859	1	(149)	—	—	(148)
Issuance of common stock under employee stock purchase plan (ESPP)	77,906	—	108	—	—	108
Stock-based compensation	—	—	11,801	—	—	11,801
Net unrealized loss on marketable debt securities	—	—	—	(117)	—	(117)
Net loss	—	—	—	—	(79,621)	(79,621)
Balance at December 31, 2025	**62,690,229**	**$ 63**	**$ 496,469**	**$ 53**	**$ (443,177)**	**$ 53,408**

	Common Stock		Additional Paid-In Capital	Accumulated Other Comprehensive Income	Accumulated Deficit	Total Stockholders' Equity
	Shares	Amount				
Balance at December 31, 2023	**44,754,853**	**$ 45**	**$ 411,821**	**$ 63**	**$ (286,225)**	**$ 125,704**
Issuance of common stock in private placement, net of offering costs	8,849,371	9	39,163	—	—	39,172
Issuance of common stock pursuant to (ATM) program, net of offering costs	4,050,000	4	12,170	—	—	12,174
Issuance of pre-funded warrants in private placement, net of offering costs	—	—	7,700	—	—	7,700
Stock options exercised	123,312	—	296	—	—	296
Issuance of restricted common stock, net of tax withholdings	2,088,109	2	(242)	—	—	(240)
Issuance of common stock under ESPP	102,169	—	224	—	—	224
Stock-based compensation	—	—	12,945	—	—	12,945
Net unrealized gains on marketable debt securities	—	—	—	107	—	107
Net loss	—	—	—	—	(77,331)	(77,331)
Balance at December 31, 2024	**59,967,814**	**$ 60**	**$ 484,077**	**$ 170**	**$ (363,556)**	**$ 120,751**

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,	
	2025	**2024**
Operating activities		
Net loss	$ (79,621)	$ (77,331)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	4,511	2,982
Stock-based compensation	11,801	12,945
Non-cash operating lease expense	824	700
Impairment of in-process research and development intangible asset	—	20,964
Accretion of discount on marketable debt securities	(2,960)	(6,109)
Changes in operating assets and liabilities:		
Prepaid expenses and other current assets	261	(203)
Accounts payable	6,026	1,200
Accrued expenses and other current liabilities	(2,823)	(1,670)
Operating lease liabilities	(1,450)	(1,231)
Deferred revenues	—	(7,660)
Deferred tax liabilities	—	(2,164)
Other	(71)	(95)
Net cash used in operating activities	**(63,502)**	**(57,672)**
Investing activities		
Redemption of marketable debt securities	165,871	168,510
Purchase of marketable debt securities	(107,005)	(160,118)
Purchase of property and equipment	(9)	(237)
Net cash provided by investing activities	**58,857**	**8,155**
Financing activities		
Proceeds from issuance of common stock and pre-funded warrants in private placement, net of offering costs	2	46,872
Proceeds from issuance of common stock pursuant to ATM program, net of offering costs	—	12,174
Tax withholding payments related to net settlement of restricted common stock	(148)	(240)
Proceeds from the exercise of stock options	632	296
Proceeds from issuance of common stock under ESPP	108	224
Net cash provided by financing activities	**594**	**59,326**
Net (decrease) increase in cash, cash equivalents and restricted cash	(4,051)	9,809
Cash, cash equivalents and restricted cash at beginning of year	20,945	11,136
Cash, cash equivalents and restricted cash at end of year	**$ 16,894**	**$ 20,945**
Supplemental cash flow information		
Cash paid for interest	$ 91	$ 10
Cash paid for income taxes	$ 1,379	$ 164
Noncash investing and financing activities		
ROU asset in exchange for financing lease liability	$ —	$ 265
Reconciliation of cash, cash equivalents and restricted cash		
Cash and cash equivalents	$ 15,422	$ 19,473
Restricted cash	1,472	1,472
Total cash, cash equivalents and restricted cash shown in the statement of cash flows	**$ 16,894**	**$ 20,945**

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 oncology company executing on a development strategy designed to address unmet medical needs in patients with solid tumors with a specific focus on head and neck squamous cell carcinoma (HNSCC) tumors.

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 fiscal quarters end on March 31, June 30 and September 30. The accompanying consolidated financial statements are prepared in accordance with generally accepted accounting principles 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.

Liquidity and Going Concern

The Company has incurred losses and negative cash flows from operations since inception, including net losses of $79.6 million and $77.3 million for the years ended December 31, 2025 and 2024, respectively. As of December 31, 2025, the Company had an accumulated deficit of $443.2 million and cash, cash equivalents, and marketable debt securities of $66.9 million.

