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, 2024

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) 221-9059

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

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

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	☐
	☒	Smaller reporting company	
Non-accelerated filer			☒

		Emerging growth company	
			☒

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

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

As of May 13, 2024, the registrant had

58,888,473
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 biopharmaceutical company with a limited operating history and have incurred significant losses since our inception. We expect to incur losses over at least the next several years and may never achieve or maintain profitability.
- We will require substantial additional capital to finance our operations, obtain regulatory approval for our product candidates, and commercialize our product candidates. If we are unable to raise such capital when needed, or on acceptable terms, we may be forced to delay, reduce or eliminate one or more of our research and product development programs or future commercialization efforts.
- We are heavily dependent on the success of PYX-201, PYX-106 and PYX-107, which are in the early stages of development, and if PYX-201, PYX-106 and/or PYX-107 are not successful in clinical trials or do not receive regulatory approval or licensure or are not successfully commercialized, our business will be materially and adversely affected.
- Our product candidates may fail in development or suffer delays that materially and adversely affect their commercial viability. If we or our existing or future collaborators are unable to initiate and complete clinical development of, obtain regulatory approval or licensure for or commercialize our product candidates or experience significant delays in doing so, our business will be materially harmed.
- Our preclinical studies and clinical trials may fail to demonstrate adequately the safety, purity and potency of any of our product candidates, which would prevent or delay development, regulatory approval or licensure and commercialization.
- Our preclinical programs may experience delays or may never advance to clinical trials, which would adversely affect our ability to obtain regulatory approval or licensure or commercialize these programs on a timely basis or at all.
- We face competition from entities that have developed or may develop product candidates for cancer treatment, including companies developing novel treatments and technology platforms. If these companies develop technologies or product candidates more rapidly than we do or if their technologies are more effective, our ability to develop and successfully commercialize product candidates may be adversely affected.
- Clinical testing and product development is a lengthy and expensive process with an uncertain outcome. We may incur unexpected costs or experience delays in completing, or ultimately be unable to complete, the clinical testing and the development of our product candidates and may never achieve commercialization for any of our product candidates.
- The regulatory licensure and approval processes of the FDA and other comparable regulatory authorities are lengthy, time-consuming and inherently unpredictable and, if we are ultimately unable to obtain marketing licensure or approval for our product candidates, our business will be substantially harmed.
- If we fail to attract and retain qualified senior management and key scientific personnel, our business may be materially and adversely affected.
- We rely on third parties to manufacture our product candidates. Any failure by a third party manufacturer to produce acceptable raw materials or product candidates for us or to obtain authorization from the FDA or comparable foreign regulatory authorities relating thereto may delay or impair our ability to initiate or complete our clinical trials, obtain regulatory licensure or approvals or commercialize approved products.
- We face substantial competition, which may result in others discovering, developing or commercializing products more quickly or marketing them more successfully than we do.
- If we are unable to obtain and maintain patent protection for our product candidates, or if the scope of the patent protection obtained is not sufficiently broad, or if our patents are insufficient to protect our product candidates for an adequate amount of time, or if we are unable to obtain adequate protection for our proprietary know-how, we may not be able to compete effectively in our markets.
- If we fail to comply with our obligations under any license, collaboration or other agreements, we may be required to pay damages and could lose intellectual property rights that are necessary for developing and protecting our product candidates or we could lose certain rights to grant sublicenses.

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

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

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

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

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, 2024	December 31, 2023
Assets		
Current assets:		
Cash and cash equivalents	$ 27,967	$ 9,664
Marketable debt securities, short-term	129,060	109,634
Restricted cash	1,472	1,472
Accounts receivable	8,000	—
Prepaid expenses and other current assets	5,880	3,834
Total current assets	172,379	124,604
Property and equipment, net	11,333	11,872
Intangible assets, net	23,730	24,308
Operating lease right-of-use assets	12,778	12,942
Total assets	**$ 220,220**	**$ 173,726**
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable	$ 2,293	$ 3,896
Accrued expenses and other current liabilities	10,828	12,971
Operating lease liabilities, current portion	1,020	1,232
Deferred revenues	—	7,660
Total current liabilities	14,141	25,759
Operating lease liabilities, net of current portion	19,759	20,099

Deferred tax liability, net	2,164	2,164
Total liabilities	36,064	48,022
Commitments and contingencies (Note 14)		
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; 58,803,126 and 44,754,853 shares issued and outstanding as of March 31, 2024 and December 31, 2023, respectively.	59	45
Additional paid-in capital	473,638	411,821
Accumulated other comprehensive (loss) income	(60)	63
Accumulated deficit	(289,481)	(286,225)
Total stockholders' equity	184,156	125,704
Total liabilities and stockholders' equity	**$ 220,220**	**$ 173,726**

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,	
	2024	**2023**
Revenues		
Royalty revenues (See Note 6)	$ 8,146	$ —
Sale of royalty rights (See Note 6)	8,000	—
Total revenues	16,146	—
Costs and operating expenses:		
Cost of revenues	475	—
Research and development	13,029	11,901
General and administrative	8,247	9,053
Total costs and operating expenses	21,751	20,954
Loss from operations	(5,605)	(20,954)
Other income, net:		
Interest and investment income	1,550	1,673
Sublease income	799	38
Total other income, net	2,349	1,711
Net loss	**$ (3,256)**	**$ (19,243)**
Net loss per common share - basic and diluted	$ (0.06)	$ (0.54)
Weighted average shares of common stock outstanding - basic and diluted	51,289,284	35,351,671
Other comprehensive (loss) income:		
Net unrealized (loss) gain on marketable debt securities	(123)	696

Other comprehensive (loss) income	(123)	696
Comprehensive loss	**(3,379)**	**(18,547)**

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	Accumulated Other Comprehensive (Loss)	Accumulated	Total Stockholders'
	Shares	Amount	Capital	Income	Deficit	Equity
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 (See Note 7)	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 7)	3,600,000	4	10,586	—	—	10,590
Issuance of pre-funded warrants in private placement, net of offering costs (See Note 8)	—	—	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**

	Common Stock		Additional Paid-In	Accumulated Other Comprehensive (Loss)	Accumulated	Total Stockholders'
	Shares	Amount	Capital	Income	Deficit	Equity
Balance at December 31, 2022	**34,958,730**	**$ 34**	**$ 373,225**	**$ —**	**$ (212,435)**	**$ 160,824**
Issuance of common stock to Pfizer Inc. (See Note 5)	1,811,594	2	4,998	—	—	5,000
Issuance of restricted common stock, net of tax withholdings	148,047	1	1	—	—	2

Stock-based compensation	—	—	4,884	—	—	4,884
Net unrealized gain on marketable debt securities	—	—	—	696	—	696
Net loss	—	—	—	—	(19,243)	(19,243)
Balance at March 31, 2023	**36,918,371**	**$ 37**	**$ 383,108**	**$ 696**	**$ (231,678)**	**$ 152,163**

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,	
	2024	**2023**
Operating activities		
Net loss	$ (3,256)	$ (19,243)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	1,116	190
Stock-based compensation	4,320	4,884
Non-cash lease expense	164	144
Accretion of discount on marketable debt securities	(1,288)	(607)
Changes in operating assets and liabilities:		
Accounts receivable	(8,000)	—
Prepaid expenses and other current assets	(2,046)	486
Accounts payable	(1,365)	(753)
Accrued expenses and other current liabilities	(2,143)	(13,273)
Operating lease liabilities	(552)	1,331
Deferred revenues	(7,660)	—
Net cash used in operating activities	**(20,710)**	**(26,841)**
Investing activities		
Redemption of marketable debt securities	74,532	—
Purchase of marketable debt securities	(92,793)	(94,987)
Purchase of property and equipment	(237)	(4,406)
Net cash used in investing activities	**(18,498)**	**(99,393)**
Financing activities		

Proceeds from issuance of common stock and pre-funded warrants in private placement, net of offering costs	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	(196)	—
Proceeds from the exercise of stock options	245	—
Net cash provided by financing activities	**57,511**	—
Net increase (decrease) in cash, cash equivalents, and restricted cash	18,303	(126,234)
Cash, cash equivalents and restricted cash at beginning of year	11,136	180,765
Cash, cash equivalents and restricted cash at end of period	**$ 29,439**	**$ 54,531**
Noncash operating, investing and financing activities:		
Property and equipment in accounts payable and accrued expenses	$ —	$ 2,261
Reconciliation of cash, cash equivalents and restricted cash:		
Cash and cash equivalents	$ 27,967	$ 53,059
Restricted cash	1,472	1,472
Total cash, cash equivalents and restricted cash shown in the statement of cash flows	**$ 29,439**	**$ 54,531**

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 company focused on defeating difficult-to-treat cancers. The Company is efficiently building next generation therapeutics that hold the potential for mono and combination therapies. The Company's therapeutic candidates are designed to kill tumor cells and to address the underlying pathologies created by cancer that enable its uncontrollable proliferation and immune evasion. The Company's antibody-drug conjugates ("ADCs") and immuno-oncology ("IO") programs employ novel and emerging strategies to target a broad range of solid tumors resistant to current standards of care.

