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, 2022

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.)**
35 Cambridgepark Drive Cambridge, Massachusetts	**02140**
(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	☐
Non-accelerated filer	☒	Smaller reporting company	☒
		Emerging growth company	☒

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

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

As of May 13, 2022, the registrant had 32,817,062 shares of common stock, $0.001 par value per share, outstanding.

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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 subsidiary. 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 preclinical 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-202, PYX-203, PYX-106 and PYX-102 all of which are in the early stages of development, and if PYX-201, PYX-202, PYX-203, PYX-106 and/or PYX-102 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.
- All of our product candidates are currently in preclinical development. 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 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 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 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, 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.
- 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.
- 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 face risks related to health epidemics and outbreaks, including the COVID-19 pandemic, which could significantly disrupt our preclinical studies and clinical trials, and therefore our receipt of necessary regulatory licensure or approvals could be delayed or prevented.
- 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 may delay or impair our ability to initiate or complete our clinical trials, obtain regulatory licensure or approvals or commercialize approved products.
- If we are unable to obtain 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, LegoChem, 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.
- If the market opportunities for any product that we develop are smaller than we believe they are, our revenue may be adversely affected, and our business may suffer.

PART I—FINANCIAL INFORMATION

Item 1. Financial Statements.

PYXIS ONCOLOGY, INC.

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

	March 31, 2022	December 31, 2021
Assets		
Current assets:		
Cash and cash equivalents	$ 247,087	$ 274,735
Restricted cash	1,472	1,472
Prepaid expenses and other current assets	2,698	2,466
Total current assets	251,257	278,673
Property and equipment, net	995	1,007
Operating lease right-of-use assets	—	232
Other assets, noncurrent	449	109
Total assets	**$ 252,701**	**$ 280,021**
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable	$ 2,055	$ 11,951
Accrued expenses and other current liabilities	17,132	6,592
Operating lease liabilities, current portion	—	165
Total current liabilities	19,187	18,708
Total liabilities	19,187	18,708
Commitments and contingencies (Note 12)		
Stockholders' equity:		
Preferred stock, par value $0.001 per share, 10,000,000 shares authorized as of March 31, 2022 and December 31, 2021, zero shares issued and outstanding as of March 31, 2022 and December 31, 2021	—	—
Common stock, $0.001 par value per share; 190,000,000 shares authorized as of March 31, 2022 and December 31, 2021; 32,843,985 and 32,792,867 shares issued as of March 31, 2022 and December 31, 2021, respectively, and 32,374,907 and 32,222,881 shares outstanding as of March 31, 2022 and December 31, 2021, respectively	32	32
Additional paid-in capital	356,580	352,999
Accumulated deficit	(123,098)	(91,718)
Total stockholders' equity	233,514	261,313
Total liabilities and stockholders' equity	**$ 252,701**	**$ 280,021**

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,	
	2022	**2021**
Operating expenses:		
Research and development	$ 20,071	$ 32,774
General and administrative	11,318	2,955
Total operating expenses	31,389	35,729
Loss from operations	(31,389)	(35,729)
Other income (expense):		
Interest income	9	4
Change in fair value of derivative liability	—	(1,100)
Total other income (expense)	9	(1,096)
Net loss and comprehensive loss	**$ (31,380)**	**$ (36,825)**
Net loss per common share - basic and diluted	$ (0.97)	$ (27.26)
Weighted average shares of common stock outstanding - basic and diluted	32,316,689	1,350,743

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

PYXIS ONCOLOGY, INC.

Condensed Consolidated Statements of Convertible Preferred Stock and Stockholders' Deficit
(In thousands, except share amounts)
(Unaudited)

	Convertible Preferred Stock		Common Stock		Additional Paid-in	Accumulated	Total Stockholders'
	Shares	Amount	Shares	Amount	Capital	Deficit	Equity (Deficit)
Balance at January 1, 2022	—	$ —	32,222,881	$ 32	$ 352,999	$ (91,718)	$ 261,313
Stock options exercised	—	—	51,118	—	176	—	176
Vesting of restricted common stock	—	—	100,908	—	1	—	1
Stock-based compensation	—	—	—	—	3,404	—	3,404
Net loss	—	—	—	—	—	(31,380)	(31,380)
Balance at March 31, 2022	**—**	**$ —**	**32,374,907**	**$ 32**	**$ 356,580**	**$ (123,098)**	**$ 233,514**

	Convertible Preferred Stock		Common Stock		Additional Paid-in	Accumulated	Total Stockholders'
	Shares	Amount	Shares	Amount	Capital	Deficit	Equity (Deficit)
Balance at January 1, 2021	22,724,925	$ 21,942	1,289,342	$ 1	$ 97	$ (15,743)	$ (15,645)
Issuance of Series B convertible preferred stock to Pfizer, Inc. (Refer to Note 5)	12,152,145	20,000	—	—	—	—	—
Issuance of Series B convertible preferred stock, net of issuance costs of $419	92,660,103	152,081	—	—	—	—	—
Vesting of restricted common stock	—	—	123,085	—	3	—	3
Stock-based compensation	—	—	—	—	2,450	—	2,450
Net loss	—	—	—	—	—	(36,825)	(36,825)
Balance at March 31, 2021	**127,537,173**	**$ 194,023**	**1,412,427**	**$ 1**	**$ 2,550**	**$ (52,568)**	**$ (50,017)**

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,	
	2022	**2021**
Operating activities		
Net loss	$ (31,380)	$ (36,825)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	158	113
Stock-based compensation	3,404	2,450
Non-cash research and development expenses	—	20,000
Non-cash lease expense	232	217
Changes in fair value of derivative liability	—	1,100
Changes in operating assets and liabilities:		
License receivable	—	(8,000)
Prepaid expenses and other assets	(232)	(71)
Other assets, noncurrent	(340)	—
Accounts payable	(9,896)	(447)
Accrued expenses and other current liabilities	10,540	(491)
Operating lease liabilities	(165)	(146)
Derivative liability	—	3,369
Net cash used in operating activities	**(27,679)**	**(18,731)**
Investing activities		
Purchase of property and equipment	(146)	(169)
Investment in joint venture	—	(50)
Net cash used in investing activities	**(146)**	**(219)**
Financing activities		
Proceeds from issuance of Series B convertible preferred stock, net of issuance costs	—	151,581
Deferred offering costs	—	(47)
Proceeds from the exercise of stock options	176	—
Net cash provided by financing activities	**176**	**151,534**
Net (decrease) increase in cash, cash equivalents, and restricted cash	(27,649)	132,584
Cash, cash equivalents and restricted cash at beginning of year	276,316	8,188
Cash, cash equivalents and restricted cash at end of year	**$ 248,667**	**$ 140,772**
Supplemental schedule of noncash investing and financing activities:		
Reconciliation of cash, cash equivalents and restricted cash:		
Cash and cash equivalents	$ 247,087	$ 140,663
Restricted cash	1,580	109
Total cash, cash equivalents and restricted cash shown in the statement of cash flows	**$ 248,667**	**$ 140,772**

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

1. Description of Business

Nature of Business

Pyxis Oncology, Inc. (the "Company"), a Delaware corporation, was founded in June 2018 and launched its operations in July 2019. The Company is a preclinical oncology company focused on developing an arsenal of next-generation therapeutics to target difficult-to-treat cancers and improve quality of life for patients. The Company develops its product candidates with the objective to directly kill tumor cells, and to address the underlying pathologies created by cancer that enable its uncontrollable proliferation and immune evasion. Since the Company's launch in 2019, the Company has developed a broad portfolio of novel antibody drug conjugate, or ADC, product candidates and monoclonal antibody, or mAb, preclinical discovery programs that the Company is developing as monotherapies and in combination with other therapies.

The Company has determined that it has one operating and reporting segment.