The Company's future cash flows are dependent on key variables such as its ability to secure additional sources of funding in the form of public or private financing of equity or debt, collaboration agreements, or a combination of these. While the Company remains optimistic to obtain additional funding, the current available cash, cash equivalents and marketable debt securities will not be sufficient to fund the Company's operations over the next 12 months from the date these consolidated financial statements were included within this Annual Report on Form 10-K. These conditions raise substantial doubt about the Company's ability to continue as a going concern for one year from the date these consolidated financial statements were issued.

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. There are inherent uncertainties as the outcome of these potential transactions are outside management's control, and therefore there are no assurances that any of these potential transactions will occur. In addition, there can be no assurances that these transactions will sufficiently improve the Company's liquidity or that the Company will otherwise realize the anticipated benefits. 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.

The accompanying consolidated financial statements do not include any adjustments that might result from the outcome of this uncertainty. Accordingly, the consolidated financial statements have been prepared on a basis that assumes the Company will continue as a going concern and which contemplates the realization of assets and satisfaction of liabilities and commitments in the ordinary course of business.

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, expenses 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, deferred tax and related valuation allowance 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 clinical 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, third party service providers such as contract research organizations (CROs) and 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 United States (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, 2025 and 2024.

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

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 the consolidated statements of operations and comprehensive loss.

Impairment of Long-Lived Assets

The Company evaluates its long-lived assets, which consist of property and equipment and 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 related to long-lived assets for the years ended December 31, 2025 and 2024.

Intangible Assets, Net

Acquired In-Process Research & Development

The Company's indefinite-lived intangible assets consisted of in-process research and development (IPR&D), which were acquired in connection with the acquisition of Apexigen Inc., (Apexigen). IPR&D represents the fair value assigned to research and development projects acquired which were 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. As described in Note 10, *Intangible Assets, Net,* the Company fully impaired its IPR&D during the year ended December 31, 2024.

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 a retained royalty right under an Apexigen agreement. The useful life was determined based on the terms and conditions underlying the licensing agreement and the expected use of the asset by the Company. Amortization of definite-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 expenses within the accompanying consolidated statements of operations and comprehensive loss. As of December 31, 2025, the Company has fully amortized its definite-lived intangible assets as the related retained royalty rights were sold during the year.

Operating 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-cancellable 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.

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

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, 2025.

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 revenue related to sales-based royalties, wherein the license is deemed to be the sole or predominant item to which the payments relate, upon the later of: (i) when the related sales occur or (ii) when the performance obligation to which some or all of the payment has been allocated has been satisfied (or partially satisfied). The Company recognizes milestone payment revenues when it is probable that a significant reversal in revenue will not occur.

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 that is at least equal to the expected life of most stock options. Therefore, the Company estimates the expected stock volatility based on a blend of the historical volatility of a publicly traded set of peer companies and the Company's own volatility. 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. When determining the grant-date fair value of stock-based awards, management further considers whether an adjustment is required to the observable market price or volatility of the Company's common stock that is used in the valuation as a result of material non-public information, if that information is expected to result in a material increase in share price.

Income Taxes

The Company accounts for income taxes under the asset and liability method. 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's policy is to recognize interest and/or penalties related to income tax matters in provision for income taxes.

The Company may be subject to withholding taxes imposed by foreign jurisdictions on upfront fees, milestone payments and royalties earned under its collaboration and license agreements. Such withholding taxes are recorded as a component of income tax expense in the period the related revenue is recognized, unless the withholding tax represents a tax collected from the customer, in which case such amounts are excluded from revenue.

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.

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 December 2023, the FASB issued ASU 2023-09, *Income Taxes - Improvements to Income Tax Disclosures*. The amendment requires (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. On January 1, 2025, the Company adopted ASU 2023-09 prospectively. The adoption of ASU 2023-09 did not have an impact on the Company's consolidated financial statements, but resulted in expanded income tax disclosures. Refer to the disclosure included in Note 16, *Income Taxes*.

Recently Issued Accounting Pronouncements

In November 2024, the FASB issued ASU 2024-03, *Income Statement - Reporting Comprehensive Income - Expense Disaggregation Disclosures (Subtopic 220-40): Disaggregation of Income Statement Expenses*. The amendment requires disaggregated disclosure of (i) certain costs and expenses, (ii) certain already required disclosures must be included in the same disclosure as the new disaggregation requirements and (iii) a qualitative description of the amounts not separately disaggregated. The amendments are effective for annual periods beginning after December 15, 2026, and interim periods beginning after December 15, 2027, early adoption is permitted. The Company is currently evaluating the impact of the new standard on the Company's consolidated financial statements and related disclosures.