On August 23, 2023, the Company completed the acquisition of Apexigen, Inc. ("Apexigen") pursuant to a business combination agreement, whereby Ascent Merger Sub Corp., a Delaware corporation and wholly-owned subsidiary of the Company merged with and into Apexigen, with Apexigen surviving as a wholly owned subsidiary of the Company (the "Merger").

The Company has

one

operating segment. The Company's chief operating decision maker, its Chief Executive Officer, manages the Company's operations on a consolidated basis for the purposes of assessing performance and allocating resources.

2. Basis of Presentation and Summary of Significant Accounting Policies

Basis of Presentation

The Company's fiscal year ends on December 31 and its first three 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 ("U.S. 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, 2024 are not necessarily indicative of those expected for the year ending December 31, 2024 or for any future period. The condensed consolidated balance sheet as of December 31, 2023 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, 2023, included in the Company's Annual Report on Form 10-K filed with the SEC on March 21, 2024 ("Fiscal 2023 10-K").

Liquidity

As of March 31, 2024, the Company had an accumulated deficit of $

289.5

million. The Company has incurred losses and negative cash flows from operations since inception, including net losses of $

3.3

million and $

19.2

million for the three months ended March 31, 2024 and 2023, 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 $

157.0

million as of March 31, 2024 will fund its operating expenses and capital requirements 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-stage companies in the biopharmaceutical industry including, but not limited to, uncertainties related to commercialization of products, regulatory approvals, dependence on key suppliers for active ingredients and third-party service providers such as contract development and manufacturing organizations ("CDMOs"), protection of intellectual property rights and the ability to make milestone, royalty or other payments due under any license, collaboration or supply agreements.

Concentration of Credit Risks

Financial instruments which potentially subject the Company to significant concentration of credit risk consist of cash and cash equivalents, restricted cash and short-term investments.

The Company invests its excess cash primarily in money market funds and highly liquid U.S. Treasury securities. The Company has adopted an investment policy that includes guidelines relative to credit quality, diversification and maturities to preserve principal and liquidity.

Significant Accounting Policies

There have been no significant changes to the Company's significant accounting policies disclosed in "Note 2 – Summary of Significant Accounting Policies" of the Company's Fiscal 2023 10-K.

Recently Adopted Accounting Pronouncements

In August 2020, the FASB issued ASU 2020-06, *Debt – Debt with Conversion and Other Options (Subtopic 470-20) and Derivatives and Hedging – Contracts in Entity's Own Equity (Subtopic 815-40)* ("ASU 2020-06"). ASU 2020-06 revises the guidance on calculating earnings per share, requiring use of the if-converted method for all convertible instruments and rescinding an entity's ability to rebut the presumption of share settlement for instruments that may be settled in cash or other assets. On January 1, 2024 , the Company adopted ASU 2020-06, which did no t have a material effect on the Company's financial position, results of operations, or cash flows.

Recently Issued Accounting Pronouncements

Recent authoritative guidance issued by the FASB (including technical corrections to the ASC), the American Institute of Certified Public Accountants ("AICPA"), and the SEC did not, or are not expected to, have a material impact on the Company's unaudited condensed 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, 2024 and December 31, 2023, respectively, in accordance with the FASB ASC 820 hierarchy (in thousands):

	March 31, 2024			
	Level 1	Level 2	Level 3	Total
Cash equivalents				
Money market funds	$ 24,767	$ —	$ —	$ 24,767
Marketable debt securities				
U.S. Treasury securities	129,060	—	—	129,060
Total	$ 153,827	$ —	$ —	$ 153,827

	December 31, 2023			
	Level 1	Level 2	Level 3	Total
Cash Equivalents				
Money market funds	$ 8,360	$ —	$ —	$ 8,360
Marketable debt securities				
U.S. Treasury securities	109,634	—	—	109,634
Total	$ 117,994	$ —	$ —	$ 117,994

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

assets or liabilities measured at fair value on a nonrecurring basis at March 31, 2024 and December 31, 2023. 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, 2024			
	Amortized Cost	Unrealized Gains	Unrealized Losses	Aggregate Fair Value
Marketable debt securities				
U.S. Treasury securities	$ 129,120	$ 6	$ (66)	$ 129,060

	December 31, 2023			
	Amortized Cost	Unrealized Gains	Unrealized Losses	Aggregate Fair Value
Marketable debt securities				
U.S. Treasury securities	$ 109,571	$ 71	$ (8)	$ 109,634

As of March 31, 2024, 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,	
	2024	2023
Interest income	$ 262	$ 1,066
Accretion of discount, net	1,288	607
Total interest and investment income	$ 1,550	$ 1,673

5. 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, 2024 and 2023, 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 PYX-201 and PYX-203, and products containing the ADC product candidates. The Company’s rights are exclusive with respect to certain patents owned or controlled by Pfizer covering the licensed ADCs. The initial licensed targets include CD123 and 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 PYX-201 and PYX-203, and products containing the ADC product candidates. Additional ADC targets may be licensed for a nominal upfront payment and milestones. In accordance with the terms of the A&R License Agreement, the Company issued

2,229,654
shares of its common stock to Pfizer in October 2022, paid $

8.0
million to Pfizer in January 2023 and issued

1,811,594
shares of its common stock to Pfizer in March 2023.

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, 2024 and 2023, 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. The Company assessed the milestone and royalty events involving the Biosion License Agreement as of March 31, 2024 and 2023, and determined that

no

such amounts were required.

Acquired Out-Licensing Agreements

In August 2023, the Company completed the acquisition of 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, 2024 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, 2024 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, 2024 and determined that

no
such amounts were receivable.

6. Sale of Royalty Rights

In March 2007, Epitomics entered into an antibody candidate discovery and development agreement with ESBATech AG (“ESBATech”) (the “ESBATech Agreement”). ESBATech was acquired by Alcon Research, Ltd. in 2009 and later merged with Novartis AG (“Novartis”) in 2011.

Novartis, the successor in interest to ESBATech, has successfully developed and commercialized one of those drug product candidates, brolucizumab-dbll, a single-chain antibody fragment (scFv) targeting all of the isoforms of VEGF-A, which was approved for commercial sale in 2019 and marketed under the brand name Beovu®.

Upon commercialization, pursuant to the ESBATech Agreement, Novartis was obligated to pay Apexigen a very low single-digit royalty on net sales of the Beovu® product. However, Novartis disputed its obligation to pay these royalties on Beovu® sales under the ESBATech Agreement. As a result, Apexigen and the Company determined that any sales-based Beovu® product royalties received under the ESBATech Agreement should be fully constrained and reported royalties received by Apexigen and the Company as deferred revenues. The Company assessed this position at each period end to determine if events or changes in circumstances indicate a change in position.

On March 25, 2024, the Company entered into the Fourth Amendment, Settlement Agreement, and Royalty Purchase Agreement (the “Settlement Agreement”) with Novartis, pursuant to which Novartis agreed to pay the Company $

8.0
million to transfer its rights to future royalties on the net sales of Beovu®. Additionally, the dispute regarding Novartis’ obligation to pay royalties on Beovu® sales was resolved and royalties previously received by Apexigen and the Company are free from any reclaim rights.

The ESBATech Agreement and the Settlement Agreement with Novartis both constitute contracts with a customer. Therefore, the Company has accounted for the payments received under these agreements as revenues in accordance with ASC 606, *Revenue Recognition*, (“ASC 606”). Upon execution of the Settlement Agreement, the $

8.0
million payment was recorded as revenue within the accompanying condensed consolidated statements of operations and comprehensive loss for the three months ended March 31, 2024. Additionally, the related deferred revenues of $

8.1
million previously constrained was also recorded as revenue within the accompanying condensed consolidated statements of operations and comprehensive loss for the three months ended March 31, 2024 as the uncertainty resulting in the revenue constraint has been resolved.

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, 2024, the Company completed the sale of an aggregate of

3,600,000
shares of common stock under the ATM offering program, with an average sale price of $

3.00
per share, resulting in gross proceeds of $

10.8
million, before deducting placement agent fees under the ATM offering program. The Company did

no
t sell any shares under the ATM offering program during the three months ended March 31, 2023.

As of March 31, 2024, the Company had $

107.9
million of remaining capacity available under the ATM facility.

Private Offerings

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

Pursuant to the Securities Purchase Agreement, the Company issued and sold to the Purchasers an aggregate of (i)

8,849,371
shares (the "Shares") of the Company's common stock, par value $

0.001
per share, at a purchase price of $

4.78
per share, and (ii) pre-funded warrants (the "Pre-Funded Warrants") to purchase up to an aggregate of

1,611,215
shares of the Company' common stock (the "Pre-Funded Warrant Shares") at a purchase price of $

4.779
per Pre-Funded Warrant.

The Private Placement closed on February 29, 2024 and the Company received gross proceeds from the Private Placement of $50 million, before deducting placement agent fees and offering expenses directly related to the Private Placement.