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 subsidiary. 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, 2022 are not necessarily indicative of those expected for the year ending December 31, 2022 or for any future period. The condensed consolidated balance sheet as of December 31, 2021 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, 2021, included in the Company's Annual Report on Form 10-K filed with the SEC on March 29, 2022.

Liquidity

As of March 31, 2022, the Company had an accumulated deficit of $123.1 million. The Company has incurred losses and negative cash flows from operations since inception, including net losses of $31.4 million and $36.8 million for the three months ended March 31, 2022 and 2021, respectively.

The Company has not generated any revenues to date and does not anticipate generating any revenues 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 and cash equivalents of $247.1 million as of March 31, 2022 to 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 financings or other sources. If the Company is not able to secure adequate additional funding, the Company may be forced to make reductions in spending, extend payment terms with suppliers, liquidate assets where possible, or suspend or curtail planned programs. Any of these actions could materially harm the Company's business, results of operations and future prospects.

Use of Estimates

The preparation of unaudited condensed consolidated financial statements in conformity with U.S. GAAP requires management to make estimates and assumptions that affect the amounts reported in the unaudited condensed consolidated financial statements and accompanying notes. The Company regularly evaluates estimates and assumptions related to assets, liabilities, stock-based compensation, derivative liability, operating leases, and research and development costs. 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.

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 research organizations, 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 that subject the Company to significant concentrations of credit risk consist primarily of cash and cash equivalents. The Company's cash and cash equivalents are held at an accredited financial institution and the Company has not experienced any losses in such accounts. The Company maintains its cash in bank deposit accounts, which at times may exceed federally insured limits. The Company's cash equivalents consist primarily of short-term money market funds held in accredited financial institutions. The Company believes it is not exposed to any significant risk in cash and cash equivalents.

Significant Accounting Policies

There have been no changes to the Company's significant accounting policies disclosed in "Note 2 – Summary of Significant Accounting Policies" of the Company's Annual Report on Form 10-K filed with the SEC on March 29, 2022.

Recent Accounting Pronouncements

Recent authoritative guidance issued by the FASB (including technical corrections to the ASC), the American Institute of Certified Public Accountants, 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, 2022 and December 31, 2021, respectively, in accordance with the FASB ASC 820 hierarchy (in thousands):

	Fair Value Measurements at March 31, 2022			
	Level 1	**Level 2**	**Level 3**	**Total**
Assets				
Money market funds	$ 227,219	$ —	$ —	$ 227,219

	Fair Value Measurements at December 31, 2021			
	Level 1	**Level 2**	**Level 3**	**Total**
Assets				
Money market funds	$ 272,210	$ —	$ —	$ 272,210

The Company's cash equivalents represent deposits in a short-term United States Treasury money market fund quoted in an active market and classified as a Level 1 asset. There were no assets or liabilities measured at fair value on a nonrecurring basis at March 31, 2022 and December 31, 2021. There were no transfers between Level 1 and Level 2 of the fair value hierarchy during the three months ended March 31, 2022 and 2021.

The Company recognized initial derivative liability of $3.4 million related to LegoChem Extra Milestone Payment and revalued it as of March 31, 2021, with a fair value adjustment to the derivative liability of $1.1 million. The fair value of the derivative liability was initially determined using a probability-weighted income approach and is revalued at each reporting date or more frequently if circumstances dictate. The significant unobservable inputs used in the fair value measurement of the derivative liability include probability of payment factors and the discount rate. Refer to Note 5, Licensing Agreements, for additional information on the derivative liability.

4. Joint Venture

In March 2021, the Company entered into definitive transaction agreements with Alloy Therapeutics, Inc. (“Alloy”) and Voxall Therapeutics, LLC (“Voxall”), to finance and operate Voxall, a joint venture company formed in collaboration with Alloy to leverage the Company’s technology and Alloy’s ATX-Gx™ platform and antibody discovery services. Voxall granted to the Company and Alloy 50% of the voting membership units of Voxall in exchange for certain initial contributions. The Company’s initial contribution included $50 thousand and a non-exclusive fully paid-up license to certain intellectual property owned or controlled by the Company and the execution of the services agreement to enable the collaboration with Voxall. Alloy’s initial contribution included $50 thousand and the execution of the Alloy license agreement and the Alloy services agreement to enable the collaboration with Voxall. Voxall is governed by a board of directors consisting of an equal number of the Company’s representatives and Alloy’s representatives. The protective provisions under Voxall’s operating agreement require the approval of both the Company and Alloy before Voxall may take certain actions.

The Company accounted for investment in Voxall under the equity method of accounting. The initial contribution of $50 thousand was recorded as “Investment in equity method investment in joint venture” in March 2021.

Voxall has incurred losses since inception and the Company has recognized its share of losses of Voxall only to the extent of the carrying value of its investment in Voxall and the promissory note issued by Voxall, which aggregated to $0.2 million in 2021. The Company has not recognized any further losses of Voxall during the three months ended March 31, 2022. The remaining unabsorbed loss will be offset against future income, if any. As the Company has no commitment to fund the losses of the equity method investment, the carrying value of the equity method investment has not been reduced below zero.

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.

Further, pursuant to the University License Agreement, the Company is obligated to pay to the University, the 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 involving the University as of March 31, 2022 and concluded no such amounts were due.

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 antibody drug conjugate ("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. Pfizer has also granted the Company a non-exclusive license to use Pfizer’s ADC technology platform to develop and commercialize the licensed ADCs and licensed products. The initial licensed targets include CD123 and extra domain B (EBD of fibronectin) 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. During the three months ended March 31, 2021, the Company paid a combined $25.0 million for the license fee, which was recorded as research and development expenses, consisting of an upfront fee equal to a cash payment of $5.0 million and the issuance of 12,152,145 shares of Series B convertible preferred stock with a value of $20.0 million to Pfizer.

Further, pursuant to the Pfizer License Agreement, the Company is obligated to pay the 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 involving Pfizer as of March 31, 2022 and concluded no such amounts were due.

LegoChem Biosciences, Inc. Agreements

In December 2020, the Company entered into a license agreement (the "LegoChem License Agreement") and an opt-in, investment and additional consideration agreement (the "Opt-In Agreement") with LegoChem Biosciences, Inc. ("LegoChem"). Pursuant to the LegoChem License Agreement, the Company obtained worldwide (other than Korea) license for development and commercialization rights for LCB67, an ADC product candidate targeting DLK-1, and products containing the licensed compound. The Company paid $9.0 million in March 2021 to LegoChem, which was recorded as research and development expenses for the three months ended March 31, 2021. Further, pursuant to the LegoChem License Agreement, the Company is obligated to pay the future contingent payments including development, regulatory and commercial milestones as well as running royalties on net sales of licensed products at varying rates.

In addition, as part of the Opt-in Agreement, LegoChem had an option to pay $8.0 million to the Company, in exchange for the right to receive a milestone payment (the "Extra Milestone Payment") of $9.6 million upon the earliest to occur of certain events, including the date of pricing or offer of the first public offering of its common stock or if the Company is the subject of a change in control transaction. The Company determined that the Extra Milestone Payment met the definition and recognition condition of derivative under ASC 815, *"Derivatives and Hedging"* for which there was a binding contract and firm commitment. An initial derivative liability was recognized for $3.4 million with an offset to research and development expenses in January 2021. The derivative liability is re-measured at each reporting date, with changes recorded in "Other income (expense)" in the unaudited condensed consolidated statements of operations and comprehensive loss. The Company recorded a fair value adjustment to the derivative liability of $1.1 million for the three months ended March 31, 2021. The Company settled derivative liability by paying the Extra Milestone Payment of $9.6 million to LegoChem in January 2022.

The Company assessed the milestone and royalty events involving LegoChem as of March 31, 2022 and concluded no such amounts were due.

License Agreement with Biosion USA, Inc.

