UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, DC 20549

FORM 10-Q

(Mark One)

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

For the quarterly period ended March 31, 2025

OR

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

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

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 is a shell company (as defined in Rule 12b-2 of the Exchange Act). Yes ☐ No ☒

As of May 14, 2025, the registrant had 61,947,665 shares of common stock, $0.001 par value per share, outstanding.

Table of Contents

SUMMARY RISK FACTORS

You should consider carefully the risks described under "Risk Factors" in Part II, Item 1A of this Quarterly Report on Form 10-Q. 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 will require substantial additional capital to finance our operations. If we are unable to raise such capital when needed, or on acceptable terms, we may be forced to delay, reduce or eliminate one or more of our research and product development programs or future commercialization efforts.
- We are heavily dependent on the success of our product candidate, micvotabart pelidotin, which is in the early stages of clinical development. If our 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 face significant competition from other 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—FINANCIAL INFORMATION

Item 1. Financial Statements.

PYXIS ONCOLOGY, INC.

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

	March 31, 2025	December 31, 2024
Assets		
Current assets:		
Cash and cash equivalents	$ 12,759	$ 19,473
Marketable debt securities, short-term	92,673	107,458
Restricted cash	1,472	1,472
Prepaid expenses and other current assets	4,967	4,037
Total current assets	111,871	132,440
Property and equipment, net	9,403	9,899
Intangible assets, net	2,544	2,600
Operating lease right-of-use asset	12,049	12,242
Total assets	**$ 135,867**	**$ 157,181**
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable	$ 2,846	$ 4,859
Accrued expenses and other current liabilities	10,076	11,371
Operating lease liabilities, current portion	1,508	1,450
Total current liabilities	14,430	17,680
Operating lease liabilities, net of current portion	18,254	18,650
Financing lease liabilities, net of current portion	80	100
Total liabilities	32,764	36,430
Commitments and contingencies (Note 13)		
Stockholders' equity:		
Preferred stock, par value $0.001 per share, 10,000,000 shares authorized; zero shares issued and outstanding	—	—
Common stock, $0.001 par value per share; 190,000,000 shares authorized; 61,631,376 and 59,967,814 shares issued and outstanding as of March 31, 2025 and December 31, 2024, respectively.	62	60
Additional paid-in capital	487,706	484,077
Accumulated other comprehensive income	49	170
Accumulated deficit	(384,714)	(363,556)
Total stockholders' equity	103,103	120,751
Total liabilities and stockholders' equity	**$ 135,867**	**$ 157,181**

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

PYXIS ONCOLOGY, INC.

Condensed Consolidated Statements of Operations and Comprehensive Loss
(In thousands, except share and per share amounts)
(Unaudited)

	Three Months Ended March 31,	
	2025	**2024**
Revenues		
Royalty revenues	$ —	$ 8,146
Sale of royalty rights	—	8,000
Total revenues	—	16,146
Costs and operating expenses		
Cost of revenues	—	475
Research and development	17,044	13,029
General and administrative	5,870	8,247
Total costs and operating expenses	22,914	21,751
Loss from operations	(22,914)	(5,605)
Other income, net:		
Interest and investment income	1,241	1,550
Sublease income	515	799
Total other income, net	1,756	2,349
Net loss	**$ (21,158)**	**$ (3,256)**
Net loss per common share - basic and diluted	$ (0.35)	$ (0.06)
Weighted average shares of common stock outstanding - basic and diluted	61,048,948	51,289,284
Other comprehensive loss:		
Net unrealized loss on marketable debt securities	(121)	(123)
Other comprehensive loss	(121)	(123)
Comprehensive loss	**$ (21,279)**	**$ (3,379)**

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

PYXIS ONCOLOGY, INC.

Condensed Consolidated Statements of Stockholders' Equity
(In thousands, except share amounts)
(Unaudited)

	Common Stock		Additional Paid-In Capital	Accumulated Other Comprehensive (Loss) Income	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
Issuance of restricted common stock, net of tax withholdings	22,728	—	(2)	—	—	(2)
Issuance of common stock under employee stock purchase plan (ESPP)	29,619	—	—	—	—	—
Stock-based compensation	—	—	3,631	—	—	3,631
Net unrealized loss on marketable debt securities	—	—	—	(121)	—	(121)
Net loss	—	—	—	—	(21,158)	(21,158)
Balance at March 31, 2025	**61,631,376**	**$ 62**	**$ 487,706**	**$ 49**	**$ (384,714)**	**$ 103,103**

	Common Stock		Additional Paid-In Capital	Accumulated Other Comprehensive (Loss) 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 at-the-market (ATM) program, net of offering costs (See Note 14)	3,600,000	4	10,586	—	—	10,590
Issuance of pre-funded warrants in private placement, net of offering costs	—	—	7,700	—	—	7,700
Issuance of restricted common stock, net of tax withholdings	1,497,921	1	(197)	—	—	(196)
Stock options exercised	100,981	—	245	—	—	245
Stock-based compensation	—	—	4,320	—	—	4,320
Net unrealized loss on marketable debt securities	—	—	—	(123)	—	(123)
Net loss	—	—	—	—	(3,256)	(3,256)
Balance at March 31, 2024	**58,803,126**	**$ 59**	**$ 473,638**	**$ (60)**	**$ (289,481)**	**$ 184,156**

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

PYXIS ONCOLOGY, INC.

Condensed Consolidated Statements of Cash Flows (In thousands)
(Unaudited)

	Three Months Ended March 31,	
	2025	**2024**
Operating activities		
Net loss	$ (21,158)	$ (3,256)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	552	1,116
Stock-based compensation	3,631	4,320
Non-cash lease expense	193	164
Accretion of discount on marketable debt securities	(1,157)	(1,288)
Changes in operating assets and liabilities:		
Accounts receivable	—	(8,000)
Prepaid expenses and other current assets	(930)	(2,046)
Accounts payable	(2,013)	(1,365)
Accrued expenses and other current liabilities	(1,315)	(2,143)
Operating lease liabilities	(338)	(552)
Deferred revenues	—	(7,660)
Net cash used in operating activities	**(22,535)**	**(20,710)**
Investing activities		
Redemption of marketable debt securities	67,173	74,532
Purchase of marketable debt securities	(51,352)	(92,793)
Purchase of property and equipment	—	(237)
Net cash provided by (used in) investing activities	**15,821**	**(18,498)**
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	—	10,590
Tax withholding payments related to net settlement of restricted common stock	(2)	(196)
Proceeds from the exercise of stock options	—	245
Net cash provided by financing activities	**—**	**57,511**
Net (decrease) increase in cash, cash equivalents and restricted cash	(6,714)	18,303
Cash, cash equivalents and restricted cash at beginning of year	20,945	11,136
Cash, cash equivalents and restricted cash at end of period	**$ 14,231**	**$ 29,439**
Reconciliation of cash, cash equivalents and restricted cash:		
Cash and cash equivalents	$ 12,759	$ 27,967
Restricted cash	1,472	1,472
Total cash, cash equivalents and restricted cash shown in the statement of cash flows	**$ 14,231**	**$ 29,439**

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

PYXIS ONCOLOGY, INC.

Notes to Condensed Consolidated Financial Statements

(Unaudited)

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 condensed consolidated financial statements are unaudited. The unaudited condensed consolidated financial statements of the Company have been prepared in accordance with generally accepted accounting principles in the United States of America (GAAP) and follow the requirements of the Securities and Exchange Commission (SEC) for interim financial reporting. Accordingly, they do not include all of the information and disclosures required by U.S. GAAP for complete financial statements as certain footnotes or other financial information that are normally required by U.S. GAAP can be condensed or omitted. The unaudited condensed consolidated financial statements have been prepared on the same basis as the audited consolidated financial statements. The unaudited condensed consolidated financial statements include the accounts of the Company and its wholly-owned subsidiaries. The Company has no unconsolidated subsidiaries. All intercompany balances and transactions have been eliminated in consolidation. Any reference in these notes to applicable guidance is meant to refer to the authoritative U.S. GAAP as found in the Accounting Standards Codification (ASC) and Accounting Standards Updates (ASU) of the Financial Accounting Standards Board (FASB).

In the opinion of management, the unaudited condensed consolidated financial statements include all normal and recurring adjustments that are considered necessary for the fair statement of results for the interim periods. The results for the three months ended March 31, 2025 are not necessarily indicative of those expected for the year ending December 31, 2025 or for any future period. The condensed consolidated balance sheet as of December 31, 2024 included herein was derived from the audited consolidated financial statements as of that date. These unaudited condensed consolidated financial statements should be read in conjunction with the Company's audited consolidated financial statements and the related notes thereto for the year ended December 31, 2024, included in the Company's Annual Report on Form 10-K filed with the SEC on March 18, 2025 (Fiscal 2024 10-K).

Liquidity

As of March 31, 2025, the Company had an accumulated deficit of $384.7 million. The Company has incurred losses and negative cash flows from operations since inception, including net losses of $21.2 million and $3.3 million for the three months ended March 31, 2025 and 2024, respectively.

The Company has not generated any revenues from product sales to date and does not anticipate generating any revenues from product sales unless and until it successfully completes development and obtains regulatory approval for its current or any future product candidates. The Company expects that its operating losses and negative cash flows will continue for the foreseeable future as the Company continues to expand its research and development programs and develop its product candidates.

The Company currently expects that its existing cash, cash equivalents and short-term investments of $105.4 million as of March 31, 2025 will fund its operating expenses and capital requirements for at least twelve months from the date these unaudited condensed consolidated financial statements are issued. Additional funding may be necessary to fund future clinical and preclinical activities.

The Company plans to continue to fund its losses from operations and capital funding needs through public or private equity, convertible or debt financing or other sources. If the Company is not able to secure adequate additional funding, the Company may be forced to make reductions in spending, extend payment terms with suppliers, liquidate assets where possible, or suspend or curtail planned programs. Any of these actions could materially harm the Company's business, results of operations and future prospects.