3. 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, 2025 and 2024, and determined that no such amounts were required.

Pfizer Inc. Agreement

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 micvotabart pelidotin (MICVO, formerly 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 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 in March 2021 and 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 MICVO 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 low-double digits to twenty percent 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 the A&R License Agreement as of December 31, 2025 and 2024, 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, manufacturing 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 ADC 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 in March 2022. Further, the Company is 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 low-double to mid-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 the Biosion License Agreement as of December 31, 2025 and 2024, and determined that no such amounts were required.

Acquired Out-Licensing Agreements

In August 2023, the Company completed the acquisition of Apexigen (hereinafter referred to as the 'Acquisition') and assumed all out-licensing agreements of Apexigen upon the Acquisition.

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 had 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 was 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.

On June 30, 2025, the National Medical Products Administration (NMPA) of China (formerly SFDA) granted final regulatory approval for suvemcitug in China. Upon suvemcitug approval by NMPA, the Company was entitled to a $3 million regulatory approval milestone under the Simcere Agreement. Accordingly, the Company recognized $2.8 million of milestone revenue ($3 million upon achievement of the regulatory milestone less $0.2 million of withholding tax in China) within the accompanying consolidated statements of operations and comprehensive loss during the year ended December 31, 2025.

Further, as described in Note 4, *Sale of Royalty Rights*, on December 11, 2025, the Company completed the sale of its rights to royalties from the commercialization of Enzeshu® (Suvemcitug for Injection) to Simcere for a one-time cash payment of $11 million and four semi-annual installments of $175,000 each.

T-Mab/Mabwell Agreement

In May 2008, Epitomics 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 T-Mab 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 with the first commercial sale in China. As of December 31, 2025 and 2024, the Company assessed the milestone and royalty events involving Mabwell and determined that no such amounts were receivable.

Toray Sublicense Agreement

In May 2012, Epitomics 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. As of December 31, 2025 and 2024, the Company assessed the milestone and royalty events involving Toray and determined that no such amounts were receivable.

4. Sale of Royalty Rights

As described in Note 3, *Acquired Out-Licensing Agreements,* upon the acquisition of Apexigen, the Company assumed the Simcere License and Collaboration Agreement, an out-licensing agreement between Apexigen and Simcere, pursuant to which Simcere was obligated to pay the Company low to high single-digit percentage royalties on net sales of suvemcitug in China until 15 years after the first commercial sale of suvemcitug.

On December 11, 2025, the Company entered into an amendment to the License and Collaboration Agreement (the Simcere Royalty Agreement) with Simcere, pursuant to which the Company relinquished its rights to future royalties on the net sales of Enzeshu® to Simcere for a one-time amount of $11.0 million and four semi-annual installments of $175,000 each.

The Simcere Royalty Agreement with Simcere constitutes a contract with a customer. Upon execution of the Simcere Royalty Agreement, the $11.0 million of payment ($11.7 million less $0.7 million of withholding tax in China) related to the sale of future royalties was recorded as revenues and the remaining definite-lived intangible asset of $2.4 million related to these royalty rights was recorded as cost of revenues within the accompanying consolidated statements of operations and comprehensive loss for the year ended December 31, 2025.

On March 25, 2024, the Company entered into the Fourth Amendment, Settlement Agreement, and Royalty Purchase Agreement (the Settlement Agreement) with Novartis, pursuant to which the Company transferred its rights to future royalties on the net sales of Beovu® to Novartis for a one-time amount of $8.0 million. Additionally, the dispute regarding Novartis' obligation to pay royalties on Beovu® sales was resolved and royalties previously received by Apexigen and the Company, aggregating to $8.1 million, were agreed to be free from any reclaim rights. Upon the Settlement Agreement, the Company recognized revenue of $16.1 million during the year ended December 31, 2024.

5. Segment Disclosures

Operating segments are defined as components of an enterprise for which separate discrete information is available for evaluation by the chief operating decision maker, or decision making group, in deciding how to allocate resources in assessing performance. The Company has one reportable segment related to the development of clinical and preclinical product candidates focused on addressing unmet medical needs in patients with solid tumors with a specific focus on HNSCC tumors. The Company's chief operating decision maker (CODM) is the Chief Executive Officer.

The accounting policies of the single segment are the same as those described in the summary of significant accounting policies. The CODM assesses performance for the segment based on net loss, which is reported on the consolidated statements of operations and comprehensive loss as net loss. The measure of segment assets is reported on the consolidated balance sheets as total assets.