On March 28, 2022, the Company entered into a license agreement, or the "Biosion License Agreement," with Biosion USA, Inc., or Biosion, pursuant to which the Company obtained exclusive, worldwide (other than Greater China (mainland China, Hong Kong, Macau and Taiwan)), licenses for development, manufacture and commercialization rights for BSI-060T, a Siglec-15 targeting antibody, an IO product candidate (now referred to as PYX-106), and products containing the licensed compound.

Pursuant to the Biosion License Agreement, the Company agreed to pay a license fee of $10 million, which was recorded as research and development expenses for the three months ended March 31, 2022. The Company paid upfront license fee of $10 million in April 2022 and is obligated to pay future contingent payments including development, regulatory and commercial milestones up to an aggregate of $217.5 million in case of normal approval and $222.5 million in case of accelerated approval. Additionally, if products are launched, the Company will pay Biosion tiered royalties on net sales of licensed products in varying royalty rates ranging from low single digits to low teens. The Company's royalty obligations apply on a licensed product-by-licensed product and country-by-country basis from first commercial sale until the latest to occur of: (1) 12 years from first commercial sale; (2) the expiration of all regulatory or data exclusivity; and (3) the expiration of the last valid claim of a licensed patent covering the licensed product in a country.

The Company assessed the milestone and royalty events involving Biosion as of March 31, 2022 and concluded no such amounts were due.

6. Convertible Preferred Stock

Series B Convertible Preferred Stock

On March 5, 2021, the Company entered into a securities purchase agreement (as amended, "Series B Agreement") with certain investors to sell shares of Series B convertible preferred stock ("Series B") at $1.6458 per share. In March 2021, the Company issued 92,356,299 shares of Series B to institutional investors at $1.6458 per share for gross cash proceeds of $152.0 million, less issuance costs of $0.4 million, resulting in net proceeds of $151.6 million. In addition, the Company granted 12,455,949 shares, or $20.5 million, of Series B convertible preferred stock through separate agreements with Pfizer, Inc. and LegoChem Biosciences Inc. The Company effected a 1-for-6.359 reverse stock split in October 2021. Upon the initial public offering, 104,812,248 shares of Series B were converted to 16,482,486 shares of common stock.

7. Stockholders' Equity

Preferred Stock

There were no issued and outstanding shares of preferred stock as of March 31, 2022 and December 31, 2021.

Common Stock

The Company was authorized to issue up to 190,000,000 shares of common stock as of March 31, 2022 and December 31, 2021, of which 32,843,985 and 32,792,867 shares were issued as of March 31, 2022 and December 31, 2021, respectively, 32,374,907 and 32,222,881 shares were outstanding at March 31, 2022 and December 31, 2021, respectively.

Voting, dividend and liquidation rights of the holders of the common stock are subject to and qualified by the rights, powers and preferences of the holders of the preferred stock.

Voting—Each holder of outstanding shares of common stock shall be entitled to one vote in respect of each share.

Reserved Shares— The Company reserved the following shares of common stock for issuance:

	March 31, 2022	December 31, 2021
Unvested restricted stock awards	2,600,538	618,494
Stock options available for issuance	620,084	1,289,259
Stock options outstanding	6,166,516	5,926,969
Employee stock purchase plan	424,595	424,595
Total	**9,811,733**	**8,259,317**

8. Stock-Based Compensation

2021 Equity Incentive Plan

On September 27, 2021, the Company's board of directors and stockholders approved the 2021 Equity Incentive Plan (the "2021 Plan"), which became effective on October 7, 2021, when the Company's registration statement was declared effective by the SEC. The 2021 Plan allows the Company to make equity-based and cash-based incentive awards to its officers, employees, directors and consultants. The Company has initially reserved 3,852,807 shares of its common stock for the issuance of awards under the 2021 Plan. The number of shares of common stock reserved for issuance under the 2021 Plan will automatically increase annually on the first day of each fiscal year, beginning with the fiscal year ending December 31, 2022, and continuing until (and including) the fiscal year ending December 31, 2031 by lesser of 5% of the total number of shares of common stock outstanding on December 31st of the immediately preceding fiscal year or number of shares as may be determined by the board of directors. As a result of the evergreen provision of the 2021 Plan, the Company added an additional 1,639,643 shares of common stock to the 2021 Plan as of January 1, 2022. The maximum number of shares of common stock that may be issued pursuant to the exercise of incentive options under the 2021 Plan is 7,705,614. As of March 31, 2022, options to purchase 2,868,303 shares of common stock and 2,131,460 restricted stock units were outstanding under the 2021 Plan and 492,687 shares remained available for future issuance under the 2021 Plan.

2019 Equity Incentive Plan

In 2019, the Company established the 2019 Plan, under which the Company grant options and restricted stock to its employees and certain non-employees. The maximum number of shares of common stock reserved for issuance under the 2019 Plan is 4,042,408 shares.

The Company may grant options to purchase authorized but unissued shares of the Company's common stock. Options granted under the 2019 Plan include incentive stock options that can be granted only to the Company's employees and non-statutory stock options that can be granted to the Company's employees, consultants, advisors and directors. The 2019 Plan also permits the Company to issue restricted stock awards.

Prior to the initial public offering, the exercise prices, vesting and other restrictions of the awards to be granted under the 2019 Plan are determined by the board of directors, except that no stock option may be issued with an exercise price less than the fair market value of the common stock at the date of the grant or have a term in excess of ten years. Options granted under the 2019 Plan are exercisable in whole or in part at any time subsequent to vesting. As of March 31, 2022, options to purchase 3,298,213 shares of common stock were outstanding under the 2019 Plan and 127,397 shares remained available for future issuance under the 2019 Plan.

Stock Options

The summary of stock option activity for the three months ended March 31, 2022 (in thousands, except share and per share amounts):

	Number of Shares	Weighted Average Exercise Price	Weighted Average Remaining Contractual Term (Years)	Aggregate Intrinsic Value
Outstanding at January 1, 2022	5,926,969	$ 10.03	9.5	$ 16,414
Granted	353,263	7.96		
Exercised	(51,118)	3.45		
Forfeited	(62,598)	4.88		
Outstanding at March 31, 2022	**6,166,516**	**$ 10.02**	**9.3**	**$ 440**
Options exercisable at March 31, 2022	**1,202,273**	**$ 5.46**	**9.0**	**$ 189**

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 $4.04 per share as of March 31, 2022. The options granted during the three months ended March 31, 2022 and 2021 had a weighted-average fair value of $6.27 per share and $3.51 per share, respectively.

The Company estimated the fair value of each option on the date of grant using the Black-Scholes option pricing model applying the range of assumptions in the following table:

	Three Months Ended March 31,	
	2022	2021
Expected volatility	98.05% - 101.66%	75.17%
Risk-free interest rate	1.60%	1.16%
Expected dividend yield	0.00%	0.00%
Expected term (in years)	6.08	6.02 – 6.08

Stock-based compensation expense related to stock options recorded is as follows (in thousands):

	Three Months Ended March 31,	
	2022	2021
Research and development	$ 472	$ 820
General and administrative	2,874	1,624
Total	**$ 3,346**	**$ 2,444**

The Company has an aggregate $36.6 million of gross unrecognized stock-based compensation expense as of March 31, 2022 remaining to be amortized over a weighted average period of 2.77 years. The Company has not recognized and does not expect to recognize in the near future, any tax benefit related to employee stock-based compensation expense as a result of the full valuation allowance related to its net deferred tax assets.

Restricted Stock Awards

Under the 2021 Plan, the Company issued 2,131,460 restricted common stock to employees. Compensation cost related to these awards were recorded based on the Company's stock price on the date of issuance.

The Company issued 994,650 shares of restricted common stock to the employee co-founders and certain non-employee consultants in 2019. The shares of restricted common stock were issued pursuant to standalone restricted stock purchase agreements that are independent of the 2019 Plan and 2021 Plan. The shares of restricted common stock carried a purchase price equivalent of $0.01 per share. The compensation cost was measured based on the fair value of the underlying common stock less the purchase price of the restricted common stock and the Company recognizes compensation costs over the requisite service period.