Use of Estimates

The preparation of unaudited condensed consolidated financial statements in conformity with GAAP requires management to make estimates and assumptions that affect the reported amounts of assets, liabilities, expense and related disclosures. The Company regularly evaluates estimates and assumptions related to assets, liabilities, stock-based compensation, operating leases, assessment of the useful lives of property and equipment, marketable debt securities, fair value of intangible assets and research and development costs, including clinical trial accruals. The Company bases its estimates and assumptions on historical experience and on various other factors that it believes to be reasonable under the circumstances, the results of which form the basis for making judgments about the carrying values of assets and liabilities that are not readily apparent from other sources.

Actual results could differ from those estimates and there may be changes to management's estimates in future periods.

Risks and Uncertainties

The Company is subject to risks common to early 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 and 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.

Significant Accounting Policies

There have been no significant changes to the Company's significant accounting policies disclosed in "Note 2 – Basis of Presentation and Summary of Significant Accounting Policies" of the Company's Fiscal 2024 10-K.

Recently Issued 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. The Company is currently evaluating the impact of the new standard on the Company's consolidated financial statements and related disclosures.

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. Fair Value Measurements

The following tables present the financial instruments carried at fair value on a recurring basis as of March 31, 2025 and December 31, 2024, respectively, in accordance with the FASB ASC 820 hierarchy (in thousands):

	March 31, 2025			
	Level 1	Level 2	Level 3	Total
Cash equivalents				
Money market funds	$ 8,242	$ —	$ —	$ 8,242
Marketable debt securities				
U.S. Treasury securities	92,673	—	—	92,673
Total	**$ 100,915**	**$ —**	**$ —**	**$ 100,915**

	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 are classified as Level 1 assets. Marketable debt securities include investments in United States Treasury securities and are classified as Level 1 assets as they are valued using quoted prices in active markets. There were no transfers between Level 1 and Level 2 of the fair value hierarchy during the periods presented.

4. Marketable Debt Securities

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

	March 31, 2025			
	Amortized Cost	Unrealized Gains	Unrealized Losses	Aggregate Fair Value
Marketable debt securities				
U.S. Treasury securities	$ 92,624	$ 53	$ (4)	$ 92,673
Total	**$ 92,624**	**$ 53**	**$ (4)**	**$ 92,673**

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

As of March 31, 2025, the remaining contractual terms of the U.S. Treasury securities were less than 12 months.

To date, the Company has not recognized any allowances for credit losses or impairments in relation to its marketable securities as these securities are comprised of high credit quality, investment grade securities that the Company does 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 consists of the following (in thousands):

	Three Months Ended March 31,	
	2025	2024
Interest income	$ 84	$ 262
Accretion of discount, net	1,157	1,288
Total interest and investment income	**$ 1,241**	**$ 1,550**

5. Segment disclosure

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 Company's significant accounting policies disclosed in "Note 2 – Basis of Presentation and Summary of Significant Accounting Policies" of the Company's Fiscal 2024 10-K. The CODM assesses performance for the segment based on net loss, which is reported on the condensed consolidated statements of operations and comprehensive loss as net loss. The measure of segment assets is reported on the condensed consolidated balance sheets as total assets.

To date, the Company has not generated any product revenue. 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, seek regulatory approval.

As such, the CODM uses cash forecast models in deciding how 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 three months ended March 31, 2025 and 2024 (in thousands):

	Three Months Ended March 31,	
	2025	**2024**
Royalty revenue and sale of royalty rights	$ —	$ 16,146
Costs and operating expenses		
Cost of revenues	—	475
Research and development		
Clinical product candidates	5,146	3,974
Clinical product manufacturing	3,384	2,563
Personnel-related expenses excluding stock-based compensation	4,739	3,504
Stock-based compensation	1,122	678
Depreciation and amortization	473	315
Other (i)	2,180	1,995
Total research and development expenses	17,044	13,029
General and administrative		
Personnel-related expenses excluding stock-based compensation	1,491	1,918
Stock-based compensation	2,509	3,643
Professional and consultant fees	814	1,080
Other (ii)	1,056	1,606
Total general and administrative expenses	5,870	8,247
Total costs and operating expenses	22,914	21,751
Other segment income (iii)	1,756	2,349
Segment net loss	**$ (21,158)**	**$ (3,256)**
Reconciliation of profit or loss		
Adjustments and reconciling items	—	—
Consolidated net loss	**$ (21,158)**	**$ (3,256)**

(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 three months ended March 31, 2025 and 2024 consisted of $1.2 million and $1.6 million of interest and investment income and $0.5 million and $0.8 million of sublease income, respectively.

6. 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 as well as running royalties on net sales of licensed products at varying rates. The Company assessed the milestone and royalty events under the University License Agreement as of March 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 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 Extradomain-B Fibronectin ("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 Flexible Antibody Conjugation Technology ("FACT") Platform technology to develop and commercialize ADC product candidates directed to certain licensed targets, including micvotabart pelidotin 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 March 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.

Pursuant to the Biosion License Agreement, the Company paid an upfront license fee of $10.0 million in March 2022. Further, the Company is also obligated to pay future contingent payments including development, regulatory and commercial milestones as well as running royalties on net sales of licensed products and sublicensing revenues at varying rates. 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 March 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, Inc. ("Apexigen") and assumed all out-licensing agreements of Apexigen upon the Merger.

Simcere License and Collaboration Agreement

In December 2008, Epitomics, Inc. ("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.

Simcere is obligated to pay the Company milestone payments for achievement of certain clinical development milestones and low to high single-digit percentage royalties on net sales of suvemcitug in China until 15 years after the first commercial sale of suvemcitug. The Company assessed the milestone and royalty events involving Simcere as of March 31, 2025 and determined that no such amounts were receivable.

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 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 Company assessed the milestone and royalty events involving Mabwell as of March 31, 2025 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 Apexigen's antibody-discovery platform (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 and sublicense revenues by Toray or its affiliates. The Company assessed the milestone and royalty events involving Toray as of March 31, 2025 and determined that no such amounts were receivable.

7. Stockholders' Equity

Shelf Registration Statement and ATM Offering Program

On November 1, 2022, the Company filed a registration statement on Form S-3 with the SEC for the issuance of common stock, preferred stock, warrants, debt securities, rights and units up to an aggregate of $250.0 million. On November 14, 2022, the registration statement was declared effective by the SEC. The registration statement includes an ATM offering program for the sale of up to $125.0 million of shares of the Company's common stock.

During the three months ended March 31, 2025, the Company did not sell any shares of common stock under the ATM offering program. As of March 31, 2025, the Company had $106.2 million of remaining capacity available under the ATM facility.

Preferred Stock

There were no issued and outstanding shares of preferred stock as of March 31, 2025 and December 31, 2024.

Common Stock

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:

	March 31, 2025	December 31, 2024
Stock options outstanding	12,228,168	9,711,075
Restricted stock units outstanding	2,421,954	2,463,601
Shares reserved for future issuance	5,382,829	4,295,342
Pre-Funded Warrant Shares	—	1,611,215
Apexigen replacement warrants	1,003,191	1,003,191
Employee stock purchase plan	653,777	573,316
Total	**21,689,919**	**19,657,740**

8. Common Stock Warrants

Apexigen Replacement Warrants

Upon the Merger, 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 approximately 5,815,613 Apexigen warrants with approximately 1,003,191 Pyxis Oncology warrants.

As of March 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 the fifth anniversary of July 29, 2022, or earlier upon redemption or liquidation. Each of the warrants with an exercise price of $8.12 per share and $10.14 per share will expire on July 30, 2028, or earlier upon redemption or liquidation.

Private Placement Warrants

In February 2024, the Company received gross proceeds of $50 million via private placement with certain institutional and accredited investors 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.

9. Stock-Based Compensation

The Company grants stock-based incentive awards pursuant to the 2021 Equity and Incentive Plan (the '2021 Plan'), 2019 Equity Incentive Plan (the '2019 Plan'), Apexigen Equity Incentive Plans (the 'Apexigen Plan') and the 2022 Equity Inducement Plan (the '2022 Inducement Plan'). As of March 31, 2025, there were 4,072,703 shares, 132,435 shares, 764,154 shares and 413,537 shares available for future issuance under the 2021 Plan, 2019 Plan, Apexigen Plan and 2022 Inducement Plan, respectively.

Stock Options

The following table summarizes stock option activity for the three months ended March 31, 2025 (in thousands, except share and per share amounts):

	Number of Options	Weighted Average Exercise Price	Weighted Average Remaining Contractual Term (Years)	Aggregate Intrinsic Value
Outstanding at January 1, 2025	9,711,075	$ 5.04	8.2	$ 44
Granted	3,104,372	0.98		
Forfeited	(587,279)	2.01		
Outstanding at March 31, 2025	**12,228,168**	**$ 4.16**	**8.2**	**$ 21**
Options exercisable March 31, 2025	**4,379,232**	**$ 7.00**	**6.2**	**$ 21**

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 $0.98 per share as of March 31, 2025. The aggregate intrinsic value of stock options exercised during the three months ended March 31, 2025 and 2024 was $0 and $0.2 million, respectively, as no stock options were exercised during the three months ended March 31, 2025.

The Company has an aggregate $11.0 million of gross unrecognized stock-based compensation expense as of March 31, 2025, remaining to be amortized over a weighted average period of 1.94 years.

The weighted-average grant-date fair value of options granted during the three months ended March 31, 2025 and 2024, was $0.78 and $2.32 per share, respectively, and was calculated using the following key input assumptions in the Black-Scholes option-pricing model:

	Three Months Ended March 31,	
	2025	2024
Expected volatility	93.920% - 99.910%	99.41% - 102.27%
Risk-free interest rate	3.960% - 4.450%	4.06% - 4.23%
Expected dividend yield	0.00%	0.00%
Expected term (in years)	5.00 - 6.08	5.00 - 6.08

Restricted Stock Units

The following table summarizes restricted stock units activity for the three months ended March 31, 2025:

	Number of Shares	Weighted Average Grant Date Fair Value
Outstanding at January 1, 2025	2,533,650	$ 3.26
Forfeited	(80,804)	3.18
Vested and settled	(30,892)	3.73
Outstanding at March 31, 2025[(1)]	**2,421,954**	**$ 3.26**

[(1)] Includes 361,263 RSUs which are vested but not settled at March 31, 2025.