On February 26, 2024, the Company also entered into a registration rights agreement (the "Registration Rights Agreement") with the Purchasers, pursuant to which the Company agreed to register for the resale of the Shares and Pre-Funded Warrants (together, the "Registrable Securities"). The Registrable Securities were registered on Form S-3 (Registration No. 333-278282) on March 27, 2024. The Form S-3 was deemed effective by the SEC on April 3, 2024.

Preferred Stock

There were

no

issued and outstanding shares of preferred stock as of March 31, 2024 and December 31, 2023.

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, 2024	December 31, 2023
Stock options outstanding	6,892,951	5,982,464
Unvested restricted stock awards and units	3,110,597	3,631,431
Shares reserved for future issuance	1,649,038	1,013,840
Pre-Funded Warrant Shares	1,611,215	—
Apexigen replacement warrants	1,003,191	1,003,191
Employee stock purchase plan	675,485	565,405
Total	**14,942,477**	**12,196,331**

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, 2024, 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 connection with the Private Placement, the Company issued Pre-Funded Warrants to purchase up to an aggregate of

1,611,215
shares of the Company's common stock at a purchase price of $

4.779
per Pre-Funded Warrant, which represents the per share purchase price of the Shares less the $

0.001
per share exercise price for each Pre-Funded Warrant. The Pre-Funded Warrants will be exercisable at any time after the date of issuance and will not expire. As of March 31, 2024,

1,611,215
Pre-Funded Warrants were outstanding.

The Company determined that the Pre-Funded Warrants and Apexigen replacement warrants met all of the criteria for equity classification. Accordingly, the warrants were recorded as a component of additional paid-in capital within the accompanying condensed consolidated balance sheets.

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, 2024, there were

793,404
shares,

107,051
shares,

476,202
shares and

272,381
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, 2024 (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, 2024	5,982,464	$ 7.31	7.6	$ 141
Granted	1,244,626	3.95		
Exercised	(100,981)	2.13		
Expired	(180,872)	12.68		
Forfeited	(52,286)	16.00		
Outstanding at March 31, 2024	**6,892,951**	**$ 6.51**	**8.1**	**$ 7,727**
Options exercisable at March 31, 2024	**3,184,805**	**$ 7.68**	**7.0**	**$ 3,621**

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 $

4.26
per share as of March 28, 2024, the last trading day prior to the quarter ended March 31, 2024. The aggregate intrinsic value of stock options exercised during the three months ended March 31, 2024 and 2023 was $

0.2
million and $

0
, respectively, as no stock options were exercised during the three months ended March 31, 2023.

The Company has an aggregate $

12.6
million of gross unrecognized stock-based compensation expense as of March 31, 2024, remaining to be amortized over a weighted average period of 2.24 years.

The weighted-average grant-date fair value of options granted during the three months ended March 31, 2024 and 2023, was $

2.32
and $

3.19
per share, respectively, and was calculated using the following key input assumptions in the Black-Scholes option-pricing model :

	Three Months Ended March 31,	
	2024	2023
Expected volatility	99.41% - 102.27%	97.82%
Risk-free interest rate	4.06% - 4.23%	3.58%
Expected dividend yield	0.00%	0.00%
Expected term (in years)	5 - 6.08	6.08

Restricted Stock Units

The following table summarizes restricted stock units activity for the three months ended March 31, 2024:

	Number of Shares	Weighted Average Grant Date Fair Value
Non-vested and unsettled at January 1, 2024	3,631,431	$ 2.51
Granted	1,187,882	3.84
Forfeited	(157,826)	2.56
Vested and settled	(1,550,890)	2.77
Non-vested and unsettled at March 31, 2024	**3,110,597**	**$ 2.89**

During the three months ended March 31, 2024, the Company issued 1,497,921 shares of its common stock from the settlement of 1,550,890 restricted common stock, with the remaining shares withheld for taxes. The Company has an aggregate $ 8.7 million of gross unrecognized restricted stock-based compensation expense as of March 31, 2024, remaining to be amortized over a weighted average period of 3.0 years.

Summary of Stock-Based Compensation Expense

The following table summarizes the total stock-based compensation expense for the three months ended March 31, 2024 and 2023, respectively (in thousands):

	Three Months Ended March 31,	
	2024	**2023**
General and administrative	$ 3,642	$ 3,256
Research and development	678	1,628
Total	**$ 4,320**	**$ 4,884**

Total stock-based compensation expense for stock options includes expense related to the 2021 ESPP of less than $

0.1
million and $

0
for the three months ended March 31, 2024 and 2023, respectively.

2021 Employee Stock Purchase Plan ("2021 ESPP")

The Company has the 2021 ESPP in force. The Company did not issue shares under the 2021 ESPP during the three months ended March 31, 2024 and 2023. As of March 31, 2024,

675,485
shares are available for issuance under the 2021 ESPP.

10. Operating Leases

Leases classified as operating leases are included in operating lease right-of-use assets ("ROU"), operating lease liabilities, current portion and operating lease liabilities, net of current portion, in the Company's accompanying condensed consolidated balance sheets.

The Company leases its office and facilities in Boston, Massachusetts under a non-cancellable operating lease agreement that continues through December 31, 2032. Cash paid for operating lease liabilities was $

1.1
million and $

0.2
million during the three months ended March 31, 2024 and 2023, respectively, which is included in operating cash flows. Operating lease expense for the three months ended March 31, 2024 and 2023 was $

0.7

million for both periods. Variable lease expense was $

0.5
million and $

0
for the three months ended March 31, 2024 and 2023, respectively. Short term lease expense was $

0
and $

0.5
million for the three months ended March 31, 2024 and 2023, respectively.

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 $

0.8
million and $

38
thousand for the three months ended March 31, 2024 and 2023, respectively.

11. Income Taxes

The Company's effective tax rate from continuing operations was

0

% for the three months ended March 31, 2024 and 2023. The Company has

no

t recorded a federal income tax provision for the three months ended March 31, 2024 and 2023. The Company recorded a nominal state and local income tax provision for the three months ended March 31, 2024 and 2023.

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,	
	2024	**2023**
Stock options outstanding	6,892,951	5,706,777
Unvested restricted stock awards and units	3,110,597	5,747,172
Shares reserved for future issuance	1,649,038	600,127
Apexigen replacement warrants	1,003,191	—
Employee stock purchase plan	675,485	644,755
Total	**13,331,262**	**12,698,831**

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 are issuable for nominal consideration.

13. Related Parties

The Company was founded out of Dr. Thomas Gajewski's laboratory at the University of Chicago. In 2020, the Company entered into the License Agreement with the University of Chicago, as well as a sponsored research agreement. During the three months ended March 31, 2024 and 2023, the Company incurred $

30

thousand and $

0

in expenses related to the University License Agreement, respectively. Refer to Note 5. Licensing Agreements for additional discussion.

Pfizer owns more than

10

% of the Company and is considered the principal owner of the Company. The Company did

no

t incur expenses related to Pfizer during the three months ended March 31, 2024. During the three months ended March 31, 2023, in accordance with the terms of the A&R License Agreement, the Company paid $

8.0

million to Pfizer in January 2023 and issued

1,811,594

shares of its common stock in March 2023. Refer to Note 5. Licensing Agreements for additional discussion.

14. 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, 2023, included in our Fiscal 2023 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.

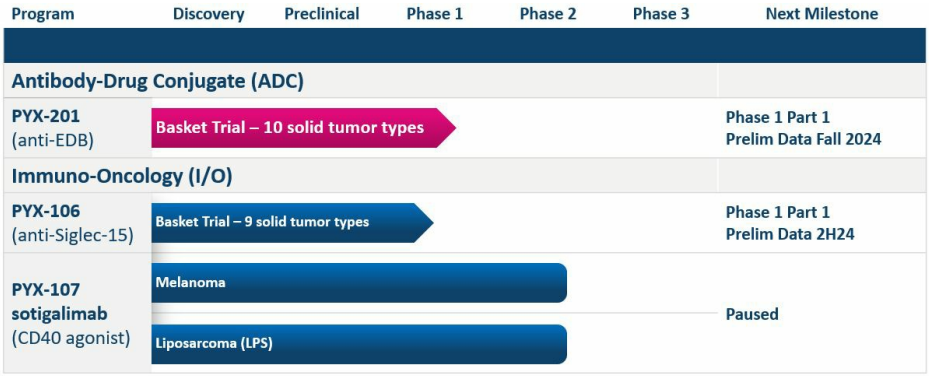
Factors that could cause or contribute to such differences include, but are not limited to, those identified herein, and those discussed in the section titled "Risk Factors" set forth in Part II, Item 1A. of this Quarterly Report on Form 10-Q and in our other filings with the SEC. These risks are not 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

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

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

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



Our Clinical Program Portfolio

PYX-201

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

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

In preclinical models of patient-derived xenograft, or PDX models, we observed tumor regression with single agent PYX-201 in a dose-dependent manner. In addition, we observed that the treatment of preclinical syngeneic tumor models with PYX-201 resulted in enhanced T-cell infiltration into the tumor microenvironment, or TME, suggesting that PYX-201 may have caused immunogenic cell death, or ICD, and could potentially trigger downstream anti-tumor immune response. Recently, we shared our latest preclinical data at the 2024 American Association for Cancer Research, or AACR, Annual Meeting in San Diego, California. The preclinical data supports that PYX-201 is designed to have improved plasma stability, better potency, and tumor permeability due to optimized auristatin payload, or Aur-0101, and improved linker stability through site-specific conjugation to engineered cysteine residues for a target drug-to-antibody ratio, or DAR, of 4. Across a panel of approximately 100 preclinical PDX models representing ten tumor types, PYX-201 demonstrated broad, deep, and durable anti-tumor activity. The recent preclinical data provides insights into the mechanism associated with this novel agent observed across multiple solid tumors. PYX-201 has potential applications in both monotherapy and combination therapy and maintains a well-tolerated safety profile based on the lack of EDB+FN expression in healthy cells.