To date, the Company has not generated any product revenue. As described in Note 3, *Licensing Agreements* and Note 4, *Sale of Royalty Right*s, the Company generated revenue during the years ended December 31, 2025 and 2024 from the milestone payment upon approval of suvemcitug in China, the sale of its royalty rights under the Simcere Royalty Agreement with Simcere and Settlement Agreement with Novartis. The Company expects to continue to incur significant expenses and operating losses for the foreseeable future as it advances the product candidate through all stages of development and clinical trials and, ultimately, seeks regulatory approval.

As such, the CODM uses cash forecast models in deciding how to allocate resources. Such cash forecast models are reviewed to assess the entity-wide operating results and performance. Net loss is used to monitor budget versus actual results. Monitoring budgeted versus actual results is used in assessing performance of the segment and in establishing management's compensation, along with cash forecast models.

The table below summarizes segment net loss, including significant expenses for the years ended December 31, 2025 and 2024 (in thousands):

	Year Ended December 31,	
	2025	**2024**
Revenue		
Sale of royalty rights	$ 11,038	$ 8,000
Milestone revenue	2,820	—
Royalty revenues	—	8,146
Total revenues	13,858	16,146
Costs and operating expenses		
Cost of revenues	2,388	475
Research and development		
Clinical product candidates	25,901	24,456
Clinical product manufacturing	19,694	11,200
Personnel-related expenses excluding stock-based compensation	15,711	14,293
Stock-based compensation	3,156	3,002
Depreciation and amortization	1,819	1,922
Other (i)	7,415	3,874
Total research and development expenses	73,696	58,747
General and administrative		
Personnel-related expenses excluding stock-based compensation	5,235	5,837
Stock-based compensation	8,645	9,943
Professional and consultant fees	4,179	4,491
Other (ii)	4,135	5,149
Total general and administrative expenses	22,194	25,420
Impairment of in-process research and development intangible asset	—	20,964
Total costs and operating expenses	98,278	105,606
Other segment income (iii)	6,185	9,965
Income tax expense (benefit)	1,386	(2,164)
Segment net loss	**$ (79,621)**	**$ (77,331)**
Reconciliation of profit or loss		
Adjustments and reconciling items	—	—
Consolidated net loss	**$ (79,621)**	**$ (77,331)**

(i) Other research and development segment items include facilities expenses, lab services, professional services and technology costs.

(ii) Other general and administrative segment items include facilities expenses, technology costs, insurance and depreciation.

(iii) Other segment income for the years ended December 31, 2025 and 2024 consisted of $3.6 million and $7.0 million of interest and investment income and $2.6 million and $2.9 million of sublease income, respectively.

6. Fair Value Measurements

The following tables present the financial instruments carried at fair value on a recurring basis as of December 31, 2025 and 2024, respectively, in accordance with the fair value hierarchy (in thousands):

	December 31, 2025			
	Level 1	Level 2	Level 3	Total
Cash equivalents				
Money market funds	$ 673	$ —	$ —	$ 673
Marketable debt securities				
U.S. Treasury securities	51,435	—	—	51,435
Total	**$ 52,108**	**$ —**	**$ —**	**$ 52,108**

	December 31, 2024			
	Level 1	Level 2	Level 3	Total
Cash Equivalents				
Money market funds	$ 9,491	$ —	$ —	$ 9,491
Marketable debt securities				
U.S. Treasury securities	107,458	—	—	107,458
Total	**$ 116,949**	**$ —**	**$ —**	**$ 116,949**

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 U.S. Treasury securities and are classified as Level 1 assets as they are valued using quoted prices in active markets. There were no transfers between Level 1 and Level 2 of the fair value hierarchy during the years ended December 31, 2025 and 2024.

7. Marketable Debt Securities

Marketable debt securities, all of which were classified as available-for-sale, consisted of the following (in thousands):

	December 31, 2025			
	Amortized Cost	Unrealized Gains	Unrealized Losses	Aggregate Fair Value
Marketable debt securities				
U.S. Treasury securities	$ 51,382	$ 53	$ —	$ 51,435

	December 31, 2024			
	Amortized Cost	Unrealized Gains	Unrealized Losses	Aggregate Fair Value
Marketable debt securities				
U.S. Treasury securities	$ 107,288	$ 170	$ —	$ 107,458

As of December 31, 2025 and 2024, the remaining contractual terms of the U.S. Treasury securities were less than 12 months. As of December 31, 2025 and 2024, the Company held no securities in an unrealized loss position. There were no securities in a continuous unrealized loss position for greater than twelve months at December 31, 2025 or 2024.