During the three months ended March 31, 2025, the Company issued 22,728 shares of its common stock from the settlement of 30,892 restricted common units, with the remaining shares withheld for taxes. The Company has an aggregate $5.04 million of gross unrecognized restricted stock-based compensation expense as of March 31, 2025, remaining to be amortized over a weighted average period of 2.4 years.

Summary of Stock-Based Compensation Expense

The following table summarizes the total stock-based compensation expense for the three months ended March 31, 2025 and 2024, respectively (in thousands):

	Three Months Ended March 31,	
	2025	2024
General and administrative	$ 2,509	$ 3,642
Research and development	1,122	678
Total	**$ 3,631**	**$ 4,320**

2021 Employee Stock Purchase Plan ("2021 ESPP")

The Company has the 2021 ESPP in force. The Company issued 29,619 shares under the 2021 ESPP during the three months ended March 31, 2025. The company did not issue any shares during the three months ended March 31, 2024. As of March 31, 2025, 653,777 shares are available for issuance under the 2021 ESPP.

10. Operating Leases

The Company leases its office and facilities in Boston, Massachusetts under a non-cancellable operating lease agreement that continues through December 31, 2032. Cash paid for operating lease liabilities were $0.8 million and $1.1 million during the three months ended March 31, 2025 and 2024, respectively, which is included in operating cash flows within the accompanying unaudited condensed consolidated statements of cash flows.

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

	Three Months Ended March 31,	
	2025	2024
Lease cost		
Operating lease cost	$ 672	$ 663
Variable lease cost	55	539
Total operating lease cost	**$ 727**	**$ 1,202**

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 March 2026. The Company recognized sublease income of $0.5 million and $0.8 million for the three months ended March 31, 2025 and 2024, respectively.

11. Income Taxes

The Company's effective tax rate from continuing operations was 0% for the three months ended March 31, 2025 and 2024. The Company has not recorded a federal income tax provision for the three months ended March 31, 2025 and 2024. The Company recorded a nominal state and local income tax provision for the three months ended March 31, 2025 and 2024.

The Company assesses the realizability of the deferred tax assets at each reporting date. The Company continues to maintain a full valuation allowance for its U.S. federal and state deferred tax assets, which significantly consists of net operating losses and tax credits. If

certain substantial changes in the entity's ownership occur, there may be an annual limitation on the amount of the carryforwards that can be utilized. The Company will continue to assess the need for a valuation allowance on its deferred tax assets.

12. Net Loss per Common Share

The following potentially dilutive securities have been excluded from the calculation of diluted net loss per common share due to their anti-dilutive effect:

	March 31,	
	2025	**2024***
Stock options outstanding	12,228,168	6,892,951
Restricted stock units outstanding	2,421,954	3,110,597
Shares reserved for future issuance	5,382,829	1,649,038
Apexigen replacement warrants	1,003,191	1,003,191
Employee stock purchase plan	653,777	675,485
Total	**21,689,919**	**13,331,262**

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

13. 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.

Item 2. 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 (1) unaudited condensed consolidated financial statements and related notes thereto included elsewhere in this Quarterly Report on Form 10-Q, and (2) consolidated financial statements and related notes and management's discussion and analysis of financial condition and results of operations for the fiscal year ended December 31, 2024, included in our Fiscal 2024 10-K. Unless the context requires otherwise, references in this Quarterly Report on Form 10-Q to "Pyxis Oncology," the "Company," "we," "us," and "our" refer to Pyxis Oncology, Inc. and its subsidiaries.

Forward-Looking Statements

This Quarterly Report on Form 10-Q contains "forward-looking statements" within the meaning of Section 27A of the Securities Act of 1933, as amended, or the Securities Act, and Section 21E of the Securities Exchange Act of 1934, as amended. These statements are often identified by the use of words 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. We cannot assure you that the events and circumstances reflected in the forward-looking statements will be achieved or occur and actual results could differ materially from those expressed or implied by these forward-looking statements.

Factors that could cause or contribute to such differences include, but are not limited to, those identified herein, and those discussed in the section titled "Risk Factors" set forth in Part II, Item 1A. of this Quarterly Report on Form 10-Q and in our other filings with the SEC. These risks are not exhaustive. New risk factors emerge from time to time and it is not possible for our management to predict all risk factors, nor can we assess the impact of all factors on our business or the extent to which any factor, or combination of factors, may cause actual results to differ materially from those contained in any forward-looking statements. In addition, statements that "we believe" and similar statements reflect our beliefs and opinions on the relevant subject. These statements are based upon information available to us as of the date of this Quarterly Report on Form 10-Q, and while 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 an exhaustive inquiry into, or review of, all potentially available relevant information. These statements are inherently uncertain and investors are cautioned not to unduly rely upon these statements. Except as required by law, we undertake no obligation to update any forward-looking statements to reflect events or circumstances after the date of such statements.

Overview

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

Our product candidate, micvotabart pelidotin, formerly referred to as PYX-201, is an investigational novel antibody-drug conjugate (ADC) that uniquely targets Extradomain-B Fibronectin (EDB+FN), a non-cellular structural component within the tumor extracellular matrix (ECM). The tumor ECM is a complex network of fibrous proteins and molecules with unique composition that play an important role in cell development and tumor growth and in some instances, in supporting metastasis. The fibronectin strands within the ECM give the tumor shape and support the clustering of tumor cells.

Fibronectin is a key component of the ECM and its downstream signaling pathways regulate cell adhesion, migration, differentiation and wound healing. EDB+FN is an alternatively spliced form of fibronectin. EDB+FN regulates blood vessel morphogenesis, which provides the tumor access to nutrition and oxygen, and provides a means to remove waste and a pathway for cells to metastasize. 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 large variety of solid tumor tissues. EDB+FN is also found to be expressed during embryogenesis.

By targeting EDB+FN, our goal is to destabilize the barrier that protects, feeds, and provides structure to the tumor, in addition to killing tumor cells directly while sparing healthy cells.

Our ADC, micvotabart pelidotin, consists of human Immunoglobulin G1 (IgG1) and is site-specifically conjugated with a cleavable linker and a microtubule inhibitor (optimized auristatin) payload. Micvotabart pelidotin is designed to optimize linker stability to enable delivery of the next generation auristatin payload that can be cleaved and released in the ECM and penetrate through the tumor cell membrane to kill tumor cells directly without the need for cell surface antigen-mediated internalization of the ADC. Unlike conventional ADCs which bind to the tumor cell surface antigens, micvotabart pelidotin is designed to deliver the auristatin payload to the extracellular environment and release the free payload to kill tumor cells as well as activated fibroblasts and vascular endothelial cells that support tumor growth. We believe the free payload kills the tumor cells through a combination of bystander effect directly killing highly proliferative cells and through stimulation of the local immune cells.

We conducted a Phase 1 dose escalation (Part 1) study, referred to as PYX-201-101 to evaluate micvotabart pelidotin monotherapy in patients with advanced solid tumors predicted to express EDB+FN. A total of 80 patients were dosed across nine solid tumor types during the PYX-201-101 (Part 1) study. In November 2024, we announced positive preliminary data from Part 1 of our Phase 1 dose escalation study of PYX-201-101 with a data cut-off date of October 4, 2024.

The recurrent and metastatic head and neck squamous cell carcinoma (R/M HNSCC) patients were observed to show the strongest tumor regression response during this Part 1 phase of the study. Among the six efficacy evaluable patients with R/M HNSCC at the therapeutically active dose response range of 3.6 mg/kg – 5.4 mg/kg IV Q3W, the study achieved a confirmed 50% objective response rate (ORR) based on RECIST 1.1 criteria including one confirmed complete response (cCR) and two confirmed partial responses (cPRs) and yielded a disease control rate (DCR) of 100%. These six heavily pre-treated patients with R/M HNSCC had either HPV-positive (HPV+) or HPV-negative (HPV-) tumors and a median of four prior lines of systemic therapy in the advanced disease setting.

While we observed evidence of tumor regression across all nine solid tumor types that were enrolled in the Phase 1 Part 1 dose escalation study, dose responses were most pronounced in six solid tumor types of interest, including R/M HNSCC, hormone receptor positive and human epidermal growth factor receptor 2 negative (HR+/HER2-) breast cancer, locally advanced / metastatic non-small cell lung cancer (NSCLC), ovarian cancer, sarcoma and triple negative breast cancer (TNBC), at the therapeutically active dose response range of 3.6 mg/kg – 5.4 mg/kg IV Q3W. Micvotabart pelidotin achieved a 26% ORR (n=31) in patients with these six solid tumor types dosed at 3.6 mg/kg – 5.4 mg/kg IV Q3W.

Recent Preclinical Data

Recently, we presented new preclinical data at the 2025 American Association for Cancer Research (AACR), Annual Meeting in Chicago. We observed broad anti-tumor activity for micvotabart pelidotin across ten solid tumor indications in PDX models, attributed to EDB+FN target expression, proteolytic activity for micvotabart pelidotin linker cleavage and tumor responsiveness to the optimized cytotoxic Auristatin0101 payload. The preclinical data is summarized below:

- 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 micvotabart pelidotin (tumor volume reached 0mm^3 for at least two consecutive measurements) were found across several tumor indications, consistent with previous analysis.
- micvotabart pelidotin was observed to be well-tolerated (3mg/kg, Q4Dx4).

We also performed differential gene expression analysis, which enabled us to identify gene signatures linked to anti-tumor activity consistent with our extracellular 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 shows upregulation of certain proteases that may contribute to increased linker cleavage and subsequent increased anti-tumor activity for micvotabart pelidotin, supporting our extracellular hypothesis.

We also conducted preclinical studies combining a mouse analog of micvotabart pelidotin with anti-PD-1 therapy. The combination of a mouse analog of micvotabart pelidotin 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 micvotabart pelidotin with anti-PD-1 therapy is summarized below:

- Monotherapy of mouse analog of micvotabart pelidotin inhibited dose-dependent tumor outgrowth of EDB+FN expressing EMT6 tumors and was well-tolerated at 6 mg/kg.
- The mouse analog of micvotabart pelidotin 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 micvotabart pelidotin (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 micvotabart pelidotin in combination with anti-PD1 therapy induced lasting immunological memory, enhancing tumor clearance and protecting against tumor recurrence in rechallenged mice.