Under the terms of the restricted stock purchase agreements, the Company has a repurchase option whereby it has the right to repurchase any unvested shares upon termination at a price per share equal to the lesser of: (i) the fair market value of the Company's common stock on the date of repurchase and (ii) the original purchase price. The shares of restricted common stock issued to the Company's co-founders and non-employee consultants vest based on a predefined number of shares.

The Company recognized an associated deposit liability for restricted stock awards issued pursuant to standalone restricted stock purchase agreements upon issuance based on the purchase price of the awards as the unvested shares are subject to repurchase upon termination. As the awards of restricted stock vest, the Company reclassifies the deposit liability to additional paid-in capital.

The summary of restricted stock activity for the three months ended March 31, 2022:

	Number of Shares	Weighted Average Grant Date Fair Value
Non-vested at December 31, 2021	618,494	$ 3.04
Granted	2,082,952	4.07
Vested	(100,908)	0.01
Non-vested at March 31, 2022	**2,600,538**	**$ 4.06**

The Company has recorded stock-based compensation expense related to the restricted stock of $58 thousand and $6 thousand for the three months ended March 31, 2022 and 2021, respectively. The Company has an aggregate $9.2 million of gross unrecognized restricted stock-based compensation expense as of March 31, 2022 remaining to be amortized over a weighted average period of 2.8 years.

2021 Employee Stock Purchase Plan

On September 27, 2021, the Company's board of directors and stockholders approved the 2021 Employee Stock Purchase Plan (the "2021 ESPP"), which became effective on October 7, 2021, when the Company's registration statement was declared effective by the SEC. The 2021 ESPP reserved and authorized the issuance of up to a total of 424,595 shares of common stock to participating employees. No shares are issued under 2021 ESPP plan as of the date of issuance of these unaudited condensed consolidated financial statements.

9. Income Taxes

The Company's effective tax rate from continuing operations was 0% for the three months ended March 31, 2022 and 2021. The Company has not recorded a federal income tax provision for the three months ended March 31, 2022 and 2021. The Company recorded a nominal state and local income tax provision for the three months ended March 31, 2022 and 2021.

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.

10. Net Loss per Common Share

Basic and diluted net loss per common share was calculated as follows (in thousands, except share and per share amounts):

	Three Months Ended March 31,	
	2022	2021
Numerator:		
Net loss	$ (31,380)	$ (36,825)
Denominator:		
Weighted-average common shares outstanding, basic and diluted	32,316,689	1,350,743
Net loss per share, basic and diluted	**$ (0.97)**	**$ (27.26)**

The Company's potentially dilutive securities, which include convertible preferred stock, restricted stock, and stock options, have been excluded from the computation of diluted net loss per common share as the effect would be to reduce the net loss per share. Therefore, the weighted-average number of common shares outstanding used to calculate both basic and diluted net loss per share attributable to common stockholders is the same.

The Company excluded the following from the computation of diluted net loss per share attributable to common stockholders at March 31, 2022 and 2021 because including them would have had an anti-dilutive effect:

	March 31,	
	2022	**2021**
Convertible preferred stock	—	20,056,145
Unvested restricted stock awards	2,600,538	765,527
Stock options outstanding	6,166,516	2,719,200
Stock options available for issuance	620,084	827,885
Employee stock purchase plan	424,595	—
Total	**9,811,733**	**24,368,757**

11. Related Parties

Prior to IPO, Pfizer along-with its affiliated entity and Bayer HealthCare LLC ("Bayer"), were principal owners of the Company. Subsequent to IPO, Pfizer and Bayer are no longer principal owners and, as a result, neither Pfizer nor Bayer are related parties of the Company. In 2020, the Company entered into the Pfizer License Agreement and it became effective in March 2021. During the three months ended March 31, 2021, the Company incurred a combined $25.0 million (which was recorded as research and development expenses), consisting of an upfront fee equal to a cash payment of $5.0 million and the issuance of 12,152,145 shares of Series B Convertible Preferred Stock with a value of $20.0 million in 2021 to Pfizer. Refer to Note 5 for additional discussion.

The Company and Alloy formed a joint venture company, Voxall Therapeutics, LLC (“Voxall”) to leverage the Company’s technology and Alloy’s ATX-Gx™ platform and antibody discovery services. The Company and Alloy contributed $50 thousand each to Voxall along with certain license in March 2021. No transactions occurred with Voxall during the three months ended March 31, 2022.

12. Commitments and Contingencies

Commitments

In the normal course of business, the Company enters into agreements with contract research organizations (“CROs”), research programs and with vendors for nonclinical studies, manufacturing and other services and products for operating purposes, which agreements 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.

Operating Leases

As of March 31, 2022, the Company has one operating lease, where the Company is the lessee or sublessee, for office and laboratory space. The original lease term expired in March 2022 and the Company has extended the term to June 2022. The Company had no finance leases as of March 31, 2022.

The Company’s rent expense was $0.2 million for the three months ended March 31, 2022 and 2021, respectively.

In addition to above lease commitment, on September 29, 2021, the Company entered into a lease agreement for an office and laboratory space in Boston, Massachusetts. The lease will expire on December 31, 2032 and have scheduled rent increases each year of 3%. There is an additional five-year option to extend the lease beyond December 31, 2032. The future undiscounted operating lease payments (base rent) under the lease agreement is $33.8 million over an initial lease period of approximately ten years. The Company will record the right-of-use asset and operating lease liability upon obtaining the possession of the property, which it expects to happen in the second quarter of 2022.

Contingencies

In March 2020, COVID-19 disease was declared a pandemic by the World Health Organization. Currently, the Company has not suffered significant adverse consequences as a result of the COVID-19 pandemic, however, the extent to which COVID-19 may impact the Company’s future financial condition or results of operations is uncertain.

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, 2021, included in our Annual Report on Form 10-K , filed with the Securities and Exchange Commission, or the SEC, on March 29, 2022. 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, 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.

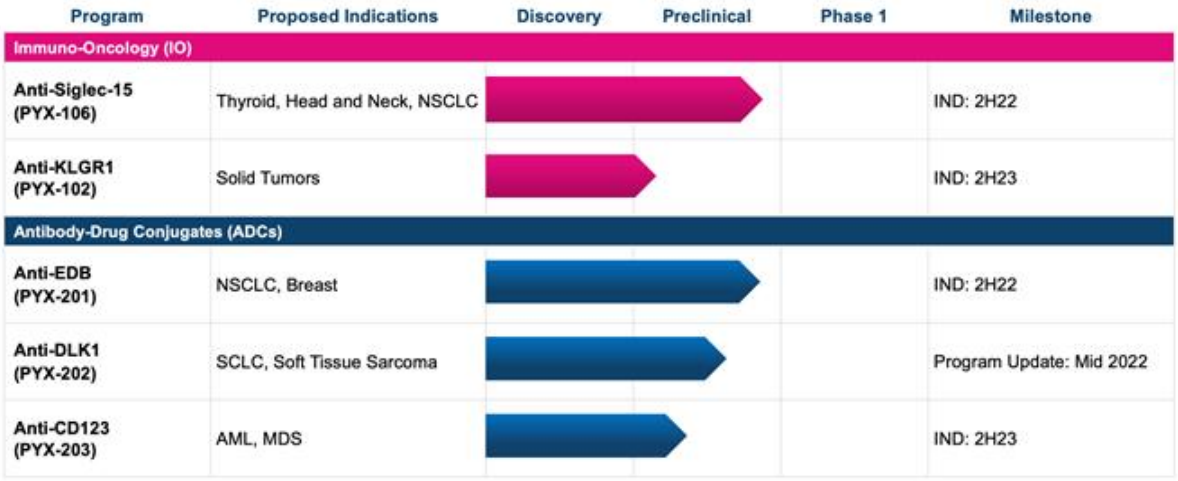
Overview

We are a preclinical oncology company focused on developing an arsenal of next-generation therapeutics to target difficult-to-treat cancers and improve quality of life for patients. We develop our product candidates with the objective to directly kill tumor cells, and to address the underlying pathologies created by cancer that enable its uncontrollable proliferation and immune evasion. We are developing multi-asset, multi-modality portfolio aimed at defeating difficult-to-treat cancers. Since our launch in 2019, we have developed a broad portfolio of novel antibody drug conjugates, or ADCs, immuno-oncology, or IO, product candidates and monoclonal antibody, or mAb, preclinical discovery programs that we are developing as monotherapies and in combination with other therapies.