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

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

To date, 42 subjects in eight cohorts have been dosed with PYX-201 in this Phase 1 trial. We are actively studying dose ranges from 5.4 mg/kg to 8 mg/kg. We plan to dose an additional 16 subjects with a continued focus on HNSCC, NSCLC, ovarian cancer, soft tissue sarcoma and PDAC based on an assessment of factors including immunohistochemistry target expression, stromal volume, unmet medical need and clinical judgment. PYX-201 safety data continues to support go-forward monotherapy and potential combination development strategies.

As we continue to analyze the data generated, we anticipate that the data from the dose finding studies will guide the selection for the RP2D for subsequent multi-dosing and potential combination studies. We anticipate reporting the study results, including efficacy, safety, PK, preclinical insights, further development plans, and the expected timing of the next anticipated milestones in the fall of 2024.

PYX-106

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

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

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

In the Phase 1 portion of the trial, the starting dose of PYX-106 was 0.5 mg/kg. The DESC approved escalating the dose after each cohort. To date, 24 subjects have been dosed with PYX-106 in the Phase 1 trial. PYX-106 is administered once every two weeks. Dose escalation will follow the BOIN design until the RP2D is determined.

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

PYX-107

On August 23, 2023, we completed the acquisition of Apexigen, a Delaware corporation and a clinical-stage biopharmaceutical company focused on discovering and developing innovative antibody therapeutics for oncology.

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

Since our inception, we have focused substantially all of our resources on conducting research and development activities, undertaking preclinical studies and clinical trials, organizing and staffing our company, business planning, raising capital, establishing and maintaining our intellectual property portfolio and identifying potential product candidates. We do not have any products approved for sale and have not generated any revenues from product sales or from any other sources. We have incurred significant operating losses since our inception. We reported net losses of $3.3 million and $19.2 million for the three months ended March 31, 2024 and 2023, respectively. As of March 31, 2024, we had an accumulated deficit of $289.5 million, net equity of $184.2 million, and cash, cash equivalents and short-term investments of $157.0 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 candidates. 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. Pursuant to the Settlement Agreement with Novartis, we transferred our rights to future royalties on the net sales of Beovu® to Novartis and recorded the remaining definite-lived intangible asset of $0.5 million related to these royalty rights to cost of revenues. Refer to Note 6. Sale of Royalty Rights, to our unaudited condensed consolidated financial statements included in Part I, Item 1 of this Quarterly Report on Form 10-Q for further information.

Research and Development Expenses

Research and development expenses consist of costs incurred for our research activities, including our discovery efforts and research work to support clinical development, and the development of our programs. Research and development expenses are presented among program-specific costs and unallocated costs.

Program-specific costs include:

- direct third-party costs, which include expenses incurred under agreements with contract research organizations, or CROs, and the cost of consultants who assist with the development of our product candidates on a program-specific basis, investigator grants, sponsored research, and any other third-party expenses directly attributable to the development of the product candidates;
- costs of acquiring, developing, and manufacturing and testing clinical and preclinical materials, including costs incurred under agreements with contract development and manufacturing organizations, or CDMOs, to the extent they can be allocated to a specific program;
- license fees and milestone payments related to the acquisition and retention of certain licensed technology and intellectual property rights for a specific product candidate; and
- costs associated with preclinical activities that are directly attributable to the development of the product candidates.

Unallocated costs include:

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

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

We expect that our research and development expenses will increase substantially in connection with our ongoing and planned preclinical and clinical development activities in the near term and in the future. The successful development of our product candidates is highly uncertain. At this time, we cannot accurately estimate or know the nature, timing and costs of the efforts that will be necessary to complete the preclinical and clinical development of any of our product candidates and we may never succeed in obtaining regulatory approval for any of our product candidates.

General and Administrative Expenses

General and administrative expenses consist primarily of salaries and personnel-related costs, including stock-based compensation, and severance for our personnel in executive, legal, finance and accounting, human resources and other administrative functions. General and administrative expenses also include professional fees for auditing, tax, and legal services, as well as insurance, board of director compensation, consulting, other administrative expenses and facility costs not otherwise included in research and development expenses.

Other Income, Net

Other income, net primarily consists of interest earned on our invested cash and cash equivalent balances, accretion of discounts associated with our marketable debt securities and sublease income under our sublease.

Results of Operations

Comparison of the Three Months Ended March 31, 2024 and 2023

The following table summarizes our results of operations for the three months ended March 31, 2024 and 2023 (in thousands):

	For the Three Months Ended March 31,		
	2024	2023	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	13,029	11,901	1,128
General and administrative	8,247	9,053	(806)
Total costs and operating expenses	21,751	20,954	797
Loss from operations	(5,605)	(20,954)	15,349
Other income, net:			
Interest and investment income	1,550	1,673	(123)
Sublease income	799	38	761
Total other income, net	2,349	1,711	638
Net loss	**$ (3,256)**	**$ (19,243)**	**$ 15,987**

Revenues

Revenues for the three months ended March 31, 2024 was $16.1 million, compared to $0 for the three months ended March 31, 2023. During the quarter, 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 one-time amount of $8.0 million and Novartis also agreed to forgo its right to reclaim royalties previously paid of $8.1 million to us and Apexigen. Both of these amounts are recognized as revenues, upon execution of the Settlement Agreement.

Costs and Operating Expenses

Cost of Revenues

Upon execution of the Settlement Agreement with Novartis, we expensed the remaining definite-lived intangible asset of $0.5 million related to these royalty rights to cost of revenues.

Research and Development Expenses

The following table summarizes our research and development expenses for the three months ended March 31, 2024 and 2023 (in thousands):

	For the Three Months Ended March 31,		
	2024	2023	Change
Program-specific costs:			
PYX-201	$ 4,357	$ 1,706	$ 2,651
PYX-106	1,989	1,127	862
Other program costs	191	410	(219)
Total program costs	**6,537**	**3,243**	**3,294**
Unallocated costs:			
Personnel-related expenses including stock-based compensation	4,182	6,740	(2,558)
Other costs	2,310	1,918	392
Total research and development expenses	**$ 13,029**	**$ 11,901**	**$ 1,128**

Research and development expenses increased by $1.1 million, from $11.9 million for the three months ended March 31, 2023 to $13.0 million for the three months ended March 31, 2024.

PYX-201 program-specific research and development costs increased by $2.7 million, primarily due to a $0.9 million increase in clinical trial related expenses for our ongoing Phase 1 clinical trial for PYX-201-101 and a $1.9 million increase in contract manufacturing costs due to timing of manufacturing runs for PYX-201.

PYX-106 program-specific research and development costs increased by $0.9 million, primarily due to costs for our ongoing Phase 1 clinical trial for PYX-106-101.

Unallocated research and development costs decreased by $2.2 million from $8.7 million for the three months ended March 31, 2023 to $6.5 million for the three months ended March 31, 2024. This decrease was primarily due to lower personnel-related expenses as a result of the reduction in workforce completed in the fourth quarter of 2023, partially offset by a $0.4 million increase in costs related to facilities rent, laboratory expenses, depreciation and amortization.

General and Administrative Expenses

The following table summarizes our general and administrative expenses for the three months ended March 31, 2024 and 2023 (in thousands):

	For the Three Months Ended March 31,		
	2024	2023	Change
Personnel-related expenses including stock-based compensation	$ 5,561	$ 5,301	$ 260
Professional and consultant fees	1,080	2,467	(1,387)
Facilities, insurance and other costs	1,606	1,285	321
Total general and administrative expenses	**$ 8,247**	**$ 9,053**	**$ (806)**

General and administrative expenses decreased by $0.8 million, from $9.1 million for the three months ended March 31, 2023 to $8.2 million for the three months ended March 31, 2024. The decrease was primarily related to higher professional and consultant fees during the prior comparable period, partially offset by higher stock-based compensation expense and facilities costs.