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

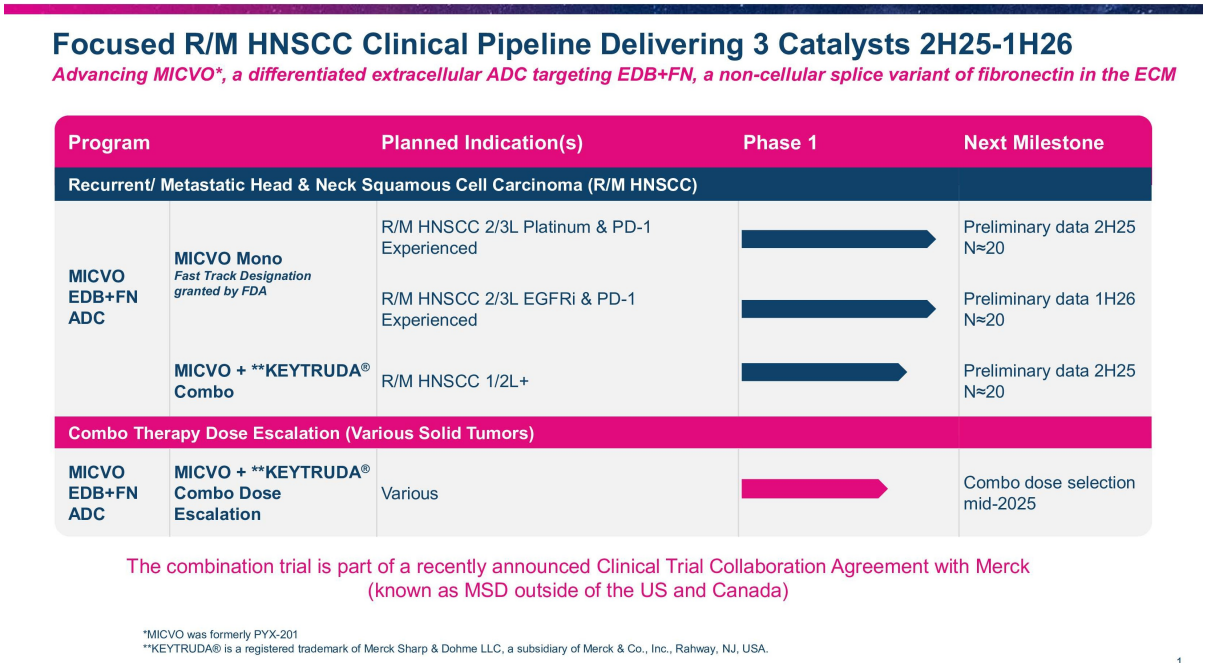
We believe the totality of our preliminary clinical and preclinical data supports further development of both micvotabart pelidotin monotherapy expansion and combination therapy trials.

Our Clinical Pipeline

In February 2025, the U.S. Food and Drug Administration (FDA) granted Fast Track Designation to micvotabart pelidotin 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.

Based on the strength of the HNSCC signal that emerged in the Part 1 dose escalation study of PYX-201-101, we have decided to prioritize our resources to focus the next stage of development on characterizing the R/M HNSCC efficacy signal.

The following table summarizes our clinical pipeline:



In early January 2025, we initiated the dose expansion phase (Part 2) of the PYX-201-101 monotherapy study with a prioritized focus to confirm the preliminary efficacy signals in R/M HNSCC seen in Part 1. Currently, we are enrolling and dosing patients for two monotherapy R/M HNSCC expansion cohorts. The Part 2 dose expansion phase includes the following two R/M HNSCC cohorts across sites in the United States (US), European Union (EU) and other countries:

- micvotabart pelidotin 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. We expect to enroll approximately 20 patients in this expansion cohort at the 5.4 mg/kg IV Q3W dose, a pharmacologically active dose identified during Part 1 of this trial where we have seen clinically meaningful anti-tumor activity with manageable safety. We anticipate having preliminary data in the second half of 2025; and
- micvotabart pelidotin 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 also at the 5.4 mg/kg IV Q3W dose and anticipate having preliminary data in the first half of 2026.

We are planning to hold a discussion with the FDA to align on our approach for finding the optimal monotherapy dose, as required under *Pro*ject Optimus and expect the dose optimization phase to commence in 2026.

In November 2024, we announced a Clinical Trial Collaboration and Supply Agreement with Merck & Co, Inc. or Merck (known as MSD outside of the US and Canada), for a Pyxis Oncology-sponsored study of micvotabart pelidotin in combination with Merck's anti-PD-(L)1 therapy, KEYTRUDA® (pembrolizumab).

In early January 2025, we initiated the Phase 1/2 combination study with KEYTRUDA® now called PYX-201-102 and are actively recruiting patients in this study. 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 micvotabart pelidotin 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, sarcoma and locally advanced or metastatic TNBC, are eligible to enroll.

We initiated Part 1 dose escalation phase of PYX-201-102 covering multiple tumor types with an aim to identify the Recommended Phase 2 Dose (RP2D) of micvotabart pelidotin in combination with pembrolizumab. Currently, we are enrolling and dosing patients to clear the three doses that will be tested in combination with pembrolizumab. During Part 1 dose escalation, we anticipate testing a fixed dose of pembrolizumab in combination with 3 different doses of micvotabart pelidotin ranging from 3.6 mg/kg – 5.4 mg/kg IV Q3W. Pembrolizumab (standard dose at 200 mg IV) will be given with escalating doses of micvotabart pelidotin with a starting dose of 3.6 mg/kg IV every 3 weeks (Q3W). Upon clearance of the initial dose level of 3.6 mg/kg IV Q3W by the Dose Escalation and Steering Committee (DESC), and depending on observed safety data, we may escalate to 4.4 mg/kg IV Q3W of micvotabart pelidotin with 200 mg IV of pembrolizumab, with a potential of dosing at 5.4 mg/kg IV Q3W of micvotabart pelidotin with 200 mg IV of pembrolizumab. We aim to select a dose of micvotabart pelidotin in combination with pembrolizumab by mid-year 2025, which will guide our discussion with the FDA about potential RP2D for further combination study.

Concurrently to the Part 1 dose escalation and assuming each dose clears the escalation step, the Phase 1/2 combination study will evaluate micvotabart pelidotin and pembrolizumab in patients with 1L and 2L+ R/M HNSCC. We expect to enroll approximately 20 patients, which will be enrolled for each dose in their respective backfill cohort upon clearance of the dose by the DESC. Pembrolizumab (standard dose at 200 mg IV) will be given with escalating doses of micvotabart pelidotin with a starting dose of 3.6 mg/kg IV every 3 weeks, followed by dose of 4.4 mg/kg IV Q3W, if DESC clears it and then a dose of 5.4 mg/kg IV Q3W, if DESC clears it. We anticipate having preliminary data on at least a subset of these R/M HNSCC patients in the second half of 2025. Timing of data availability from the full recruitment and dosing of R/M HNSCC patients is dependent on the timing of activation of additional clinical trial sites and patient enrollment. Further guidance on anticipated timing of the full preliminary data readout will be provided in mid-year of 2025.

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 $21.2 million and $3.3 million for the three months ended March 31, 2025 and 2024, respectively. As of March 31, 2025, we had an accumulated deficit of $384.7 million, net equity of $103.1 million, and cash, cash equivalents and short-term investments of $105.4 million. We expect to continue to incur significant expenses and operating losses for the foreseeable future. We expect that our expenses and capital expenditures will increase substantially in connection with our ongoing activities. Our operations to date have been financed primarily through sales of convertible preferred stock and sale of equity securities and additional funding may be necessary to fund future clinical and preclinical activities.

Components of Our Results of Operations

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, 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.

Operating Expenses

Cost of Revenues

The components of our cost of revenues are expenses directly attributable to revenues. During the three months ended March 31, 2025, the Company has not incurred any costs with respect to revenue.

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 candidate on a program-specific basis, investigator grants, sponsored research, and any other third party expenses directly attributable to the development of the product candidate;
- costs of acquiring, developing, and 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 activities that are directly attributable to the development of the product candidate.

Unallocated costs include:

- employee-related expenses for research and development personnel, including salaries, bonus, payroll taxes, related benefits, severance and other staff-related expenses;
- stock-based compensation expenses for employees engaged in research and development activities;
- facilities and other costs, which include allocated expenses for rent and maintenance of facilities, depreciation of leasehold improvements and equipment, laboratory supplies, third party cost for discovery research and the cost of consultants who assist with our research and development and costs related to contract manufacturing, but are not allocated to a specific program.

We expense research and development costs as incurred. Non-refundable advance payments that we make for goods or services to be received in the future for use in research and development activities are recorded as prepaid expenses. The prepaid amounts are expensed as the related goods are delivered or the services are performed, or when it is no longer expected that the goods will be delivered, or the services rendered.

We expect that our research and development expenses will increase substantially in connection with our ongoing and planned preclinical and clinical development activities in the near term and in the future. The successful development of our product 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 any of our product candidate and we may never succeed in obtaining regulatory approval for any of 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 income under our sublease.

Results of Operations

Comparison of the Three Months Ended March 31, 2025 and 2024

The following table summarizes our results of operations for the three months ended March 31, 2025 and 2024 (in thousands):

	Three Months Ended March 31,		
	2025	**2024**	**Change**
Revenues			
Royalty revenues	$ —	$ 8,146	$ (8,146)
Sale of royalty rights	—	8,000	(8,000)
Total revenues	—	16,146	(16,146)
Costs and operating expenses			
Cost of revenues	—	475	(475)
Research and development	17,044	13,029	4,015
General and administrative	5,870	8,247	(2,377)
Total costs and operating expenses	22,914	21,751	1,163
Loss from operations	(22,914)	(5,605)	(17,309)
Other income, net			
Interest and investment income	1,241	1,550	(309)
Sublease income	515	799	(284)
Total other income, net	1,756	2,349	(593)
Net loss	**$ (21,158)**	**$ (3,256)**	**$ (17,902)**

Revenues

Revenues for the quarter ended March 31, 2025, were $0, compared to $16.1 million for the quarter ended March 31, 2024. In March 2024, we entered into the settlement agreement with Novartis, pursuant to which we transferred our rights to future royalties on the net sales of Beovu® to Novartis for a one-time amount of $8.0 million. Novartis also agreed to forgo its right to reclaim royalties previously paid of $8.1 million to us and Apexigen.