We take a holistic view of attacking the key drivers of tumor growth and progression within the tumor microenvironment, or TME, including targeting of tumor antigens and modulating the innate and adaptive immune response. The TME is an immunosuppressive environment consisting of cancer cells and stroma, which includes the blood vessels, immune cells, fibroblasts, signaling molecules, and the extracellular matrix that surrounds the tumor. The TME plays multiple roles in tumor formation, progression and metastasis as well as anti-tumor immune activity. We are developing our ADC and IO product candidates and mAb preclinical discovery programs to precisely target key modulators of the adaptive and innate immune system within the TME for difficult-to-treat solid and hematologic tumors. We believe that the diversification of a multi-modality approach optimizes our ability to effectively progress multiple assets for the benefit of patients.

Our ADCs utilize next-generation technologies that, based on observations from preclinical studies, may allow for increased stability and a reduced off target side-effect profile. We in-licensed two ADC programs in March 2021 from Pfizer, one ADC program from LegoChem in December 2020 and one IO program from Biosion in March 2022. Two of our product candidates, PYX-201, and PYX-106 are scheduled for IND submission in the second half of 2022 whereas PYX-203 and PYX-102 are scheduled for IND submission in the second half of 2023. We have additional preclinical mAb discovery programs derived from 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-202 in South Korea and PYX-106 in Greater China (mainland China, Hong Kong, Macau and Taiwan). We are focusing our efforts on eliminating tumor cells through the selective antibody mediated delivery of cytotoxic payloads and by modulating key immune-associated pathways in the TME. We intend to develop each of our programs as a monotherapy and potentially also in combination with other therapies. We have designed our product candidates to overcome the limitations of ADCs that use conventional conjugation with the aim of providing patients with safer and more efficacious treatment options.

Our current pipeline is summarized below.



PYX-106

On March 28, 2022, we entered into a license agreement, or the "Biosion License Agreement," with Biosion USA, Inc., or Biosion, pursuant to which we licensed worldwide (other than Greater China (mainland China, Hong Kong, Macau and Taiwan)) development 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. PYX-106 is a fully human monoclonal antibody and is engineered with high affinity to block Siglec-15 induced immune suppression and is therefore designed to restore T cell proliferation, function and anti-tumor immunity in the TME. PYX-106 is a novel immune checkpoint inhibitor targeting Siglec-15, whose expression profile is generally non-overlapping with PD-L1. Siglec-15 is expressed on M2 macrophages but can also be expressed by tumor cells. Binding of Siglec-15 to an as of yet unknown receptor on T cells leads to suppression of T cell proliferation and function. This inhibition also reduces IFNγ secretion which may further promote Siglec-15 expression. PYX-106 may synergize with and rescue PD(L)-1 targeted therapy activity, with the potential for sequential drug administration to synergize for enhanced anti-tumor activity.

We are initially evaluating our Siglec-15 targeting antibody for the treatment of advanced or metastatic solid tumors, which could include thyroid cancer, Head & Neck Squamous Cell Carcinoma, or HNSCC, non-small cell lung cancer, or NSCLC and other solid tumors where high unmet need exists. We plan to submit an IND for PYX-106 in the second half of 2022.

PYX-102

The anti-KLRG1 mAb, which we referred to as PYX-102, is our first organically built IO development candidate from our internal discovery engine. PYX-102 was identified as a promising IO target through our proprietary target catalog licensed from Thomas Gajewski's lab at the University of Chicago. PYX-102 is an investigational immune-therapeutic consisting of a ligand-blocking antibody which is designed to rescue KLRG1-mediated suppression of human CD8+ T cells. PYX-102 is an inhibitory immunoreceptor trysine-based inhibitory motif-containing receptor engineered to expressed on T cells and NK cells in the tumor microenvironment and acts as an inhibitory immune checkpoint receptor via its interactions with E- and N-Cadherin ligands. We believe that targeting KLRG1 to reprogram these suppressed T and NK cells represents an exciting strategy to promote the full anti-tumor activity of cytotoxic T cells and NK cells in the tumor microenvironment. We are working through our development plans and we anticipate IND submission in the second half of 2023.

PYX-201 is an investigational, novel ADC consisting of an Immunoglobulin G1, or IgG1, anti-fibronectin Extradomain-B, or EDB, mAb site-specifically conjugated to auristatin via a cathepsin B-cleavable linker. Fibronectin is a glycoprotein found in the extracellular matrix. Fibronectin EDB regulates blood vessel morphogenesis, which provides the tumor access to nutrition and oxygen, a means to remove waste, and a pathway for metastasizing cells. EDB 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 addition, we observed that the treatment of preclinical syngeneic tumor models with PYX-201 resulted in enhanced T cell infiltration into the TME, which is a hallmark of immunogenic cell death, or ICD, enabling synergistic activity in combination with a checkpoint inhibitor. We anticipate submitting an IND in the second half of 2022.

PYX-202 is an investigational, novel ADC consisting of an IgG1 anti-Delta-like 1 homolog, or DLK1, mAb conjugated to MMAE via a site-specific plasma-stable ß-glucuronide linker. DLK1 is a transmembrane protein normally expressed in embryonic tissues but highly restricted in healthy adult tissues. DLK1 becomes re-expressed in certain solid tumor malignancies. PYX-202 is designed to use the microtubule-disrupting MMAE payload, which is utilized in three currently marketed ADCs providing clinical support that the payload has anti-tumor effect potential. We in-licensed LCB67, an ADC product candidate targeting DLK1 (referred to as PYX-202) from LegoChem in December 2020. In studies conducted by LegoChem of preclinical small cell lung cancer, or SCLC, PDX models, as well as in a human cell line-based, or CDX, mouse model of cancer, we have observed significant anti-tumor activity as measured by durable tumor regression. In preparation for our IND filing and based on observation of our GLP studies to date, we have determined that we will need to conduct additional GLP and non-GLP toxicity studies to determine whether PYX-202 is a viable clinical candidate. We will continue to monitor the progress of our PYX-202 program and expect to provide an update about PYX-202 in mid-2022.

PYX-203 is an investigational ADC consisting of an IgG1 anti-CD123 mAb antibody conjugated to a novel cyclopropylpyrroloindoline, or CPI dimer payload via a site-specific plasma-stable, cleavable linker. CD123, or IL-3Ra, is a cell surface antigen highly expressed on leukemic stem cells and leukemic blasts in acute myeloid leukemia, or AML. PYX-203, utilizes a novel DNA-damaging toxin, CPI, and we have observed significant anti-tumor activity as measured by the reduction in the frequency of the leukemic cells in the blood and bone marrow in nine disseminated preclinical AML models. We anticipate submitting an IND in the second half of 2023.

In addition to the programs identified above, we are conducting research and development activities on various targets, leveraging our expertise in monoclonal antibodies and understanding of immuno-oncology. Our preclinical discovery programs are novel antibody programs intended to enhance the anti-tumor activity of natural killer, or NK cells, and T cells and to overcome immunosuppressive activity of tumor resident myeloid cells such as tumor associated macrophages, or TAMs, and myeloid derived suppressor cells, or MDSCs.