Other Income, Net

Other income, net for the three months ended March 31, 2024 and 2023 was $2.3 million and $1.7 million, respectively. The increase was primarily due to higher sublease income on account of full quarter of sublease income for 2024 as against partial period for 2023.

Liquidity and Capital Resources

We had cash, cash equivalents, and short-term investments of $157.0 million as of March 31, 2024. For the three months ended March 31, 2024 and 2023, we had net losses of $3.3 million and $19.2 million, respectively. As of March 31, 2024, we had an accumulated deficit of $289.5 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.

On January 30, 2024, we completed the sale of an aggregate of 3,600,000 shares of our common stock under the ATM offering program, with an average sale price of $3.00 per share, resulting in gross proceeds of $10.8 million, before the placement agent fees.

On February 29, 2024, we completed the private placement with certain accredited investors and issued and sold to the purchasers an aggregate of (i) 8,849,371 shares of Common Stock at a purchase price of $4.78 per share and (ii) Pre-Funded Warrants to purchase up to an aggregate of 1,611,215 shares of Common Stock at a purchase price of $4.779 per Pre-Funded Warrant. We received aggregate gross proceeds from the private placement of $50 million, before deducting placement agent fees and offering expenses.

On March 25, 2024, we entered into the Settlement Agreement with Novartis, pursuant to which Novartis agreed to pay $8.0 million to transfer our rights to future royalties on the net sales of Beovu®, which was received on April 8, 2024.

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

- the cost associated with Phase 1 clinical trials for PYX-201, PYX-106 and clinical trials for PYX-107;
- the manufacture of drug products and drug substance for our product candidates for PYX-201, PYX-106 and PYX-107;
- the timing and progress of our other preclinical and clinical development activities;
- the number and scope of other preclinical and clinical programs we decide to pursue;
- the progress of the development efforts of parties with whom we have entered or may in the future enter into in-licensing, collaborations and research and development agreements;
- the costs and timing of future commercialization activities, including product manufacturing, marketing, sales and distribution, for any of our product candidates for which we receive marketing licensure;

- our ability to maintain our current licenses and research and development programs and to establish new collaboration arrangements;
- the costs involved in prosecuting, maintaining and enforcing patent and other intellectual property rights;
- the costs of maintaining, expanding and protecting our intellectual property portfolio;
- the cost and timing of regulatory licenses;
- our efforts to hire additional clinical, regulatory, scientific, operational, financial and management personnel; and
- insurance, legal and other regulatory compliance expenses to operate as a public company.

Until such time, if ever, we can generate substantial product 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 candidates, or grant licenses on terms that may not be favorable to us. If we are unable to raise additional funds through equity or debt financings when needed, we may be required to delay, limit, reduce or terminate our product development or future commercialization efforts or grant rights to develop and market product candidates that we would otherwise prefer to develop and market ourselves.

Cash Flows

The following table provides information regarding our cash flows for the periods presented (in thousands):

	Three Months Ended March 31,	
	2024	**2023**
Net cash used in operating activities	$ (20,710)	$ (26,841)
Net cash used in investing activities	(18,498)	(99,393)
Net cash provided by financing activities	57,511	—
Net increase (decrease) in cash, cash equivalents, and restricted cash	**$ 18,303**	**$ (126,234)**

Operating Activities

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.

During the three months ended March 31, 2023, net cash used in operating activities was $26.8 million, which consisted of our net loss of $19.2 million and a net change in our operating assets and liabilities of $12.2 million, partially offset by non-cash charges of $4.6 million. The non-cash charges of $4.6 million was primarily due to $4.9 million in stock-based compensation and $0.6 million of accretion of discounts on marketable debt securities. The net change in our operating assets and liabilities was primarily due to a decrease of $13.3 million in accrued expenses, which relates to a one-time payment of $8.0 million made to Pfizer in January 2023 pursuant to the Pfizer A&R License Agreement, in addition to routine changes in working capital resulting from the timing of payments to our service providers.

Investing Activities

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.

During the three months ended March 31, 2023, net cash used in investing activities was $99.4 million, which consisted primarily of purchases of marketable debt securities of $95.0 million and leasehold improvement of $4.4 million.

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.

During the three months ended March 31, 2023, net cash provided by financing activities consisted primarily of proceeds from exercise of stock options.

Outlook

As of March 31, 2024, we had approximately $157.0 million in cash, cash equivalents, and short-term investments. Additionally, on April 8, 2024, we received $8.0 million from Novartis pursuant to the Settlement Agreement. We believe that our cash and cash equivalents as of March 31, 2024, along with the payment received from Novartis 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 $27.8 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 5. 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 2023 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 biopharmaceutical company with a limited operating history and have incurred significant losses since our inception. We expect to incur losses over at least the next several years and may never achieve or maintain profitability.

We are a clinical stage biopharmaceutical company with a limited operating history. Since our inception, we have incurred significant operating losses. We reported net losses of $3.3 million and $19.2 million for the three months ended March 31, 2024 and 2023, respectively. As of March 31, 2024 we had an accumulated deficit of $289.5 million. To date, we have not generated any revenues from product sales and have financed our operations primarily through sales of our equity interests. As such, we expect that it will be several years, if ever, before we have a product candidate ready for regulatory licensure and commercialization. We may never succeed in these activities and, even if we do, may never generate revenues that are significant enough to achieve profitability. To become and remain profitable, we must succeed in developing, obtaining marketing licensure for and commercializing products that generate significant revenues. This will require us to be successful in a range of challenging activities, including, without limitation, procuring clinical- and commercial-scale manufacturing, successfully completing preclinical studies and clinical trials of our product candidates, establishing arrangements with third parties for the conduct of our clinical trials, obtaining marketing licensure for our product candidates, manufacturing, marketing and selling any products for which we may obtain marketing licensure, discovering or obtaining rights to additional product candidates, identifying collaborators to develop product candidates we identify or additional uses of existing product candidates and successfully completing development of product candidates for our collaboration partners. In addition, for certain of our licensees from whom we are entitled to receive royalty payments if they successfully develop and commercialize any products covered by the licenses we acquired in the Merger, there is no guarantee that their product development and commercialization will lead to any such payments even if any such product candidates receive regulatory approval for commercial sale.

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

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

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

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

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

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

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

As of March 31, 2024, we had approximately $157.0 million in cash, cash equivalents, and short-term investments. Following the end of the first quarter of 2024, on April 8, 2024, we received $8.0 million from Novartis to transfer our rights to future royalties on the net sales of Beovu®. We believe that our cash, cash equivalents and short-term investments as of March 31, 2024, along with the payment received from Novartis will be sufficient to fund our operations into the second half of 2026.

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

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

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

- the costs involved in prosecuting, maintaining and enforcing patent and other intellectual property rights;
- any delays or interruptions that we experience in our preclinical studies, clinical trials and/or supply chain;
- the cost and timing of regulatory licenses; and
- our efforts to hire additional clinical, regulatory, scientific, operational, financial and management personnel.

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

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

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

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

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

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

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

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

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

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

Risks Related to the Discovery and Development of our Product Candidates

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

• not obtain marketing licensure at all;

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

Our APXiMAB platform has enabled the discovery of several product candidates with potential utility in multiple therapeutic areas and has resulted in five programs that have been licensed to third parties, including larger global biopharmaceutical companies and mid-sized regional or China-focused companies. Our likely counterparties for future licensing and collaboration arrangements include large and mid-size pharmaceutical companies, regional and national pharmaceutical companies, and biotechnology companies. Such arrangements generally allow the licensing parties to control the amount and timing of resources that they dedicate to the development or potential commercialization of any product candidates they develop from the technology we have licensed to them, subject to any territorial or field of use restrictions in the license.

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 revenues from them. Our ability to generate revenues 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 revenues to us.

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

- counterparties generally have significant discretion, if not total control, in determining the efforts and resources that they will apply to these development efforts;
- counterparties may not properly or adequately obtain, maintain, enforce, or defend intellectual property or proprietary rights relating to our intellectual property or may use our proprietary information in such a way as to expose us to potential litigation or other intellectual property-related proceedings, including proceedings challenging the scope, ownership, validity, and enforceability of our intellectual property;
- counterparties may own or co-own with us intellectual property covering their product candidates, and, in such cases, we typically will not have the exclusive right to commercialize such intellectual property or their product candidates based on the terms of the licensing agreement;
- we may need the cooperation of these counterparties to enforce or defend any intellectual property we contribute to the program;
- counterparties typically will control the interactions with regulatory authorities related to their product candidates, which may impact our ability to obtain and maintain regulatory approval of our own product candidates;
- disputes may arise between the counterparties and us that result in the delay or termination of the research, development, or commercialization of our product candidates or research programs or that result in costly litigation or arbitration that diverts management attention and resources;
- counterparties may decide to not pursue development and commercialization of any product candidates that are derived from our licensed technology, or may elect not to continue or renew development or commercialization programs based on clinical trial results, changes in the counterparties' strategic focus or available funding or external factors such as an acquisition that diverts resources or creates competing priorities, or counterparties may elect to fund or commercialize a competing product;
- counterparties could independently develop, or develop with third parties, products that compete directly or indirectly with our product candidates or research programs if the collaborators believe that competitive products are more likely to be successfully developed or can be commercialized under terms that are more economically attractive than ours;
- counterparties may not commit sufficient resources to the marketing and distribution of their product candidates, resulting in lower royalties to us;
- counterparties may grant sublicenses to our technology or undergo a change of control, and the sublicensees or new owners may decide to pursue a strategy with respect to the program which is not in our best interest;
- counterparties may become bankrupt, which may significantly delay our research or development programs, or may cause us to lose access to valuable technology, know-how, or intellectual property of the counterparty relating to our technology in relation to the terms of the licensing agreement;
- if these counterparties do not satisfy their obligations under our agreements with them, or if they terminate our licensing agreements with them, we may be adversely impacted; and
- licensing agreements may not lead to development or commercialization of product candidates in the most efficient manner or at all.