Costs and Operating Expenses

Research and Development Expenses

The following table summarizes our research and development expenses for the three months ended March 31, 2025 and 2024 (in thousands):

	Three Months Ended March 31,		
	2025	**2024**	**Change**
Program-specific costs:			
Micvotabart pelidotin	$ 7,098	$ 4,357	$ 2,741
PYX-106	936	1,989	(1,053)
Other program costs	496	191	305
Total program costs	**8,530**	**6,537**	**1,993**
Unallocated costs:			
Personnel-related expenses including stock-based compensation	5,861	4,182	1,679
Other costs	2,653	2,310	343
Total research and development expenses	**$ 17,044**	**$ 13,029**	**$ 4,015**

Research and development expenses increased by $4.0 million, from $13.0 million for the three months ended March 31, 2024 to $17.0 million for the three months ended March 31, 2025.

Micvotabart Pelidotin program-specific research and development costs increased by $2.7 million, primarily due to a $1.1 million increase in contract manufacturing costs due to the timing of manufacturing runs for micvotabart pelidotin, $0.8 million increase in clinical trial related expenses related to our dose expansion phase (Part 2) of the PYX-201-101 monotherapy study and trial set up costs related to combination study, PYX-201-102, and $0.4 million increase in preclinical and translation work to support clinical development work of micvotabart pelidotin .

PYX-106 program-specific research and development costs decreased by $1.0 million as we paused the clinical development of PYX-106-101 in December 2024.

Unallocated research and development increased by $2.0 million from $6.5 million for the three months ended March 31, 2024 to $8.5 million for the three months ended March 31, 2025. This increase was primarily due to severance cost of $1 million due to the reduction in workforce announced in March 2025 and increase in stock based compensation by $0.4 million.

General and Administrative Expenses

The following table summarizes our general and administrative expenses for the three months ended March 31, 2025 and 2024 (in thousands):

	Three Months Ended March 31,		
	2025	2024	Change
Personnel-related expenses including stock-based compensation	$ 4,000	$ 5,561	$ (1,561)
Professional and consultant fees	814	1,080	(266)
Facilities, insurance and other costs	1,056	1,606	(550)
Total general and administrative expenses	**$ 5,870**	**$ 8,247**	**$ (2,377)**

General and administrative expenses decreased by $2.4 million, from $8.3 million for the three months ended March 31, 2024 to $5.9 million for the three months ended March 31, 2025. The decrease was primarily related to decrease in stock-based compensation by $1.2 million, decrease in professional and consultant fees and lower corporate insurance cost.

Other Income, Net

Other income, net for the three months ended March 31, 2025 and 2024 was $1.8 million and $2.3 million, respectively. The decrease was primarily due to a decrease in interest and investment income as compared to the previous quarter.

Liquidity and Capital Resources

We had cash, cash equivalents and short-term investments of $105.4 million as of March 31, 2025. For the three months ended March 31, 2025 and 2024, we had net losses of $21.2 million and $3.3 million, respectively. As of March 31, 2025, we had an accumulated deficit of $384.7 million.

On November 1, 2022, we filed a registration statement on Form S-3 with the SEC for the issuance of common stock, preferred stock, warrants, debt securities, rights and units up to an aggregate of $250.0 million. On November 14, 2022, the registration statement was declared effective by the SEC. The registration statement includes an at-the-market, or ATM, offering program for the sale of up to $125.0 million of shares of our common stock. As of March 31, 2025, we had $106.2 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 clinical trials for our product candidate in development. 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 micvotabart pelidotin;
- the manufacture of drug products and drug substance for micvotabart pelidotin;
- 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 any of our product candidates for which we receive marketing licensure;
- our ability to maintain our current licenses and research and development programs and to establish new collaboration arrangements;
- the costs involved in prosecuting, maintaining and enforcing patent and other intellectual property rights;
- the costs of maintaining, expanding and protecting our intellectual property portfolio;
- the cost and timing of regulatory licenses; 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 periods presented (in thousands):

	Three Months Ended March 31,	
	2025	**2024**
Net cash used in operating activities	$ (22,535)	$ (20,710)
Net cash provided by (used in) investing activities	15,821	(18,498)
Net cash provided by financing activities	—	57,511
Net (decrease) increase in cash, cash equivalents and restricted cash	**$ (6,714)**	**$ 18,303**

Operating Activities

During the three months ended March 31, 2025, net cash used in operating activities was $22.5 million, which consisted of our net loss of $21.2 million and a net change in our operating assets and liabilities of $4.6 million, partially offset by non-cash charges of $3.2 million. The non-cash charges of $3.2 million was primarily due to $3.6 million of stock-based compensation, $0.6 million of depreciation and amortization expenses, offset by $1.2 million related to accretion of discounts on marketable debt securities. The net change in our operating assets and liabilities was primarily due to decrease in accounts payable by $2.0 million, accrued expenses and other current liabilities by $1.3 million and reduction in prepaid expenses by $0.9 million primarily related to the timing of vendor payments and services performed related to our ongoing clinical trials.

During the three months ended March 31, 2024, net cash used in operating activities was $20.7 million, which consisted of our net loss of $3.3 million and a net change in our operating assets and liabilities of $21.8 million, partially offset by non-cash charges of $4.3 million. The non-cash charges of $4.3 million was primarily due to $4.3 million of stock-based compensation, $1.1 million of depreciation and amortization expense, offset by $1.3 million of accretion of discounts on marketable debt securities. The net change in our operating assets and liabilities was primarily due to an increase in accounts receivable of $8.0 million and a decrease in deferred revenues of $7.7 million related to the Settlement Agreement with Novartis, and reductions in prepaid expenses and other current assets and accounts payable driven primarily by the timing of payments and services performed related to our ongoing clinical trials.

Investing Activities

During the three months ended March 31, 2025, net cash provided by investing activities was $15.8 million, which consisted primarily of redemption of marketable debt securities of $67.2 million, partially offset by purchase of marketable debt securities of $51.4 million.

During the three months ended March 31, 2024, net cash used in investing activities was $18.5 million, which consisted primarily of purchases of marketable debt securities of $92.8 million and purchases of property and equipment of $0.2 million, partially offset by redemption of marketable debt securities of $74.5 million.

Financing Activities

During the three months ended March 31, 2025, there were no major financing activities.

During the three months ended March 31, 2024, net cash provided by financing activities was $57.5 million, which consists primarily of net proceeds of $46.9 million from the Private Placement which closed in February 2024 and net proceeds of $10.6 million from our ATM program.

Outlook

As of March 31, 2025, we had approximately $105.4 million in cash, cash equivalents and short-term investments. We believe that our cash, cash equivalents and short-term investments as of March 31, 2025, will be sufficient to fund our operations into the second half of 2026. However, we have based this estimate on assumptions that may prove to be wrong, and our operating plan may change as a result of many factors currently unknown to us. In addition, we could utilize our available capital resources sooner than we expect.

Contractual Obligations and Commitments

Operating lease obligation

We lease an office and laboratory space in Boston, Massachusetts with lease payments that continue through December 31, 2032, and have scheduled rent increases each year of 3%. Additionally, we sublease 17,729 square feet of office and laboratory space in the building located at 321 Harrison Avenue, Boston, Massachusetts. The remaining contractual fixed lease payments, net of sublease payments and tenant improvement allowance, over the term of the lease aggregate to $26.4 million. The operating lease obligation is discussed in Note 10. Leases to our unaudited condensed consolidated financial statements included in Part I, Item 1 of this Quarterly Report on Form 10-Q for further information.

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 revenues 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 6. Licensing Agreements, to our unaudited condensed consolidated financial statements included in Part I, Item 1 of this Quarterly Report on Form 10-Q 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 unaudited condensed consolidated financial statements are prepared in accordance with generally accepted accounting principles in the United States. The preparation of our unaudited condensed 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.

There have been no significant changes to our critical accounting policies and estimates as compared to those described in “Note 2 – Summary of Significant Accounting Policies” to our audited financial statements set forth in our Fiscal 2024 10-K.

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 to our unaudited condensed consolidated financial statements included in Part I, Item 1 of this Quarterly Report on Form 10-Q.

Jumpstart Our Business Startups Act

The Jumpstart Our Business Startups Act of 2012, or the JOBS Act, permits an “emerging growth company” to take advantage of an extended transition period to comply with new or revised accounting standards. We are an “emerging growth company,” as defined in the JOBS Act. Thus, an emerging growth company can delay the adoption of certain accounting standards until those standards would otherwise apply to private companies.

We 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 3. 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 4. Controls and Procedures.

Evaluation of Disclosure Controls and Procedures

Our management, with the participation of our Chief Executive Officer and Chief Financial Officer, has evaluated the effectiveness of our disclosure controls and procedures as of the end of the period covered by this Quarterly Report on Form 10-Q. The term "disclosure controls and procedures," as defined in Rules 13a-15(e) and 15d-15(e) under the Securities Exchange Act of 1934, as amended, or the Exchange Act, means controls and other procedures of a company that are designed to ensure that information required to be disclosed by a company in the reports that it files or submits under the Exchange Act is recorded, processed, summarized, and reported within the time periods specified in the SEC's rules and forms. Disclosure controls and procedures include, without limitation, controls and procedures designed to provide reasonable assurance that information required to be disclosed by a company in the reports that it files or submits under the Exchange Act is accumulated and communicated to the company's management, including its principal executive and principal financial officers, or persons performing similar functions, as appropriate to allow timely decisions regarding required disclosure. Based on such evaluation, our Chief Executive Officer and Chief Financial Officer concluded that, as of the end of the period covered by this Quarterly Report on Form 10-Q, our disclosure controls and procedures were effective at the reasonable assurance level.