Since our inception, we have focused substantially all our resources on organizing and staffing our company, business planning, raising capital, conducting research and development activities, filing and prosecuting patent applications, identifying potential product candidates and undertaking preclinical studies and a clinical trial. We do not have any products approved for sale and have not generated any revenue from product sales or from any other sources. To date, we have funded our operations with proceeds from sales of convertible preferred stock and our recent IPO. Our ability to generate any product revenue, and in particular to generate product revenue sufficient to achieve profitability, will depend on the successful development and eventual commercialization of one or more of our product candidates.

We have incurred significant operating losses since our inception. We reported net losses of $31.4 million and $36.8 million for the three months ended March 31, 2022 and 2021. As of March 31, 2022, we had an accumulated deficit of $123.1 million, net equity of $233.5 million and cash and cash equivalents of $247.1 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.

COVID-19 Business Update

We continue to monitor the potential impact of the COVID-19 pandemic on our business and consolidated financial statements. To date, we have not experienced material business disruptions. We are following, and will continue to follow, recommendations from the U.S. Centers for Disease Control and Prevention as well as federal, state and local governments regarding working-from-home practices for non-essential employees. We cannot be certain what the overall impact of the COVID-19 pandemic will be on our business, and it has the potential to adversely affect our business. For additional information about risks and uncertainties related to the COVID-19 pandemic that may impact our business, financial condition and results of operations, see the section titled “Risk Factors” under Part II, Item 1A in this Quarterly Report.

Licensing and Collaboration Agreements

License Agreement with Pfizer, Inc.

In December 2020, we entered into a license agreement, as amended, the "Pfizer License Agreement," with Pfizer, Inc., or Pfizer, for worldwide development and commercialization rights to two of Pfizer's proprietary ADC product candidates (now referred to as PYX-201 and PYX-203), as well as other ADC product candidates directed to the licensed targets. The Pfizer License Agreement became effective in March 2021. The initial exclusively licensed targets are extra domain B (EBD of fibronectin) and CD123 and we have the option to expand the scope of our license to add other licensed targets. Pfizer has also granted us a non-exclusive license to use Pfizer's FACT platform technology to develop and commercialize the licensed ADCs. In March 2021, we entered into an amendment to the Pfizer License Agreement to include additional know-how within the scope of our license.

Pursuant to the Pfizer License Agreement, we incurred a combined $25.0 million for license fee, consisting of an upfront fee of $5.0 million and issued 12,152,145 shares of Series B convertible preferred stock in 2021 to Pfizer, and are obligated to pay future contingent payments and royalties, including up to an aggregate of $660 million in milestones for the first four licensed ADCs. Additional ADC targets may be licensed for an additional upfront fee, and such targets would be subject to additional regulatory and commercial sales milestones.

Additionally, if products are launched, we will pay Pfizer tiered royalties on net sales of licensed products in varying royalty rates ranging from low single digits to mid-teens. Our royalty obligations apply on a licensed product-by-licensed product and country-by-country basis from first commercial sale until the latest to occur of: (1) 12 years from first commercial sale; (2) the expiration of all regulatory or data exclusivity; and (3) the expiration of the last valid claim of a licensed patent covering the licensed product in a country. We are also obligated to pay Pfizer a percentage of certain sublicensing revenue ranging from low-double digits to thirty percent based on the stage of development of the licensed product at the time of entering into the applicable sublicense.

License Agreement with the University of Chicago

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

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

Agreements with LegoChem Biosciences, Inc.

In December 2020, we entered into a license agreement, or the "LegoChem License Agreement," with LegoChem Biosciences, Inc., or LegoChem, pursuant to which we licensed worldwide (other than Korea) development and commercialization rights for LCB67, an ADC product candidate targeting DLK1 (now referred to as PYX-202), and products containing the licensed compound. We have the right to ask LegoChem to use commercially reasonable efforts at our cost to modify the licensed compound if there are certain technical failures of the licensed compound that we believe are attributable to the linker or the payload used in the licensed compound, and the modified compound will replace the unmodified version as the licensed compound. In February 2021, we entered into an amendment to the LegoChem License Agreement to include additional patents within the scope of our license.

Pursuant to the LegoChem License Agreement, we paid an upfront fee of $0.5 million in 2020 and $9.0 million in 2021 and are required to purchase certain initial quantities of licensed product from LegoChem for an estimated cost of $7.0 million. We are also obligated to pay up to an aggregate of $284.5 million to LegoChem if certain development, regulatory and sales milestones are achieved, as well as tiered royalties on net sales of licensed products ranging from mid-single digit to high single digit royalty rates. Our royalty obligations apply on a licensed product-by-licensed product and country-by-country basis until the latest to occur of: (1) the date of expiration of the last valid claim of a licensed patent covering the licensed product; (2) 10 years from first commercial sale; and (3) the expiration of regulatory or data exclusivity.

In December 2020, we also entered into an opt-in, investment and additional consideration agreement with LegoChem, or the "Opt-In Agreement." Under the Opt-In Agreement, we issued to LegoChem shares of Series B convertible preferred stock as part of our Series B financing in March 2021. We are also obligated to pay LegoChem a percentage of sublicensing revenue ranging from low-double digits to thirty percent based on the stage of development of the licensed product at the time of entering into the applicable sublicense, which percentage may be increased to up to fifty percent for any upfront payment from a sublicensee under certain circumstances. LegoChem has exercised its option under the Opt-In Agreement to make a $8.0 million payment to us, which payment was made in April 2021, in exchange for the right to receive an extra milestone payment of $9.6 million upon the earliest to occur of certain events, including the date of pricing or offer of the first public offering of our common stock or if we are the subject of a change of control transaction. Upon our IPO in October 2021, the extra milestone payment event triggered and we paid $9.6 million in January 2022 to LegoChem.

The Voxall Joint Venture with Alloy Therapeutics, Inc.

In March 2021, we entered into definitive transaction agreements with Alloy to finance and operate Voxall, a joint venture company formed in collaboration with Alloy to leverage Pyxis Oncology's site-specific target catalog and Alloy's ATX-Gx™ platform and antibody discovery services.

Voxall granted to both Pyxis Oncology and Alloy 50% of the voting membership units of Voxall in exchange for certain initial contributions. Our initial contribution included $50 thousand and a non-exclusive fully paid-up license to certain intellectual property owned or controlled by us to enable the collaboration with Voxall. Alloy's initial contribution included $50 thousand and the execution of a license agreement and a services agreement to enable the collaboration with Voxall. Voxall is governed by a board of directors consisting of an equal number of our representatives and Alloy's representatives. The protective provisions under Voxall's operating agreement require the approval of both Pyxis Oncology and Alloy before Voxall may take certain actions.

In connection with the formation of Voxall, we entered into a three-year research collaboration with Alloy and Voxall to identify and select certain biological targets and create development candidate antibodies directed to those targets for further preclinical development, clinical development and commercialization. Under the collaboration agreement, the parties will conduct research under a mutually agreed research plan and budget for up to six research programs focused on mutually selected targets. Each of us and Alloy will provide research support for the collaboration through separate services agreements with Voxall, which services will be paid in the form of promissory notes issued by Voxall. Voxall will own all intellectual property arising from the collaboration, subject to certain exceptions for intellectual property relating to Alloy's ATX-Gx™ platform.

If a development candidate antibody under a research program meets certain mutually agreed selection criteria, we will have the exclusive option to obtain an exclusive license from Voxall to further develop and commercialize all the development candidate antibodies discovered under that research program. We may in-license one research program on certain pre-agreed financial terms. For all other in-licensed research programs, we will be obligated to pay fair market value as determined by a third-party valuation. Any research program that we do not in-license may be licensed by Voxall to a third party.

License Agreement with Biosion USA, Inc.