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

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

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

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

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

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

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

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

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

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

- the timing of our receipt of any marketing and commercialization licensures;

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

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

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

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

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

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

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

- the severity of the disease under investigation;
- the size and nature of the patient population;
- the eligibility criteria for the trial in question;

• the competing clinical trials or approved therapies which present an attractive alternative to patients and their physicians;

• the perceived risks and benefits of the product candidate under study, including as a result of adverse effects observed in similar or competing therapies;

• the efforts to facilitate timely enrollment in clinical trials;

• the patient referral practices of physicians;

• the burden on patients due to the scope and invasiveness of required procedures under clinical trial protocols, some of which may be inconvenient and/or uncomfortable;

• the ability to monitor patients adequately during and after treatment;

• the proximity and availability of clinical trial sites for prospective patients;

• the risk that enrolled patients will drop out or die before completion of the trial;

• patients failing to complete a clinical trial or returning for post-treatment follow-up; and

• our ability to manufacture the requisite materials for a patient and clinical trial.

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

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

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

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

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

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

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

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

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

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

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

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

• the product may become less competitive; and

• our reputation may suffer.

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

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

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

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

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

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

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

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

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

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

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

The Affordable Care Act, or ACA, includes a subtitle called the Biologics Price Competition and Innovation Act of 2009, or BPCIA, which created an abbreviated licensure pathway for biological products that are biosimilar to or interchangeable with an FDA-licensed reference biological product. Under the BPCIA, an application for a biosimilar product may not be submitted to the FDA until four years following the date that the reference product was first licensed by the FDA. In addition, the licensure of a biosimilar product may not be made effective by the FDA until 12 years from the date on which the reference product was first licensed. During this 12-year period of exclusivity, another company may still market a competing version of the reference product if the FDA approves a full BLA for the competing product containing the sponsor's own preclinical data and data from adequate and well-controlled clinical trials to demonstrate the safety, purity and potency of their product. The law is complex and is still being interpreted and implemented by the FDA. As a result, its ultimate impact, implementation, and meaning are subject to uncertainty. While it is uncertain when such processes intended to implement BPCIA may be fully adopted by the FDA, any such processes could have an adverse effect on the future commercial prospects for our product candidates.

There is a risk that any product candidates we may develop that are licensed as a biological product under a BLA would not qualify for the 12-year period of exclusivity or that this exclusivity could be shortened due to congressional action or otherwise, or that the FDA will not consider any product candidates we may develop to be reference products for competing products, potentially creating the opportunity for competition sooner than anticipated. Other aspects of the BPCIA, some of which may impact the BPCIA exclusivity provisions, have also been the subject of recent litigation, including litigation challenging the constitutionality of the ACA.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

- regulatory authorities may withdraw their licensure of the biological product or seize the biological product;
- we, or any future collaborators, may be required to recall the biological product, change the way the biological product is administered or conduct additional clinical trials;
- additional restrictions may be imposed on the marketing of, or the manufacturing processes for, the particular biological product;
- we may be subject to fines, injunctions or the imposition of civil or criminal penalties;
- regulatory authorities may require the addition of labeling statements, such as a "black box" warning or a contraindication;
- we, or any future collaborators, may be required to create a medication guide outlining the risks of the previously unidentified side effects for distribution to patients;
- we, or any future collaborators, could be sued and held liable for harm caused to patients;
- the biological product may become less competitive in the marketplace; and
- our reputation may suffer.

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

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

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

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

- restrictions on such products, manufacturers or manufacturing processes;
- restrictions and warnings on the labeling or marketing of a product;
- restrictions on product distribution or use;
- requirements to conduct post-marketing studies or clinical trials;
- warning letters or untitled letters;
- withdrawal of the products from the market;
- refusal to approve pending applications or supplements to approved applications that we submit;
- recall of products;
- fines, restitution or disgorgement of profits or revenues;
- suspension or withdrawal of marketing licenses;
- suspension of any ongoing clinical trials;
- damage to relationships with any potential collaborators;
- unfavorable press coverage and damage to our reputation;
- refusal to permit the import or export of our products;
- product seizure;
- injunctions or the imposition of civil or criminal penalties; or
- litigation involving patients using our products.

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

- restrictions on the marketing or manufacturing of our products, withdrawal of the product from the market or voluntary or mandatory product recalls;
- fines, warning letters or holds on clinical trials;
- refusal by the FDA and similar foreign authorities to approve pending applications or supplements to approved applications filed by us or suspension or revocation of licenses;
- product seizure or detention or refusal to permit the import or export of our product candidates; and

• injunctions or the imposition of civil or criminal penalties.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

In the EU, the criteria for designating an “orphan medicinal product” are similar in principle to those in the United States. A medicinal product may be designated as orphan if (1) it is intended for the diagnosis, prevention or treatment of a life-threatening or chronically debilitating condition (2) either (a) such condition affects no more than five in 10,000 persons in the EU when the application is made or (b) the product, without the benefits derived from orphan status, would not generate sufficient return in the EU to justify investment and (3) there exists no satisfactory method of diagnosis, prevention or treatment of such condition authorized for marketing in the EU, or if such a method exists, the product will be of significant benefit to those affected by the condition. The application for Orphan Drug Designation must be submitted before the marketing authorization application. Orphan Drug Designations entitle a party to financial incentives such as reduction of fees or fee waivers and are, upon grant of a marketing authorization, entitled to 10 years of market exclusivity. During the 10-year market exclusivity period, the EMA cannot accept another marketing authorization application, or grant a marketing authorization or accept an application to extend an existing marketing authorization, for the same therapeutic indication, in respect of a similar medicinal product. An orphan medicinal product can also obtain an additional two years of market exclusivity in the EU for pediatric studies. No extension to any supplementary protection certificate can be granted on the basis of pediatric studies for orphan indications. Orphan Drug Designation does not convey any advantage in, or shorten the duration of, the regulatory review and approval process.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

Our ability to successfully commercialize our product candidates will depend, in part, on the extent to which coverage and adequate reimbursement for any products for which we obtain marketing authorization will be available from third-party payors. In the United States, no uniform policy for coverage and reimbursement for pharmaceutical products exists among third-party payors. Third-party payors often rely upon Medicare coverage policy and payment limitations in setting reimbursement policies, but also have their own methods and approval processes apart from Medicare coverage and reimbursement determinations. Therefore, coverage and reimbursement for products for which we may obtain marketing authorization could differ significantly from payor to payor. One payor's determination to provide coverage for a product does not assure that other payors will also provide coverage and reimbursement for the product. Payors consider a number of factors when determining whether to cover a new product, including, for example, whether the product is a covered benefit under its health plan; safe, effective and medically necessary; appropriate for the specific patient; cost-effective; and neither experimental nor investigational. Third-party payors may also limit coverage to specific products on an approved list, or formulary, which might not include all of the FDA-approved products for a particular indication.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

If we or our third-party manufacturers and suppliers fail to comply with environmental, health and safety laws and regulations, we could become subject to fines or penalties or incur costs that could have an adverse effect on the success of our business.

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

Although we maintain workers' compensation insurance to cover us for costs and expenses, we may incur due to injuries to our employees resulting from the use of hazardous materials or other work-related injuries, this insurance may not provide adequate coverage against potential liabilities. We do not carry specific biological waste or hazardous waste insurance coverage, workers' compensation or property and casualty and general liability insurance policies that include coverage for damages and fines arising from biological or hazardous waste exposure or contamination.

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

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

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

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

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

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

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

As of May 13, 2024, we had 51 full-time employees. As our development and commercialization plans and strategies develop, and as we continue to operate as a public company, we expect to expand our employee base for managerial, operational, financial and other resources. In addition, we have limited experience in product development. As our product candidates enter and advance through preclinical studies and clinical trials, we will need to expand our development, regulatory and manufacturing capabilities or contract with other organizations to provide these capabilities for us. In the future, we expect to have to manage additional relationships with collaborators or partners, suppliers and other organizations. Our ability to manage our operations and future growth will require us to integrate products and technology from the Merger and continue to improve our operational, financial and management controls, reporting systems and procedures. We may not be able to implement improvements to our management information and control systems in an efficient or timely manner and may discover deficiencies in existing systems and controls. Our inability to successfully manage our growth and expand our operations could have a material and adverse effect on our business, financial condition, results of operations and prospects.