Changes in Internal Control Over Financial Reporting

There were no changes in our internal control over financial reporting identified in connection with the evaluation required by paragraph (d) of Exchange Act Rules 13a-15 or 15d-15 that occurred during the period covered by this Quarterly Report on Form 10-Q that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

Inherent Limitations on Effectiveness of Controls and Procedures

Our management, including our Chief Executive Officer and Chief Financial Officer, believes that our disclosure controls and procedures and internal control over financial reporting are designed to provide reasonable assurance of achieving their objectives and are effective at the reasonable assurance level. However, management does not expect that our disclosure controls and procedures or our internal control over financial reporting will prevent or detect 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. 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 the company have been detected. The design of any system of controls also is based in part upon certain assumptions about the likelihood of future events, and there can be no assurance that any design will succeed in achieving its stated goals under all potential future conditions. Over time, controls may become inadequate because of changes in conditions, or the degree of compliance with the policies or procedures may deteriorate. Because of the inherent limitations in a cost-effective control system, misstatements due to error or fraud may occur and not be detected.

PART II—OTHER INFORMATION

Item 1. Legal Proceedings.

From time to time, we may become involved in various legal proceedings that arise in the ordinary course of our business. We are not currently a party to any material legal proceedings, and are not aware of any pending or threatened legal proceeding against us that we believe could have an adverse effect on our business, operating results or financial condition.

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 Form 10-Q, including our financial statements and related notes appearing in this Form 10-Q. 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 Form 10-Q 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.

We are a clinical stage oncology company with a limited operating history. Since our inception, we have incurred significant operating losses. We reported net losses of $21.2 million and $3.3 million for the three months ended March 31, 2025 and 2024, respectively. As of March 31, 2025, we had an accumulated deficit of $384.7 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 existing product candidate and successfully completing development of 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 micvotabart pelidotin;
- 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 will require substantial additional capital to finance our operations. If we are unable to raise such capital when needed, or on acceptable terms, we may be forced to delay, reduce or eliminate one or more of our research and product development programs or future commercialization efforts.

The development of biopharmaceutical products, including conducting preclinical studies and clinical trials, is a very time-consuming, expensive and uncertain process that takes years to complete. Our operations have consumed substantial amounts of cash since inception, and we expect our expenses to increase in connection with our ongoing and planned activities, particularly as we continue our clinical trials for micvotabart pelidotin. We currently expect that our existing cash, cash equivalents and short-term investments of $105.4 million as of March 31, 2025, will fund our projected operating expenses and capital requirements into the second half of 2026. 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 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 product candidates 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.

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

If we are required to conduct additional clinical trials or other testing of our product 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.

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

Our product development costs also will increase if we experience delays in preclinical studies or clinical trials or in obtaining marketing 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, micvotabart pelidotin, which is in the early stages of clinical development. If micvotabart pelidotin 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 micvotabart pelidotin. Our future success is substantially dependent on our ability to successfully initiate and complete clinical development for, obtain regulatory licensure for, and successfully commercialize micvotabart pelidotin, 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 micvotabart pelidotin 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 micvotabart pelidotin 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 micvotabart pelidotin 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 micvotabart pelidotin 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 micvotabart pelidotin. 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 micvotabart pelidotin, our financial position will be materially adversely affected, and we may not be able to generate sufficient revenues to continue our business.

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 micvotabart pelidotin.

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 micvotabart pelidotin, 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 similar product candidates 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 product candidates proceeding through preclinical studies and clinical trials. Product candidates in later stages of clinical trials may fail to show the desired safety, purity, and potency profile despite having progressed successfully through preclinical studies and/or initial clinical trials. Likewise, early, smaller-scale clinical trials may not be predictive of eventual safety, purity and potency in large-scale pivotal clinical trials. Many companies in the biopharmaceutical industry have suffered significant setbacks in advanced clinical trials due to lack of potency, insufficient durability of potency or unacceptable safety issues, notwithstanding promising results in earlier trials. Most product candidates that commence preclinical studies and clinical trials are never approved or licensed for commercialization. In addition,

preclinical studies or clinical trials we conduct may contradict, undermine or otherwise not replicate or advance the results of the research programs and preclinical studies that were completed prior to our in-licensing or acquisition of product candidates, which may materially and adversely affect our business, results of operations and prospects.

Additionally, our PYX-201-101 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 November 2024, we announced preliminary data from our Phase 1 clinical trial of micvotabart pelidotin. 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.

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

Our business depends not only on our ability to successfully develop, obtain regulatory licensure for, and commercialize our product candidate, but to continue to generate new product candidates through our FACT Platform and APXiMAB Platform (the Platforms). Any failures or setbacks involving the Platforms, including adverse events, could have a detrimental impact on our research pipeline and future success. For example, we may uncover a previously unknown risk associated with the Platforms or other issues that may be more problematic than we currently believe, which may prolong the period of observation required for obtaining regulatory approval, necessitate additional clinical testing or result in the failure to obtain regulatory licensure. If the Platforms or any of their respective components that are used in our product candidate are not safe, we would be required to abandon or redesign other product candidates we develop via the Platforms, which could have a material adverse effect on our business, financial condition, results of operations and prospects. If we cannot validate our technology platform by successfully commercializing product candidates, we may not be able to obtain product, licensing or collaboration revenue in future periods, which would adversely affect our business, financial condition, results of operations and prospects.

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

Our APXiMAB Platform has enabled the discovery of several product candidates with potential utility in multiple therapeutic areas and has resulted in 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 particular product candidates and fail to capitalize on product candidates that may be more profitable or for which there is a greater likelihood of success.

As a result of our limited financial and managerial resources, we must make strategic decisions as to which targets and product candidates to pursue and may forego or delay pursuit of opportunities with other targets or product candidates or for other indications that later prove to have greater commercial potential. Our resource allocation decisions may cause us to fail to capitalize on viable commercial products or profitable market opportunities. Failure to properly assess potential product candidates could result in our focus on product candidates with low market potential, which would harm our business, financial condition, results of operations and prospects. Our spending on current and future research, product candidates and discovery programs for specific targets or indications may not yield any commercially viable products. If we do not accurately evaluate the commercial potential or target market for a particular product candidate, we may relinquish valuable rights to that product candidate through collaboration, licensing or other royalty arrangements in cases in which it would have been more advantageous for us to retain sole development and commercialization rights to such product candidate.

The market may not be receptive to micvotabart pelidotin 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. Micvotabart pelidotin 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 product candidate, micvotabart pelidotin, 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 candidates performed satisfactorily in preclinical studies and clinical trials nonetheless have failed to obtain marketing licensure of their products. Our clinical trials may not ultimately be successful or support further clinical development of micvotabart pelidotin. There is a high failure rate for product candidates proceeding through clinical trials. Many companies in the pharmaceutical and biotechnology industries have suffered significant setbacks in clinical development even after achieving encouraging results in earlier studies. Any such setbacks in our clinical development could materially harm our business, results of operations, financial condition and prospects.

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 product candidates. 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 2025, there were approximately 650 ADCs in clinical or preclinical development worldwide, of which the vast majority are being developed for the treatment of various cancer indications. Additionally, there are several large and small companies working on various immunotherapy approaches for treatment of cancer. Multiple companies are also involved in the development of ADC therapeutics and immunotherapies, including, but not limited to, AbbVie Inc., Abcure, Inc., ADC Therapeutics SA, Alligator Bioscience AB, Astellas Pharma, Inc., AstraZeneca plc, Celldex Therapeutics, Inc., Daiichi Sankyo Company, Ltd., Eucure Biopharma, a subsidiary of Biocytogen, Genentech, Inc., Gilead Sciences, Inc, GlaxoSmithKline, plc, Lyvgen Biopharma, Nextcure, Inc., Pfizer, Philogen S.p.A., Merck Sharpe Dohme (MSD) and Rakuten Medical, Inc.

We face competition on specific targets, including the target of our micvotabart pelidotin candidate, EDB+FN, from Philogen S.p.A. as well as other emerging agents in key indications of interest including R/M HNSCC. Merus's EGFR and LGR5 targeting biclonic, petosemtamab, and Bicara's EGFR/TGF-beta targeting bifunctional, ficerafusp alfa (BCA101), are notable competitors that are targeting patient populations of interest to micvotabart pelidotin and pose a potentially significant threat to our clinical development strategy.

Other competitors may also include agents targeting specific segments such as HPV+ HNSCC, namely Hookipa's and PDS Biotech's vaccines and agents such as Nanobiotix's radioenhancer that may be used earlier in the treatment sequence. Furthermore, there are also some ADCs such as Sacituzumab govitecan, Gilead's TROP-2 ADC and Pfizer's Nectin-4 targeting ADC, enfortamab vedotin that are in clinical development in HNSCC and have shown preliminary clinical efficacy in early stage trials. Additional competitive dynamic changes may be observed with clinical development updates in the other lines of HNSCC treatment, including the recent positive data from pembrolizumab in the Keynote-689 trial suggests a potential upcoming paradigm shift in treating perioperative patients. The potential implementation of using IO in the earlier disease settings could impact patient segmentation and treatment choices in the R/M setting.

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 candidates 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 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 not approve the price we intend to charge for our products, may grant a license contingent on the performance of costly post-marketing clinical trials, or may approve or license a product candidate with a label that does not include the labeling claims necessary or desirable for the successful commercialization of that product candidate. Any of the foregoing scenarios could materially harm the commercial prospects for our product 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 postapproval 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 micvotabart pelidotin 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 micvotabart pelidotin in pancreatic cancer. Also, the FDA granted Orphan Drug Designation for PYX-107 in the treatment of soft tissue carcinoma, esophageal and GEJ cancers. 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.

The U.S. Congress is also considering updates to the orphan drug provisions of the Federal Food, Drug, and Cosmetic Act (FDCA) in response to a 2021 11th Circuit decision. Any changes to the orphan drug provisions could change our opportunities for, or likelihood of success in obtaining, orphan drug exclusivity and would materially adversely affect our business, financial condition, results of operations, cash flows and prospects.