On March 28, 2022, we entered into a license agreement, or the "Biosion License Agreement," with Biosion USA, Inc., or Biosion, pursuant to which we obtained exclusive, worldwide (other than Greater China (mainland China, Hong Kong, Macau and Taiwan)), licenses for development, manufacture and commercialization rights for BSI-060T, a potentially best-in-class 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, we agreed to pay an upfront fee of $10 million and are obligated to pay future contingent payments including development, regulatory and commercial milestone up to an aggregate of $217.5 million in case of normal approval and $222.5 million in case of accelerated approval. Additionally, if products are launched, we will pay Biosion tiered royalties on net sales of licensed products in varying royalty rates ranging from low single digits to low teens. Our royalty obligations apply on a licensed product-by-licensed product and country-by-country basis from first commercial sale until the latest to occur of: (1) 12 years from first commercial sale; (2) the expiration of all regulatory or data exclusivity; and (3) the expiration of the last valid claim of a licensed patent covering the licensed product in a country.

Components of Our Results of Operations

Operating Expenses

Research and Development Expenses

Research and development expenses consist of costs incurred for our research activities, including our discovery efforts, and the development of our programs. These expenses include:

- employee-related expenses, including salaries, payroll taxes, related benefits and stock-based compensation expense for employees engaged in research and development activities;

- expenses incurred in connection with our product candidates and the development of research programs, including under agreements with third parties, such as consultants, contractors, contract manufacturing organizations, or CMOs, and contract research organizations, or CROs;
- laboratory supplies and research materials; and
- facilities, depreciation and other expenses, which include direct and allocated expenses for rent and maintenance of facilities and insurance.

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.

Our direct external research and development expenses consist of costs that include fees, reimbursed materials and other costs paid to consultants, contractors, CMOs and CROs in connection with our preclinical and clinical activities. We do not allocate employee costs, costs associated with our discovery efforts, laboratory supplies, and facilities expenses, including depreciation or other indirect costs, to specific product development programs because these costs are deployed across multiple programs and our platform and, as such, are not separately classified.

Product candidates in later stages of clinical development generally have higher development costs than those in earlier stages of clinical development, primarily due to the increased size and duration of later-stage clinical trials. 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, for our personnel in executive, legal, finance and accounting, human resources and other administrative functions. General and administrative expenses also include legal fees relating to patent and corporate matters; professional fees paid for accounting, auditing, consulting and tax services; insurance costs; travel expenses; and facility costs not otherwise included in research and development expenses.

We anticipate that our general and administrative expenses will increase in the future as we increase our headcount to support our continued research activities and development of our programs and platform. We also anticipate that we will incur increased accounting, audit, legal, regulatory, compliance, director and officer insurance, and investor and public relations expenses associated with operating as a public company.

Other Income (Expense)

Interest income consists of interest earned on our invested cash and cash equivalent balances.

The change in fair value of derivative liability represents the increase in the fair value of the derivative liability recorded as a result of an Opt-in, Investment and Additional Consideration Agreement with LegoChem, or the "Opt-In Agreement".

Results of Operations

Comparison of the Three Months Ended March 31, 2022 and 2021

The following table summarizes our results of operations for the three months ended March 31, 2022 and 2021 (in thousands):

	Three Months Ended March 31,		
	2022	**2021**	**Change**
Operating expenses:			
Research and development	$ 20,071	$ 32,774	$ (12,703)
General and administrative	11,318	2,955	8,363
Total operating expenses:	31,389	35,729	(4,340)
Loss from operations	(31,389)	(35,729)	4,340
Other income (expense):			
Interest income	9	4	5
Change in fair value of derivative liability	—	(1,100)	1,100
Total other income (expense):	9	(1,096)	1,105
Net loss	**$ (31,380)**	**$ (36,825)**	**$ 5,445**

Research and Development Expenses

The following table summarizes our research and development expenses for the three months ended March 31, 2022 and 2021 (in thousands):

	Three Months Ended March 31,		
	2022	2021	Change
Research and development program expenses	$ 15,898	$ 30,533	$ (14,635)
Personnel-related expenses including stock-based compensation	2,683	1,748	935
Other research and development expenses	1,490	493	997
Total research and development expenses	**$ 20,071**	**$ 32,774**	**$ (12,703)**

Research and development expenses decreased by $12.7 million, from $32.8 million for the three months ended March 31, 2021 to $20.1 million for the three months ended March 31, 2022. The program expenses decreased by $14.6 million was primarily due to a decrease in licensing fees of $19.4 million offset by increases of cell line development fees of $4.5 million and laboratory supplies of $0.2 million. Personnel-related expenses including stock-based compensation increased by $0.9 million was primarily due to an increase in headcount to support our research and development activities. Other research and development expenses increased by $1.0 million which was primarily related to the increase in facility maintenance costs and higher depreciation on laboratory equipment.

General and Administrative Expenses

The following table summarizes our general and administrative expenses for the three months ended March 31, 2022 and 2021 (in thousands):

	Three Months Ended March 31,		
	2022	2021	Change
Personnel-related expenses including stock-based compensation	$ 5,469	$ 2,102	$ 3,367
Professional and consultant fees	4,549	617	3,932
Facilities, insurance and other costs	1,300	236	1,064
Total general and administrative expenses	**$ 11,318**	**$ 2,955**	**$ 8,363**

General and administrative expenses increased by $8.4 million, from $2.9 million for the three months ended March 31, 2021 to $11.3 million for the three months ended March 31, 2022. Personnel-related expenses including stock-based compensation increased by $3.4 million primarily due to the increased headcount. Professional and consultant fees increased by $3.9 million primarily due to increase in legal, professional, recruiting and consulting fees to support our growth and operations. Increase in facilities, insurance and other costs was mainly due to directors and officers insurance expense.

Other Income (Expense)

Other expense consists of change in fair value of the derivative liability of $1.1 million for the three months ended March 31, 2021 as a result of the Opt-In Agreement.

Liquidity and Capital Resources

Overview

We had cash and cash equivalents of $247.1 million as of March 31, 2022. For the three months ended March 31, 2022 and 2021, we had net losses of $31.4 million and $36.8 million, respectively. As of March 31, 2022, we had an accumulated deficit of $123.1 million.

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

- the manufacture of product candidates, completion of our IND enabling studies and initiation of Phase 1 clinical trials for PYX-201, PYX-202, PYX-203, PYX-106, and PYX-102;
- 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, including due to the COVID-19 pandemic, that we experience in our preclinical studies, future 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; and
- incur insurance, legal and other regulatory compliance expenses to operate as a public company.

Until such time, if ever, we can generate substantial product revenue, we expect to finance our operations through a combination of equity offerings, debt financings, collaborations, strategic alliances and marketing, distribution or licensing arrangements. To the extent that we raise additional capital through the sale of equity or convertible debt securities, your ownership interest will be diluted, and the terms of these securities may include liquidation or other preferences that adversely affect your rights as a common stockholder. Debt financing and preferred equity financing, if available, may involve agreements that include covenants limiting or restricting our ability to take specific actions, such as incurring additional debt, making acquisitions, engaging in acquisition, merger or collaboration transactions, selling or licensing our assets, making capital expenditures, redeeming our stock, making certain investments or declaring dividends.

If we raise additional funds through collaborations, strategic alliances or marketing, distribution or licensing arrangements with third parties, we may have to relinquish valuable rights to our technologies, future revenue streams, research programs or product candidates, or grant licenses on terms that may not be favorable to us. If we are unable to raise additional funds through equity or debt financings when needed, we may be required to delay, limit, reduce or terminate our product development or future commercialization efforts or grant rights to develop and market product candidates that we would otherwise prefer to develop and market ourselves.

Cash Flows

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

	Three Months Ended March 31,	
	2022	**2021**
Net cash used in operating activities	$ (27,679)	$ (18,731)
Net cash used in investing activities	(146)	(219)
Net cash provided by financing activities	176	151,534
Net (decrease) increase in cash, cash equivalents and restricted cash	**$ (27,649)**	**$ 132,584**

Operating Activities

During the three months ended March 31, 2022, $27.7 million of cash was used in operating activities. This was primarily attributable to our net loss of $31.4 million and net change in our operating assets and liabilities of $0.1 million, partially offset by non-cash charges of $3.8 million. The non-cash charges of $3.8 million was primarily due to $3.4 million in stock-based compensation. The net change in our operating assets and liabilities was primarily due to a decrease of $9.9 million in accounts payable, which is primarily due to the $9.6 million payment made pursuant to the LegoChem License Agreement and accrual of $10.0 million of license fees pursuant to Biosion License Agreement.