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, Net

Interest and investment income, net consisted of the following (in thousands):

	Year Ended December 31,	
	2025	2024
Interest income, net	$ 650	$ 930
Accretion of discount, net	2,960	6,109
Total interest and investment income, net	**$ 3,610**	**$ 7,039**

8. Prepaid Expenses and Other Current Assets

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

	December 31,	
	2025	2024
Research and development	$ 1,465	$ 2,602
Royalty rights receivable	700	—
Insurance	586	761
Software licenses	399	240
Other	626	434
Total prepaid expenses and other current assets	**$ 3,776**	**$ 4,037**

9. Property and Equipment, Net

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

	December 31,	
	2025	2024
Leasehold improvements	$ 10,742	$ 10,742
Laboratory equipment	3,120	3,159
Furniture and office equipment	1,028	1,029
Financing lease right-of-use asset	114	202
	15,004	15,132
Less: accumulated depreciation and amortization	(7,007)	(5,233)
Total property and equipment, net	**$ 7,997**	**$ 9,899**

Depreciation and amortization expense on property and equipment for the years ended December 31, 2025 and 2024, was $1.9 million and $2.0 million, respectively, of which $1.6 million and $1.4 million, respectively, was included within research and development expenses and $0.3 million and $0.6 million, 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, 2025			
	Gross Carrying Amount	Accumulated Amortization	Cost of Revenues (See below)	Net Carrying Amount
Royalty rights	$ 2,902	$ (514)	$ (2,388)	$ —
Total	**$ 2,902**	**$ (514)**	**$ (2,388)**	**$ —**

	As of December 31, 2024			
	Gross Carrying Amount	Accumulated Amortization	Impairment (See below)	Net Carrying Amount
Royalty rights	$ 2,902	$ (302)	$ —	$ 2,600
IPR&D	20,964	—	(20,964)	—
Total	**$ 23,866**	**$ (302)**	**$ (20,964)**	**$ 2,600**

As described in Note 3, *Licensing Agreements*, the Company assumed all out-licensing agreements of Apexigen upon the completion of the Acquisition.

As described in Note 4, *Sale of Royalty Right*s, the Company sold its royalty rights under Simcere Royalty Agreement in 2025 and the Settlement Agreement with Novartis in 2024; therefore, the carrying value of intangible assets on the date of sale of royalty rights of $2.4 million and $0.5 million, respectively, were expensed as cost of revenue in the accompanying consolidated statements of operations and comprehensive loss for the years ended December 31, 2025 and 2024, respectively.

IPR&D relates to the research and development assets of Apexigen, renamed PYX-107, acquired by the Company in 2023. In December 2024, the Company announced a strategic realignment plan to prioritize resources towards clinical development of MICVO and continue to defer further clinical development of PYX-107. Given the uncertain timing of the future clinical development of PYX-107, the

Company recognized an impairment loss of $21.0 million during the year ended December 31, 2024. No impairment loss was recorded during the year ended December 31, 2025.

Amortization expense of $0.2 million and $0.3 million for the years ended December 31, 2025 and 2024, respectively, were recorded as part of research and development expense within the accompanying consolidated statements of operations and comprehensive loss.

11. Accrued Expenses and Other Current Liabilities

Accrued expenses and other current liabilities consisted of the following (in thousands):

	December 31,	
	2025	2024
Research and development expenses	$ 3,997	$ 6,365
Employee compensation and benefits	3,316	3,983
Legal and professional fees	810	380
Other	431	643
Total accrued expenses and other current liabilities	**$ 8,554**	**$ 11,371**

12. Operating Leases

Leases classified as operating leases are included in operating lease 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.

The Company subleases approximately 17,729 square feet of office and laboratory space in the building located at 321 Harrison Avenue, Boston, Massachusetts. The Company remains jointly and severally liable under the head lease and accounts for the sublease as an operating lease. The lease term commenced on March 24, 2023, and is expected to end in May 2026. The Company recognized sublease income of $2.6 million and $2.9 million for the years ended December 31, 2025 and 2024, respectively.