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

We currently have no marketing, sales, and distribution capabilities because all our product candidates are still in preclinical or clinical development. If any of our product candidates complete clinical development and are approved, we intend to either establish a sales and marketing organization with technical expertise and supporting distribution capabilities to commercialize our product candidates in a legally compliant manner, or to outsource this function to a third party. There are risks involved if we decide to establish our own sales and marketing capabilities or enter into arrangements with third parties to perform these services. To the extent that we enter into collaboration agreements with respect to marketing, sales or distribution, our product revenues 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 revenues will suffer and we may incur significant additional losses, which would have a material adverse effect on our business, financial condition, and results of operations.

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

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

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

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

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

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

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

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

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

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

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

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

- differing regulatory requirements and reimbursement regimes in foreign countries;
- unexpected changes in tariffs, trade barriers, price and exchange controls and other regulatory requirements;
- economic weakness, including inflation, or political instability in particular foreign economies and markets;
- compliance with tax, employment, immigration and labor laws for employees living or traveling abroad;
- foreign taxes, including withholding of payroll taxes;
- foreign currency fluctuations, which could result in increased operating expenses and reduced revenues, and other obligations incident to doing business in another country;
- difficulties staffing and managing foreign operations;
- workforce uncertainty in countries where labor unrest is more common than in the United States;
- potential liability under the FCPA or comparable foreign regulations;
- challenges enforcing our contractual and intellectual property rights, especially in those foreign countries that do not respect and protect intellectual property rights to the same extent as the United States;
- production shortages resulting from any events affecting raw material supply or manufacturing capabilities abroad; and
- business interruptions resulting from geo-political actions, including war and terrorism.

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

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

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

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

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

Risks Related to Our Dependence on Third Parties

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

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

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

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

In addition, we face significant competition in seeking appropriate strategic partners and the negotiation process for these sorts of transactions is time-consuming, complex and expensive. Moreover, we may not be successful in our efforts to establish a strategic partnership or other alternative arrangements for our product candidates because they may be deemed to be at too early of a stage of development for collaborative effort and third parties may not view our product candidates as having the requisite potential to demonstrate safety, potency, purity and efficacy and obtain marketing approval. Additionally, our existing partners may decide to acquire or partner with other companies developing oncology therapeutics, which may have an adverse impact on our business prospects, financial condition and results of operations.

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

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

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

The manufacturing process for a product candidate is subject to FDA and foreign regulatory authority review. Suppliers and manufacturers must meet applicable manufacturing requirements and undergo rigorous facility and process validation tests required by regulatory authorities in order to comply with regulatory standards, such as cGMPs. In the event that any of our manufacturers fail to comply with such requirements or to perform its obligations to us in relation to quality, timing or otherwise, or if our supply of components or other materials becomes limited or interrupted for other reasons, we may be forced to manufacture the materials ourselves, for which we currently do not have the capabilities or resources, or enter into an agreement with another third party, which we may not be able to do on reasonable terms, if at all. In some cases, the technical skills or technology required to manufacture our product candidates may be unique or proprietary to the original manufacturer and we may have difficulty transferring such skills or technology to another third party and a feasible alternative may not exist. These factors would increase our reliance on such manufacturer or require us to obtain a license from such manufacturer in order to have another third party manufacture our product candidates. If we are required to change manufacturers for any reason, we will be required to verify that the new manufacturer maintains facilities and procedures that comply with quality standards and with all applicable regulations and guidelines. The delays associated with the verification of a new manufacturer could negatively affect our ability to develop product candidates in a timely manner or within budget.

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

- an inability to initiate or continue clinical trials of product candidates under development;
- delay in submitting regulatory applications, or receiving regulatory licenses, for product candidates;
- loss of the cooperation of an existing or future collaborator;
- subjecting third party manufacturing facilities or our manufacturing facilities to additional inspections by regulatory authorities;
- requirements to cease distribution or to recall batches of our product candidates; and
- the inability to commercialize a product candidate, and an inability to meet commercial demands for such products.

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

- reliance on the CDMO for regulatory, compliance and quality assurance;
- the possible breach of the manufacturing agreement by the CDMO;
- the possible misappropriation of our proprietary information, including our trade secrets and know-how; and
- the possible termination or nonrenewal of the agreement by the CDMO at a time that is costly or inconvenient for us.

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

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

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

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

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

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

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

We currently contract manufacturing operations to third parties, and large quantities of our product candidates are manufactured by these third parties globally, including in China. Any disruption in production or inability of our manufacturers to produce adequate quantities to meet our needs could impair our ability to operate our business on a day-to-day basis and to continue our development of our product candidates. Foreign CDMOs may be subject to U.S. legislation, including the proposed BIOSECURE Act, sanctions, trade restrictions and other foreign regulatory requirements which could increase the cost or reduce the supply of material available to us, delay the procurement or supply of such material or have an adverse effect on our ability to manufacture our product candidates. Any of these matters could materially and adversely affect our business and results of operations. Any recall of the manufacturing lots or similar action regarding our product candidates used in clinical trials could delay the trials or detract from the integrity of the trial data and its potential use in future regulatory filings.

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

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

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

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

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

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

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

If these CROs do not successfully carry out their contractual duties, meet expected deadlines or conduct our clinical trials in accordance with regulatory requirements or our stated protocols, we will not be able to obtain, or may be delayed in obtaining, marketing licenses for our product candidates and will not be able to, or may be delayed in our efforts to, successfully commercialize our product candidates.

Risks Related to Our Intellectual Property

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

The degree of future protection afforded by our intellectual property rights is uncertain because intellectual property rights have limitations and may not adequately protect our business. The following examples are illustrative:

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

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

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

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

The licensing or acquisition of third-party intellectual property rights is a competitive area, and more established companies may also pursue strategies to license or acquire third-party intellectual property rights that we may consider attractive or necessary. These established companies may have a competitive advantage over us due to their size, capital resources and greater clinical development and commercialization capabilities. In addition, companies that perceive us to be a competitor may be unwilling to assign or license rights to us. We also may be unable to license or acquire third-party intellectual property rights on terms that would allow us to make an appropriate return on our investment or at all. If we are unable to successfully obtain rights to required third-party intellectual property rights or maintain the existing intellectual property rights we have, we may have to abandon development of the relevant program or product candidate(s), which could have a material adverse effect on our business, financial condition, results of operations and prospects. Furthermore, even if we were able to obtain a license, it could be non-exclusive, thereby giving our competitors and other third parties access to the same technologies licensed to us, and it could require us to make substantial licensing and royalty payments. We could be forced, including by court order, to cease developing, manufacturing and commercializing the infringing technology or product candidate. In addition, we could be found liable for monetary damages, including treble damages and attorneys' fees, if we are found to have willfully infringed a patent or other intellectual property right. We may be required to indemnify collaborators or contractors against such claims. A finding of infringement could prevent us from manufacturing and commercializing our current or any future product candidates or force us to cease some or all of our business operations, which could materially harm our business. Even if we are successful in defending against such claims, litigation can be expensive and time consuming and would divert management's attention from our core business. Claims that we have misappropriated the confidential information or trade secrets of third parties could have a similar negative impact on our business, financial condition, results of operations and prospects.

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

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

In addition, we may in the future be subject to claims by our former employees or consultants asserting an ownership right in our patents or patent applications, as a result of the work they performed on our behalf. Although it is our policy to require our employees and contractors who may be involved in the conception or development of intellectual property to execute agreements assigning such intellectual property to us, we may be unsuccessful in executing such an agreement with each party who, in fact, conceives or develops intellectual property that we regard as our own, and we cannot be certain that our agreements with such parties will be upheld in the face of a potential challenge or that they will not be breached, for which we may not have an adequate remedy. The assignment of intellectual property rights may not be self-executing, or the assignment agreements may be breached, and we may be forced to bring claims against third parties, or defend claims that they may bring against us, to determine the ownership of what we regard as our intellectual property.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

Since we rely on third parties to help us discover, develop, manufacture or commercialize our current and any future product candidates, or if we collaborate with third parties for the development, manufacturing or commercialization of our current or any future product candidates, we must, at times, share trade secrets with them. We may also conduct joint research and development programs that may require us to share trade secrets under the terms of our research and development partnerships or similar agreements. We seek to protect our proprietary technology in part by entering into confidentiality agreements and, if applicable, material transfer agreements, consulting agreements or other similar agreements with our advisors, employees, third-party contractors and consultants prior to beginning research or disclosing proprietary information. These agreements typically limit the rights of the third parties to use or disclose our confidential information, including our trade secrets. Despite the contractual provisions employed when working with third parties, the need to share trade secrets and other confidential information increases the risk that such trade secrets become known by our competitors, are inadvertently incorporated into the technology of others, or are disclosed or used in violation of these agreements. Given that our proprietary position is based, in part, on our know-how and trade secrets, a competitor's discovery of our trade secrets or other unauthorized use or disclosure could have an adverse effect on our business and results of operations.