Accelerated approval by the FDA, even if granted, may not lead to a faster development or regulatory review or approval process and it does not increase the likelihood that our product candidate will receive marketing licensure. If not granted, we may be required to conduct additional nonclinical 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 micvotabart pelidotin 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. If such confirmatory post-marketing trials fail to confirm the product's clinical profile or risks and benefits, the FDA may withdraw accelerated approval of the product.

The FDA has broad discretion with regard to licensure through the Accelerated Approval Program and even if we believe that the Accelerated Approval Program is appropriate for one of our products, we cannot assure you that the FDA will ultimately agree. The FDA may also change its policies with respect over accelerated approval over time. For example, in March 2023, the FDA announced the availability of draft guidance on "Clinical Trial Considerations to Support Accelerated Approval of Oncology Therapeutics," in which the Agency outlined, and invited public comment on, its "preferred approach" of randomized controlled trials, including those that provide for longer term follow-up that could fulfill a 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" made available in 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 postapproval 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 postapproval 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 postapproval 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 product candidates, and which will require separate regulatory clearance or approval prior to commercialization. This process could include additional meetings with health authorities, such as a pre-submission meeting and the requirement to submit an investigational device exemption (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 candidates for which we obtain marketing licensure. Our current and future arrangements with healthcare professionals, principal investigators, consultants, customers, drug wholesalers/distributors, pharmacy benefit managers, and third party payors subject us to various federal and state fraud and abuse laws and other healthcare laws that may constrain the business or financial arrangements and relationships through which we research, develop, sell, market and distribute our product 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 candidates 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 Annual Report on Form 10-K (Fiscal 2024 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.

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, agency leadership, 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, including, 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 lead to 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 of these changes, or a combination of such changes 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.

The biopharmaceutical and medical device industries are 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 HHS, CMS, FDA and other agencies with significant oversight of the biopharmaceutical and medical device industries. 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. 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, which may lead to 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.

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 Lara Sullivan, M.D., our President, Chief Executive

Officer and Chief Medical Officer, and Pamela Connealy, our Chief Financial Officer and Chief Operating 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 candidates.

Competition for qualified personnel in the pharmaceutical, biopharmaceutical and biotechnology field is intense due to the limited number of individuals who possess the skills and experience required by our industry. We 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 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:

- 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 revenues, 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.

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 2018 and 2019, the U.S. government shut down several times and certain regulatory agencies, such as the FDA and the SEC, had to furlough critical employees and stop critical activities. If a prolonged government shutdown occurs, it could significantly impact the ability of the FDA to timely review and process our regulatory submissions, which could have a material adverse effect on our business. Further, future government shutdowns could impact our ability to access the public markets and obtain necessary capital in order to properly capitalize and continue our operations.

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

Risks Related to Our Dependence on Third Parties

If we fail to comply with our obligations under any license, collaboration or other agreements, we may be required to pay damages and could lose intellectual property rights that are necessary for developing and protecting our product 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 candidates. Our current license agreements and our collaboration agreement impose, and any future license agreements or collaboration agreements we enter into are likely to impose, various development, commercialization, funding, milestone, royalty, diligence, sublicensing, insurance, patent prosecution and enforcement and/or other obligations on us. If we breach any of these obligations, or use the intellectual property licensed to us in an unauthorized manner, we may be required to pay damages and the licensor may have the right to terminate the license, which could result in us being unable to develop, manufacture and sell products that are covered by the licensed technology or enable a competitor to gain access to the licensed technology. Moreover, our licensors may own or control intellectual property that has not been licensed to us and, as a result, we may be subject to claims, regardless of their merit, that we are infringing or otherwise violating the licensor's rights. In addition, while we cannot currently determine the amount of the royalty obligations we would be required to pay on sales of future products, if any, the amounts may be significant. The amount of our future royalty obligations will depend on the technology and intellectual property we use in products that we successfully develop and commercialize, if any. Therefore, even if we successfully develop and commercialize products, we may be unable to achieve or maintain profitability.

We 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 candidates. 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 nonrenewal of the agreement by the CDMO at a time that is costly or inconvenient for us.

We have only limited technology transfer agreements in place with respect to our product 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.

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. 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.

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 candidates, or even if such patents provide coverage, the coverage obtained may not provide any competitive advantage. The patent applications that we own, or in-license, may fail to result in issued patents with claims that cover our current or future product candidates 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 candidates. 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 candidates, it could dissuade companies from collaborating with us to develop and commercialize product candidates and future drugs and threaten our ability to commercialize future drugs. Any such outcome could have a negative effect on our business.

The patent position of biotechnology and pharmaceutical companies generally is highly uncertain, involves complex legal and factual questions and has in recent years been the subject of much litigation. In addition, the laws of foreign countries may not protect our intellectual property rights to the same extent as the laws of the 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 candidates.

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 candidates, we may be open to competition from generic and/or biosimilar versions of such products. Given the amount of time required for the development, testing and regulatory review of new product candidates, patents protecting such candidates might expire before or shortly after such candidates are commercialized. As a result, our owned and licensed patent rights may not provide us with sufficient rights to exclude others from commercializing drugs similar or identical to ours. 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 candidate 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 candidate 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 candidate, 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 candidate, 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 candidate 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 candidate, 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 micvotabart pelidotin 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 parte reexaminations, inter partes 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 candidate, 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 Quarterly Report on Form 10-Q 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 May 14, 2025, 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 38.3% 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 provide only two years of audited financial statements, in addition to any required unaudited interim financial statements, with correspondingly reduced "Management's Discussion and Analysis of Financial Condition and Results of Operations" disclosure;
- not being required to comply with the auditor attestation requirements 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. 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. As of December 31, 2024, our federal and state net operating losses (NOLs) in the U.S. were $63.1 million ($300.7 million before tax) and $15.1 million ($229.6 million before tax), respectively. The federal NOL carryforwards in the U.S. after tax year 2017 can be carried forward indefinitely but may be subject to annual usage limitations to the extent certain substantial changes our ownership occur. The federal NOL and the state NOL carryforwards of the Company will begin to expire in 2033 and 2035, respectively. In addition, the federal and state credit carryovers of the Company will begin to expire in 2030. These loss and credit carryforwards are subject to review and possible adjustment by the relevant taxing authorities.

Our NOL and credit carryforwards are subject to review and possible adjustment by the IRS, and state tax authorities. Under Section 382 of the Internal Revenue Code of 1986, as amended, 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, which 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. 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 2. Unregistered Sales of Equity Securities and Use of Proceeds.

Use of Proceeds from Initial Public Offering

Our initial public offering of common stock, or the IPO, was effected through a Registration Statement on Form S-1 (File No. 333-259627) that was declared effective by the U.S. Securities and Exchange Commission (SEC) on October 7, 2021. We issued and sold in aggregate 10,500,000 shares of common stock, at a public offering price of $16.00 per share, for net proceeds of $152.3 million after deducting underwriting discounts, commissions and other offering costs of $15.7 million. BofA Securities, Inc., Jefferies LLC, Credit Suisse Securities (USA) LLC, William Blair & Company, L.L.C. and LifeSci Capital LLC acted as underwriters for the offering. None of the underwriting discounts and commissions or offering expenses were incurred or paid to directors or officers of ours or their associates or to persons owning 10% or more of our common stock or to any of our affiliates. We have invested the net proceeds from the IPO in a money market fund.

Our planned use of the net proceeds from the IPO as described in our final prospectus filed with the SEC on October 8, 2021 has changed due to the re-prioritizations of our pipeline contemplated in connection with our reorganization announced in November 2023 and our portfolio prioritization announced in December 2024. As a result, we currently expect to use our cash and cash equivalents, which include the net proceeds from our IPO, to advance the clinical development of micvotabart pelidotin, as well as for general corporate purposes.

Item 3. Defaults Upon Senior Securities.

None.

Item 4. Mine Safety Disclosures.

Not applicable.

Item 5. Other Information.

None.

Item 6. Exhibits.

Exhibit Number	Description	Form	File No.	Exhibit	Filing Date	Filed Here with
10.1	Separation Agreement and General Release of Ken Kobayashi					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
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 Quarterly Report on Form 10-Q 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.

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned thereunto duly authorized.

Pyxis Oncology, Inc.

Date: May 15, 2025

By: /s/ Lara Sullivan
Lara Sullivan, M.D.
President, Chief Executive Officer and Chief Medical Officer

By: /s/ Pamela Connealy
Pamela Connealy
Chief Financial Officer and Chief Operating Officer

Exhibit 10.1

SEPARATION AGREEMENT AND GENERAL RELEASE

THIS SEPARATION AGREEMENT AND GENERAL RELEASE (this "***Agreement***") is made and entered into as of March 18, 2025 (the "***Effective Date***") by and between **PYXIS ONCOLOGY, INC.**, having an address at 321 Harrison Avenue, 11th Floor, Suite 1, Boston MA 02118 ("***Pyxis***"), and Ken Kobayashi, residing at 15957 Avenida Calma, Rancho Santa Fe, CA 92091 ("***Employee***").

WHEREAS, the parties desire to set forth in this Agreement the terms upon which they have mutually agreed to an orderly termination of Employee's employment with Pyxis;

NOW THEREFORE, in consideration of the mutual agreements and other consideration contained in this Agreement, the parties agree as follows:

1. Severance and Other Benefits. In accordance with the terms of the executive employment agreement between Pyxis and Employee, dated November 21, 2023 (the "***Employment Agreement***"), which is attached hereto and incorporated herein as Attachment A, Pyxis agrees to pay Employee the severance benefits set forth in Section 4(b)(i) of the Employment Agreement in accordance with the terms thereof.