The components of lease expense were as follows (in thousands):

	Year Ended December 31,	
	2025	2024
Lease cost		
Operating lease cost	$ 2,653	$ 2,653
Variable lease cost	1,047	1,737
Short-term lease cost	21	27
Total operating lease cost	**$ 3,721**	**$ 4,417**
Other information		
Cash paid for amounts included in the measurement of lease liabilities, included in operating cash flows	$ 3,359	$ 3,295
Weighted-average remaining lease term (in years)	7.0	8.0
Weighted-average discount rate	9.4%	9.4%

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 for the next five years, as of December 31, 2025, are as follows (in thousands):

Years Ending December 31,	Operating Lease Payments	Sublease Receipts	Net Operating Lease Payments
2026	$ 3,375	$ 738	$ 2,637
2027	3,473	—	3,473
2028	3,575	—	3,575
2029	3,680	—	3,680
2030	3,788	—	3,788
Thereafter	7,916	—	7,916
Total undiscounted payments	25,807	$ 738	$ 25,069
Less: present value adjustment	(7,157)		
Present value of future payments	18,650		
Less: current portion of operating lease liabilities	(1,692)		
Operating lease liabilities, net of current portion	$ 16,958		

13. Stockholders' Equity

Shelf Registration Statement and ATM Offering Program

On November 26, 2025, 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 $350.0 million. On December 09, 2025, the registration statement was declared effective by the SEC. The registration statement includes an ATM offering program for the sale of up to $150.0 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, 2024, the Company completed the sale of an aggregate of 4,050,000 shares of common stock under the ATM offering program, with an average sale price of $3.07 per share, resulting in gross proceeds of $12.4 million. The Company paid commissions of $0.3 million to the placement agent under the ATM offering program.

During the year ended December 31, 2025, the Company did not sell any shares of common stock under the ATM offering program. As of December 31, 2025, the Company had $150.0 million of remaining capacity available under the ATM facility.

Preferred Stock

As of December 31, 2025, 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, 2025 and 2024.

Common Stock

The Company was authorized to issue up to 190,000,000 shares of common stock as of December 31, 2025 and 2024, of which 62,690,229 and 59,967,814 shares were issued and outstanding as of December 31, 2025 and 2024, 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,	
	2025	**2024**
Stock options outstanding	12,468,296	9,711,075
Restricted stock units outstanding	1,634,519	2,463,601
Shares reserved for future issuance	4,925,963	4,295,342
Pre-Funded Warrant Shares	—	1,611,215
Apexigen replacement warrants	1,003,191	1,003,191
Employee stock purchase plan	605,490	573,316
Total	**20,637,459**	**19,657,740**

14. Common Stock Warrants

Apexigen Replacement Warrants

Upon the Acquisition, each outstanding warrant issued by Apexigen 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. The Company replaced 5,815,613 Apexigen warrants with 1,003,191 Pyxis Oncology warrants.

As of December 31, 2025, 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 July 29, 2027, 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.

Private Placement Warrants

In February 2024, the Company completed the private placement with certain institutional and accredited investors and received gross proceeds of $50 million by issuing (i) 8,849,371 shares of the Company's common stock, par value $0.001 per share, at a purchase price of $4.78 per share, and (ii) pre-funded warrants ('Pre-Funded Warrant') to purchase up to an aggregate of 1,611,215 shares of the Company' common stock at a purchase price of $4.779 per Pre-Funded Warrant.

In January 2025, the pre-funded warrant holder exercised their right to convert the Pre-Funded Warrants to common stock and accordingly, the Company issued 1,611,215 shares of the Company's common stock to the warrant holder.

15. Stock-Based Compensation

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.

As of December 31, 2025, options to purchase 1,822,815 shares of common stock and 363,444 restricted stock units were outstanding, and 264,094 shares remained available for future issuance under the 2019 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. On October 23, 2024, the Company's stockholders approved an increase of 5,500,000 shares of common stock available for issuance 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, 2025, the number of shares of common stock available for issuance under the 2021 Plan increased by 2,998,390 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, 2025, options to purchase 8,536,460 shares of common stock and 1,100,077 restricted stock units were outstanding, and 3,998,507 shares remained available for future issuance under the 2021 plan.

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, the 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, 2025, options to purchase 987,753 shares of common stock and 107,485 restricted stock units were outstanding, and 56,002 shares remained available for future issuance under the 2022 Inducement Plan.

2022 Equity Incentive Plan

Upon the Acquisition, 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, 2025, the number of shares of common stock available for issuance under the 2022 Plan increased by 517,222 shares as a result of the evergreen provision. Unless earlier terminated by the Board, the 2022 Plan will terminate on the tenth anniversary of the effective date.

As of December 31, 2025, options to purchase 1,121,268 shares of common stock and 63,513 restricted stock units were outstanding under the 2022 Plan and 607,360 shares remained available for future issuance under the 2022 Plan.

2020 Equity Incentive Plan

The Company also assumed Apexigen's 2020 Equity Incentive Plan, (the 2020 Plan) as a result of the Acquisition. 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, 2025, 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, 2025, the Company issued 77,906 shares of common stock pursuant to the ESPP.