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

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

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

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

Risks Related to Our Common Stock

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

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

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

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

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

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

- results of our preclinical studies, IND submissions and clinical trials, if any, of our product candidates, or those of our competitors or our existing or future collaborators;
- regulatory or legal developments in the U.S. and other countries, especially changes in laws or regulations applicable to our products;
- the success of competitive products or technologies;
- introductions and announcements of new products by us, our future commercialization partners, or our competitors, and the timing of these introductions or announcements;
- actions taken by regulatory agencies with respect to our products, our product candidates, preclinical studies, clinical trials, manufacturing process or sales and marketing terms;
- actual or anticipated variations in our financial results or those of companies that are perceived to be similar to us;
- the success of our efforts to acquire or in-license additional technologies, products or product candidates;
- developments concerning any future collaborations, including but not limited to those with our sources of manufacturing supply and our commercialization partners;
- market conditions in the pharmaceutical and biotechnology sectors;
- announcements by us or our competitors of significant acquisitions, strategic collaborations, joint ventures or capital commitments;
- developments or disputes concerning patents or other proprietary rights, including patents, litigation matters and our ability to obtain patent protection for our products;

- our ability or inability to raise additional capital and the terms on which we raise it;
- the recruitment or departure of key personnel;
- changes in the structure of healthcare payment systems;
- actual or anticipated changes in earnings estimates or changes in stock market analyst recommendations regarding our common stock, other comparable companies or our industry generally;
- our failure or the failure of our competitors to meet analysts' projections or guidance that we or our competitors may give to the market;
- fluctuations in the valuation of companies perceived by investors to be comparable to us;
- announcement and expectation of additional financing efforts;
- speculation in the press or investment community;
- trading volume of our common stock;
- sales of our common stock by us, our insiders or our other stockholders;
- the concentrated ownership of our common stock;
- changes in accounting principles;
- terrorist acts, acts of war or periods of widespread civil unrest;
- the impact of any natural disasters or public health emergencies and other calamities; and
- general economic, industry and market conditions.

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

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

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

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

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

Our principal stockholders and management own a significant percentage of our stock and will be able to exert significant control over matters subject to stockholder approval and their interests may conflict with your interests as an owner of our common stock.

As of May 13, 2024, our executive officers and directors, together with holders of five percent or more of our outstanding common stock and their respective affiliates, beneficially own approximately 44.8% of our outstanding common stock. As a result, these stockholders, if acting together, have significant influence over the outcome of corporate actions requiring stockholder approval, including the election of directors, any merger, consolidation or sale of all or substantially all of our assets and any other significant corporate transaction. The interests of these stockholders may not be the same as or may even conflict with interests of our other stockholders. For example, these stockholders could delay or prevent a change of control of our company, even if such a change of control would benefit our other stockholders, which could deprive our stockholders of an opportunity to receive a premium for their common stock as part of a sale of our company or our assets and might affect the prevailing market price of our common stock. The significant concentration of stock ownership may adversely affect the trading price of our common stock due to investors' perception that conflicts of interest may exist or arise.

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

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

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

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

We are an "emerging growth company," as defined in the JOBS Act. We will remain an emerging growth company until the earlier of (i) the last day of the fiscal year (a) following the fifth anniversary of the completion of our initial public offering, or IPO, (b) in which we have total annual gross revenues 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 revenues were 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 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.

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

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

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

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

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

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

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

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

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

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

We are subject to the periodic reporting requirements of the Exchange Act. We designed our disclosure controls and procedures to reasonably assure that information we must disclose in reports we file or submit under the Exchange Act is accumulated and communicated to management, and recorded, processed, summarized and reported within the time periods specified in the rules and forms of the SEC. We believe that any disclosure controls and procedures or internal controls and procedures, no matter how well-conceived and operated, can provide only reasonable, not absolute, assurance that the objectives of the control system are met.

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

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

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

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

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

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

Our amended and restated certificate of incorporation provides that, unless we consent in writing to the selection of an alternative forum, the Court of Chancery of the State of Delaware (or, if the Court of Chancery of the State of Delaware does not have jurisdiction, another state court located within the State of Delaware, or the federal district court for the District of Delaware) shall be the sole and exclusive forum for the following types of proceedings: (1) any derivative action or proceeding brought on our behalf under Delaware law, (2) any action asserting a claim of breach of a fiduciary duty owed by any of our directors, officers or other employees to us or our stockholders, (3) any action arising pursuant to any provision of the Delaware General Corporation Law or our amended and restated certificate of incorporation or bylaws, (4) any other action asserting a claim that is governed by the internal affairs doctrine or (5) any other action asserting an "internal corporate claim," as defined in Section 115 of the Delaware General Corporation Law. This provision would not apply to suits brought to enforce a duty or liability created by the Securities Act, the Exchange Act or any other claim for which the U.S. federal courts have exclusive jurisdiction. Furthermore, Section 22 of the Securities Act creates concurrent jurisdiction for federal and state courts over all such Securities Act actions. Accordingly, both state and federal courts have jurisdiction to entertain such claims. Our amended and restated bylaws further provide that the federal district courts of the United States of America will be the exclusive forum to the fullest extent permitted by law, for resolving any complaint asserting a cause of action arising under the Securities Act or the Exchange Act. This choice of forum provision may limit a stockholder's ability to bring a claim in a judicial forum that it finds favorable for disputes with us or our directors, officers or other employees, which may discourage such lawsuits against us and our directors, officers and employees. Alternatively, if a court were to find these provisions of our amended and restated certificate of incorporation and amended and restated bylaws inapplicable to, or unenforceable in respect of, one or more of the specified types of actions or proceedings, we may incur additional costs associated with resolving such matters in other jurisdictions, which could adversely affect our business and financial condition. Any person or entity purchasing or otherwise acquiring any interest in shares of our capital stock shall be deemed to have notice of and to have consented to the provisions of our amended and restated certificate of incorporation and amended and restated bylaws described above.

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

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

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

Item 2. Unregistered Sales of Equity Securities and Use of Proceeds.

Private Placement Offering

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

On February 29, 2024, we completed the Private Placement in which we issued and sold (i) 8,849,371 shares, or the Shares, of our common stock, par value $0.001 per share, or the Common Stock, at a purchase price of $4.78 per share, and (ii) pre-funded warrants, or the Pre-Funded Warrants, to purchase up to an aggregate of 1,611,215 shares of Common Stock at a purchase price of $4.779 per Pre-Funded Warrant, which represents the per share purchase price of the Shares less the $0.001 per share exercise price for each Pre-Funded Warrant.

The offer and sale of securities in the Private Placement were exempt from registration under the Securities Act under Section 4(a)(2) of the Securities Act as transactions by an issuer not involving a public offering. Each of the Purchasers was an accredited person and had adequate access to information about the Company. Leerink Partners LLC acted as the lead placement agent and LifeSci Capital LLC acted as co-placement agent for the Private Placement.

On February 26, 2024, we also entered into a registration rights agreement, or the Registration Rights Agreement, with the Purchasers, pursuant to which we agreed to register for the resale of the Shares and Pre-Funded Warrants, together, the Registrable Securities. The Shares and Pre-Funded Warrants were registered on Form S-3 (Registration No. 333-278282) on March 27, 2024. The Form S-3 was deemed effective by the SEC on April 3, 2024.

Use of Proceeds from Initial Public Offering

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

Our planned use of the net proceeds from the IPO as described in our final prospectus filed with the SEC on October 8, 2021 has changed due to the re-prioritization of our pipeline contemplated in connection with our reorganization. As a result, we currently expect to use our cash and cash equivalents, which include the net proceeds from our IPO, to advance the clinical development of PYX-201 and PYX-106, as well as for general corporate purposes.

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
4.1	Form of Pre-Funded Warrant	8-K	001-40881	4.1	February 28, 2024	
10.1†	Securities Purchase Agreement, dated February 26, 2024, by and among Pyxis Oncology, Inc. and each of the purchasers as party thereto	8-K	001-40881	10.1	February 28, 2024	
10.2	Form of Registration Rights Agreement	8-K	001-40881	10.2	February 28, 2024	
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.

† Certain confidential information contained in this exhibit, marked by [***], has been omitted pursuant to Item 601(b)(10)(iv) of Regulation S-K.

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 14, 2024

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

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

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 14, 2024

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

Exhibit 31.2

CERTIFICATION

I, Pamela Connealy, certify that:

1. I have reviewed this 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 14, 2024

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

Exhibit 32.1

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

In connection with the Quarterly Report of Pyxis Oncology, Inc. (the "Company") on Form 10-Q for the period ended March 31, 2024 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 14, 2024

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

Exhibit 32.2

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

In connection with the Quarterly Report of Pyxis Oncology, Inc. (the "Company") on Form 10-Q for the period ended March 31, 2024 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 14, 2024

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