2. Release. In consideration for the payments made pursuant to Section 1 above, Employee, on behalf of Employee, Employee's heirs, executors, administrators, successors and assigns, hereby releases, acquits and forever discharges Pyxis and any and all of its current or former subsidiaries and other affiliated entities and benefit plans, as well as its and/or their officers, directors, representatives, attorneys, agents, servants, employees, stockholders, successors, predecessors and affiliates, each in their respective capacities from any and all claims, liabilities, demands, causes of action, costs, expenses, attorneys' fees, damages, indemnities and obligations of every kind and nature, in law, in equity or otherwise, known or unknown, suspected and unsuspected, disclosed and undisclosed, arising out of or in any way related to agreements, acts or conduct at any time as of or prior to the Effective Date, including, but not limited to: all such claims under California's Fair Employment and Housing Act; all such claims or demands arising from Employee's employment or the termination of Employee's employment; all such claims and demands related to salary, bonuses, commissions, stock, stock options (except as provided in Section 4 of the Employment Agreement), expense reimbursements, or any form of compensation; claims pursuant to any federal, state or local law or cause of action including, but not limited to, the Federal Civil Rights Acts of 1964, as amended, the Age Discrimination in Employment Act of 1967, as amended; statutory wage and hour claims under Massachusetts or California law (including but not limited to claims for violation of the Massachusetts Wage Act); claims under any law or legal principle of similar effect in any other relevant jurisdiction; contract claims; tort claims; or claims of wrongful discharge, discrimination, fraud, defamation, and emotional distress. Employee further agrees not to sue or otherwise institute or cause to be instituted or in any way voluntarily participate in the prosecution of any complaints or charges against any persons or entities released herein in any federal, state or other court, administrative agency or other forum concerning any claims released herein. Notwithstanding the foregoing, this release by Employee excludes (i) any rights to payment under Section 4(b)(i) of the Employment Agreement, (ii) any rights to vested accrued benefits and compensation under the Company's applicable plans and arrangements (including with respect to equity awards), (iii) any right to indemnification by the Company or its affiliates and (iv) any right to coverage under applicable directors' and officers' or other third party liability insurance policies.

Excluded from this Agreement are any claims which by law cannot be waived in a private agreement between an employer and employee, including claims by Employee for workers' compensation benefits or unemployment insurance benefits. This Release does not prohibit Employee from filing a charge with the Equal Employment Opportunity Commission (the "EEOC") or equivalent state agency in Employee's state or participating in an EEOC or state agency investigation. Employee agrees to waive his right to monetary or other recovery should any claim be pursued with the EEOC, state agency, or any other federal, state or local administrative agency on his behalf arising out of or related to his employment with and/or separation from Pyxis, if this waiver is allowed by applicable law.

3. Release of Unknown Claims. Employee acknowledges that the general release above is intended to include claims that Employee does not know or suspect to exist at the time of Employee's execution of this Agreement, regardless of whether the knowledge of such claims would have affected Employee's decision to execute this Agreement. Thus, Employee hereby waives any rights Employee may have under California Civil Code Section 1542 which states:

A GENERAL RELEASE DOES NOT EXTEND TO CLAIMS THAT THE CREDITOR OR RELEASING PARTY DOES NOT KNOW OR SUSPECT TO EXIST IN HIS OR HER FAVOR AT THE TIME OF EXECUTING THE RELEASE AND THAT, IF KNOWN BY HIM OR HER, WOULD HAVE MATERIALLY AFFECTED HIS OR HER SETTLEMENT WITH THE DEBTOR OR RELEASED PARTY.

4. Non solicitation. Employee agrees and acknowledges that the non-solicitation restrictions set forth in the Proprietary Information, Inventions and Non-Solicitation Agreement between Pyxis and Employee, dated November 21, 2023 (the "***Proprietary Information, Inventions and Non-Solicitation Agreement***"), remain in full force and effect until the one-year anniversary of the date of Employee's termination (i.e., until March 18, 2026). Employee further agrees that Employee's other post-employment restrictions and obligations set forth in the Proprietary Information, Inventions, and Non-Solicitation Agreement remain valid and binding and Employee agrees to comply with such obligations.

5. Additional Covenants. The parties covenant and agree that for a one-year period following the Effective Date, each shall refrain from making any defamatory, derogatory or other unfavorable statements regarding the other or, in the case of Employee, Pyxis's business, officers, directors, employees and agents.

6. Confidentiality. Except for his own attorney, his tax advisor and his immediate family, Employee agrees that the existence and the terms of this Agreement shall be confidential, and that he, his attorney, his tax advisor and his immediate family will not disclose any information concerning the terms of this Agreement to anyone, including but not limited to past, present or future employees of Pyxis. In addition, Employee is party to and bound by the provisions of the Proprietary Information, Inventions and Non-Solicitation Agreement, including with respect to confidentiality.

Notwithstanding Paragraphs 4 and 5, nothing in this Agreement prevents Employee from discussing or disclosing information about unlawful acts in the workplace, such as harassment or discrimination or any other conduct that Employee has reason to believe is unlawful.

7. No Admission. Employee understands and agrees that nothing contained in this Agreement is to be considered an admission by Pyxis of any wrongdoing under any federal, state or local statute, regulation, public policy, tort law, contract law, common law.

8. Acknowledgement. **Employee acknowledges that he has read and understands this Agreement and executes it knowingly, voluntarily and without coercion. Employee acknowledges that he is being advised herein in writing to consult with an attorney prior to executing this Agreement, that he has consulted with an attorney, and he has been given a period of at least 21 days within which to consider and execute this Agreement, unless he voluntarily chooses to execute this Agreement before the end of the 21 day period by executing the attached Election to Execute Prior to Expiration of 21 Day Consideration Period. Employee understands that he has 7 days following his execution of this Agreement to revoke his execution of this Agreement. The Effective Date of this Agreement shall be the 8th day after it is executed and has not been revoked. For any revocation to be effective, written notice of revocation must be delivered to Pyxis Oncology, attention: Pam Connealy, CFO & COO at pconnealy@pyxisoncology.com, no later than 5:00 p.m. ET on the 7th calendar day after Employee signs this Agreement. If Employee revokes this Agreement, it shall not be effective or enforceable and he shall not receive the benefits described herein. No payments shall be made under the terms of this Agreement until the 7-day revocation period described in this paragraph has expired without revocation by Employee.**

9. Modifications. This Agreement may not be modified in any way except in a written agreement signed by both Employee and an authorized representative of Pyxis.

10. Governing Law. This Agreement shall be governed by, and construed in accordance with, the laws of the Commonwealth of Massachusetts without giving effect to its conflict of law provisions.

11. Entire Agreement. This Agreement constitutes the entire agreement and understanding between the parties relating to Employee's separation from Pyxis. Employee acknowledges and agrees that in executing this Agreement, Employee has not relied on any promises or representations other than those set forth in this Agreement. For the avoidance of doubt, this Agreement does not alter, amend or otherwise change the rights or obligations of Employee or Pyxis in respect of grants of any stock options or other equity compensation, which such rights or obligations are set forth in the applicable plan and grant documents.

IN WITNESS THEREOF, Employee and Pyxis, after carefully reading the provisions of this Agreement, herein declare that they understand such provisions and willingly accept and agree thereto by executing this Agreement.

PYXIS ONCOLOGY, INC.

Sincerely,

By: /s/ Ken Kobayashi
Ken Kobayashi

By: /s/ Lara Sullivan
Lara S. Sullivan M.D.
President & Chief Executive Officer

ELECTION TO EXECUTE PRIOR TO EXPIRATION
OF 21 DAY CONSIDERATION PERIOD

I, Ken Kobayashi, understand that I have at least 21 days within which to consider and execute the foregoing Separation Agreement and General Release. However, after having an opportunity consult counsel, I have freely and voluntarily elected to execute the Separation Agreement and General Release before the 21-day period has expired.

By : /s/ Ken Kobayashi
Ken Kobayashi

Exhibit 31.1

CERTIFICATION

I, Lara Sullivan, M.D., certify that:

1. I have reviewed this Quarterly Report on Form 10-Q of Pyxis Oncology, Inc.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

   a. Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

   b. Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

   c. Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

   d. Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

   a. All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

   b. Any fraud, whether or not material, which involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: May 15, 2025

By: /s/ Lara Sullivan
Lara Sullivan, M.D.
President, Chief Executive Officer and Chief Medical Officer

Exhibit 31.2

CERTIFICATION

I, Pamela Connealy, certify that:

1. I have reviewed this Quarterly Report on Form 10-Q of Pyxis Oncology, Inc.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

   a. Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

   b. Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

   c. Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

   d. Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

   a. All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

   b. Any fraud, whether or not material, which involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: May 15, 2025

By: /s/ Pamela Connealy
Pamela Connealy
Chief Financial Officer and Chief Operating Officer

Exhibit 32.1

CERTIFICATION PURSUANT TO
18 U.S.C. SECTION 1350, AS ADOPTED PURSUANT TO
SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

In connection with the Quarterly Report of Pyxis Oncology, Inc. (the "Company") on Form 10-Q for the period ended March 31, 2025, as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I certify, pursuant to 18 U.S.C. § 1350, as adopted pursuant to § 906 of the Sarbanes-Oxley Act of 2002, that:

1. The Report fully complies with the requirements of section 13(a) or 15(d) of the Securities Exchange Act of 1934; and
2. The information contained in the Report fairly presents, in all material respects, the financial condition and result of operations of the Company.

Date: May 15, 2025

By: /s/ Lara Sullivan
Lara Sullivan, M.D.
President, Chief Executive Officer and Chief Medical Officer

Exhibit 32.2

CERTIFICATION PURSUANT TO
18 U.S.C. SECTION 1350, AS ADOPTED PURSUANT TO
SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

In connection with the Quarterly Report of Pyxis Oncology, Inc. (the "Company") on Form 10-Q for the period ended March 31, 2025, as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I certify, pursuant to 18 U.S.C. § 1350, as adopted pursuant to § 906 of the Sarbanes-Oxley Act of 2002, that:

1. The Report fully complies with the requirements of section 13(a) or 15(d) of the Securities Exchange Act of 1934; and
2. The information contained in the Report fairly presents, in all material respects, the financial condition and result of operations of the Company.

Date: May 15, 2025

By: /s/ Pamela Connealy
Pamela Connealy
Chief Financial Officer and Chief Operating Officer