As of December 31, 2025, the authorized number of shares and shares available for issuance under the 2021 ESPP is 605,490.

Stock Options

Stock options granted under the 2022 Inducement Plan, 2022 Plan, 2021 Plan, 2020 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, 2025:

	Number of Options	Weighted Average Exercise Price	Weighted Average Remaining Contractual Term (Years)	Aggregate Intrinsic Value (in thousands)
Outstanding at January 1, 2025	9,711,075	$ 5.04	8.2	$ 44
Granted	5,168,854	1.36		
Exercised	(345,435)	1.83		
Expired	(629,653)	5.10		
Forfeited	(1,436,545)	1.66		
Outstanding at December 31, 2025	**12,468,296**	**$ 3.99**	**7.8**	**$ 595**
Options exercisable December 31, 2025	**7,738,663**	**$ 5.27**	**7.0**	**$ 150**

The weighted-average grant-date fair value of stock options granted during the years ended December 31, 2025 and 2024 was $1.06 and $1.93 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 $1.15 per share as of December 31, 2025, the last trading day of 2025. The aggregate intrinsic value of stock options exercised during the years ended December 31, 2025 and 2024 was approximately $0.9 million and $0.3 million, respectively.

The Company has an aggregate $6.0 million of gross unrecognized stock-based compensation expense as of December 31, 2025, remaining to be amortized over a weighted average period of 2.9 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 stock option on the date of grant using the following key input assumptions in the Black-Scholes option-pricing model:

	Year Ended December 31,	
	2025	**2024**
Expected volatility	93.92% - 101.51%	93.23% - 102.27%
Risk-free interest rate	3.68% - 4.45%	3.55% - 4.48%
Expected dividend yield	0.00%	0.00%
Expected term (in years)	5.00 - 6.08	5.00 - 6.08

Restricted Stock Units (RSU)

The following table summarizes restricted stock unit activity for the year ended December 31, 2025:

	Number of Units	Weighted Average Grant Date Fair Value
Outstanding at January 1, 2025	2,533,650	$ 3.26
Granted	24,260	0.92
Forfeited	(146,130)	3.27
Vested and settled	(777,261)	3.21
Outstanding at December 31, 2025[(1)(2)]	**1,634,519**	**$ 2.61**

(1) Includes 786,671 RSUs which are vested but not settled at December 31, 2025.
(2) Includes the impact of equity modifications.

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.

During the year ended December 31, 2025, the Company issued 687,859 shares of its common stock from the settlement of 777,261 shares of 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, 2025 and 2024 was $2.5 million and $5.2 million, respectively.

The Company has an aggregate $1.9 million of gross unrecognized restricted stock-based compensation expense as of December 31, 2025, remaining to be amortized over a weighted average period of 1.8 years.

Summary of Stock-Based Compensation Expense

The following tables summarize the total stock-based compensation expense for the years ended December 31, 2025 and 2024, respectively (in thousands):

	Year Ended December 31,	
	2025	**2024**
Stock options	$ 9,391	$ 7,653
Restricted stock	2,410	5,292
Total	**$ 11,801**	**$ 12,945**

	Year Ended December 31,	
	2025	**2024**
General and administrative	$ 8,645	$ 9,943
Research and development	3,156	3,002
Total	**$ 11,801**	**$ 12,945**

Total stock-based compensation expense for stock options includes expense related to the 2021 ESPP of $0.1 million and $0.1 million for the years ended December 31, 2025 and 2024, respectively.

16. Income Taxes

On January 1, 2025, the Company adopted the guidance in ASU 2023-09, *Income Taxes - Improvements to Income Tax Disclosures* on a prospective basis.

Components of income tax expense (benefit) consist of the following (in thousands):

	Year Ended December 31,	
	2025	**2024**
Current:		
Federal	**$ —**	**$ —**
State	53	87
Foreign	1,333	—
Total current tax expense	1,386	87
Deferred:		
Federal	—	(874)
State	—	(1,377)
Foreign	—	—
Total deferred tax benefit	—	(2,251)
Total income tax expense (benefit)	**$ 1,386**	**$ (2,164)**

Cash paid for income taxes, net of refunds received, by jurisdiction for the year ended December 31, 2025 is as follows (in thousands):

	2025
Federal	**$ —**
State	46
Foreign:	
China	1,333
Total income taxes paid	**$ 1,379**

The majority of state tax was paid to Massachusetts.

A reconciliation of the expected income tax expense computed using the federal statutory income tax rate to the Company's effective income tax rate is as follows for the year ended December 31, 2025:

		Year Ended December 31, 2025	
		Amount	%
Income tax computed at federal statutory rate %	$	(16,417)	21.0%
State taxes, net of federal benefit [1]		42	(0.1)%
Foreign tax effects:			
China		1,333	(1.7)%
Change in federal valuation allowance		16,006	(20.5)%
Research and development credit carryovers – federal		(1,294)	1.7%
Nontaxable or nondeductible items:			
Stock-based compensation		1,885	(2.4)%
Other		(169)	0.2%
Total	**$**	**1,386**	**(1.8)%**

[1] State taxes in Massachusetts made up the majority (greater than 50%) of the tax effect in this category.

The Company recorded an income tax expense of $1.4 million with an effective tax rate of (1.8%) for the year ended December 31, 2025.

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 year ended December 31, 2024:

	Year Ended December 31, 2024
	%
Income tax computed at federal statutory rate %	21.0%
State taxes, net of federal benefit	5.2%
Stock-based compensation	(2.4)%
Change in valuation allowance	(26.3)%
Change in state apportionment	1.9%
Provision to tax return differences	1.5%
Research and development credit carryovers	2.1%
Permanent differences	(0.4)%
Effective income tax rate %	**2.6%**

The Company recorded an income tax benefit with an effective tax rate of 2.6% for the year ended December 31, 2024. A full valuation allowance eliminated 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 recorded for income tax purposes. Significant components of the Company's net deferred tax assets as of December 31, 2025 and 2024 were as follows (in thousands):

	Year Ended December 31,	
	2025	2024
Deferred tax assets:		
Net operating losses	$ 96,337	$ 78,213
Tax credit carryforwards	12,866	11,816
Capitalized research expenditures	25,036	31,593
License fees	11,331	13,044
Stock-based compensation	3,606	3,452
Operating lease liability	3,219	3,844
Derivative	1,068	1,248
Reserves and accruals	796	1,181
Intangibles	49	—
Other	276	208
Total gross deferred tax assets before valuation allowance	154,584	144,599
Less: valuation allowance	(151,586)	(140,461)
Total deferred tax assets	$ 2,998	$ 4,138
Deferred tax liabilities:		
Operating lease ROU assets	(2,998)	(3,508)
Intangibles	—	(630)
Total deferred tax liabilities	(2,998)	(4,138)
Net deferred tax	**$ —**	**$ —**

As of December 31, 2025, the Company's federal and state net operating losses in the United States were $82.1 million ($390.9 million before tax) and $14.3 million ($218.2 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, 2025, the Company had $10.0 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 date 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 $151.6 million as of December 31, 2025, representing the portion of the deferred tax asset that is not more likely than not to be realized. For the years ended December 31, 2025 and 2024, the valuation allowance for deferred tax assets increased by $11.1 million and $21.0 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 Company has not completed a recent study of its research and development credit carryforward; accordingly, a portion of the tax credit carryforward may not be available to offset future income tax. Until a study is completed and any adjustment is known, no amounts are being presented as an uncertain tax position. A full valuation allowance has been provided against the Company's research and development credits and, if an adjustment is required, this adjustment would be offset by an adjustment to the 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, 2022 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.

A reconciliation of the beginning and ending amounts of unrecognized tax benefits is as follows (in thousands):

	Year Ended December 31,	
	2025	2024
Gross unrecognized tax benefit at January 1	$ 2,003	$ 2,003
Additions for positions taken during a prior period	—	—
Gross unrecognized tax benefit at December 31	**$ 2,003**	**$ 2,003**

17. Net Loss per Share

The Company's potentially dilutive securities, which include replacement warrants, restricted stock units, 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,	
	2025	2024
Numerator:		
Net loss	$ (79,621)	$ (77,331)
Denominator:		
Weighted-average common shares outstanding, basic and diluted	62,143,166	58,445,765
Net loss per share, basic and diluted	**$ (1.28)**	**$ (1.32)**

Pre-funded Warrant Shares of 1,611,215 shares were included in the computation of basic and diluted net loss per common share for the year ended December 31, 2024 as the Pre-Funded Warrants were issuable for nominal consideration.

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,	
	2025	2024
Stock options outstanding	12,468,296	9,711,075
Non-vested and unsettled restricted stock units	847,848	2,463,601
Shares reserved for future issuance	4,925,963	4,295,342
Apexigen replacement warrants	1,003,191	1,003,191
Employee stock purchase plan	605,490	573,316
Total	**19,850,788**	**18,046,525**

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 less than $0.1 million and less than $0.1 million during the years ended December 31, 2025 and 2024, respectively, with regards to the University License Agreement. Refer to Note 3, *Licensing Agreements,* 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.

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