During the three months ended March 31, 2021, $18.7 million of was cash used in operating activities. This was primarily attributable to our net loss of $36.8 million and net change in our operating assets and liabilities of $5.8 million, partially offset by non-cash charges of $23.9 million. The non-cash charges of $23.9 million was primarily due to the $20.0 million of research and development license fees incurred pursuant to the Pfizer License Agreement, $2.5 million in stock-based compensation and $1.1 million for a change in fair value of the derivative liability. The change in our operating assets and liabilities was primarily due to an increase of $8.0 million in receivables pursuant to the LegoChem License Agreement, partially offset by a derivative liability recorded of $3.4 million pursuant to the LegoChem License Agreement.

Investing Activities

During the three months ended March 31, 2022 and 2021, net cash used in investing activities was $0.1 million and $0.2 million, respectively, due to purchases of property and equipment. During the three months ended March 31, 2021, we also made an investment in our joint venture, Voxall Therapeutics, LLC, for $0.1 million.

Financing Activities

During the three months ended March 31, 2022 and 2021, net cash provided by financing activities was $0.2 million and $151.5 million, respectively. During the three months ended March 31, 2022, the $0.2 million provided consisted of net proceeds from stock option exercises. During the three months ended March 31, 2021, the $151.5 million provided consisted primarily of net proceeds of $151.6 million from the sale of our Series B convertible preferred stock.

Outlook

Based on our existing cash balance as of March 31, 2022 of $247.1 million and our research & development and business development plans, we expect to be able to fund our operating expenses and capital expenditure requirements into the third quarter of 2024. 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

The following summarizes our contractual obligations as of March 31, 2022, and the effects that such obligations are expected to have on our liquidity and cash flows in future periods.

On September 29, 2021, we entered into a lease agreement for an office and laboratory space in Boston, Massachusetts. The lease will expire on December 31, 2032, with future undiscounted operating lease payments (base rent) under the lease agreement of $33.8 million over an initial lease period of approximately ten years.

Pursuant to the Pfizer License Agreement, we are obligated to pay future contingent payments and royalties, including up to an aggregate of $660 million in milestones for the first four licensed ADCs. Additional ADC targets may be licensed for an additional upfront fee, and such targets would be subject to additional regulatory and commercial sales milestones. Additionally, if products are launched, we will pay Pfizer tiered royalties on net sales of licensed products in varying royalty rates ranging from low single digits to mid-teens. Our royalty obligations apply on a licensed product-by-licensed product and country-by-country basis from first commercial sale until the latest to occur of: (1) 12 years from first commercial sale; (2) the expiration of all regulatory or data exclusivity; and (3) the expiration of the last valid claim of a licensed patent covering the licensed product in a country. We are also obligated to pay Pfizer a percentage of certain sublicensing revenue ranging from low-double digits to thirty percent based on the stage of development of the licensed product at the time of entering into the applicable sublicense.

Pursuant to the LegoChem License Agreement, we are obligated to pay up to an aggregate of $284.5 million to LegoChem if certain development, regulatory and sales milestones are achieved, as well as tiered royalties on net sales of licensed products ranging from mid-single digit to high single digit royalty rates. Our royalty obligations apply on a licensed product-by-licensed product and country-by-country basis until the latest to occur of: (1) the date of expiration of the last valid claim of a licensed patent covering the licensed product; (2) 10 years from first commercial sale; and (3) the expiration of regulatory or data exclusivity.

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

Pursuant to the Biosion License Agreement, we are obligated to pay future contingent payments including development, regulatory and commercial milestone up to an aggregate of $217.5 million in case of normal approval and $222.5 million in case of accelerated approval. Additionally, if products are launched, we will pay Biosion tiered royalties on net sales of licensed products in varying royalty rates ranging from low single digits to low teens. Our royalty obligations apply on a licensed product-by-licensed product and country-by-country basis from first commercial sale until the latest to occur of: (1) 12 years from first commercial sale; (2) the expiration of all regulatory or data exclusivity; and (3) the expiration of the last valid claim of a licensed patent covering the licensed product in a country.

We also enter into contracts in the normal course of business with CMOs, and other third parties for preclinical studies. 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 contractual obligations above as the amount and timing of such payments are not known.

Off-Balance Sheet Arrangements

We did not have during the periods 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 and the related notes thereto included elsewhere in this Quarterly Report on Form 10-Q are prepared in accordance with U.S. generally accepted accounting principles (U. S. GAAP). The preparation of unaudited condensed consolidated financial statements also requires us to make estimates and assumptions that affect the reported amounts of assets, liabilities, costs and expenses, and related disclosures. We base our estimates on historical experience and on various other assumptions that we believe to be reasonable under the circumstances. Actual results could differ significantly from the estimates made by management. To the extent that there are differences between our estimates and actual results, our future financial statement presentation, financial condition, results of operations, and cash flows will be affected.

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 Annual Report on Form 10-K filed with the SEC on March 29, 2022.

Recently Issued Accounting Pronouncements

See Note 2 to our unaudited condensed consolidated financial statements included in Part I, Item 1 of this Quarterly Report on Form 10-Q for a discussion of recent accounting pronouncements.

Jumpstart Our Business Startups Act

The Jumpstart Our Business Startups Act of 2012 (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. Section 107(b) of the JOBS Act provides that an emerging growth company can take advantage of an extended transition period for complying with new or revised accounting standards. Thus, an emerging growth company can delay the adoption of certain accounting standards until those standards would otherwise apply to private companies. We have irrevocably elected not to avail ourselves of this extended transition period, and, as a result, we will adopt new or revised accounting standards on the relevant dates on which adoption of such standards is required for other public companies.

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

Item 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 (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 preclinical 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 preclinical stage biopharmaceutical company with a limited operating history. Since our inception, we have incurred significant operating losses. We reported net loss of $76.0 million for the year ended December 31, 2021 and our net loss was $31.4 million and $36.8 million for the three months ended March 31, 2022 and 2021, respectively. As of March 31, 2022, we had an accumulated deficit of $123.1 million. To date, we have not generated any revenue from product sales and have financed our operations primarily through sales of our equity interests. As such, we expect that it will be several years, if ever, before we have a product candidate ready for regulatory licensure and commercialization. We may never succeed in these activities and, even if we do, may never generate revenues that are significant enough to achieve profitability. To become and remain profitable, we must succeed in developing, obtaining marketing licensure for and commercializing products that generate significant revenue. This will require us to be successful in a range of challenging activities, including, without limitation, procuring clinical- and commercial-scale manufacturing, successfully completing preclinical studies and clinical trials of our product candidates, establishing arrangements with third parties for the conduct of our clinical trials, obtaining marketing licensure for our product candidates, manufacturing, marketing and selling any products for which we may obtain marketing licensure, discovering or obtaining rights to additional product candidates, identifying collaborators to develop product candidates we identify or additional uses of existing product candidates and successfully completing development of product candidates for our collaboration partners.

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, conduct IND enabling studies and submit INDs and initiate Phase 1 clinical trials for our ADC product candidates, PYX-201, PYX-202 and PYX-203 and our IO product candidates, PYX-106 and PYX-102;
- select antibody programs to take into development including manufacture product candidates, conduct IND enabling studies and submit INDs and initiate Phase 1 clinical trials;
- initiate, conduct and successfully complete later-stage 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 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.

Further, since our IPO, we have incurred and expect to continue to incur additional costs associated with operating as a public company, including significant legal, accounting, insurance, investor relations and other expenses that we did not incur as a private 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 planned 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 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 work to prepare for IND submissions and initiate Phase 1 clinical trials of our product candidates PYX-201, PYX-202, PYX-203, PYX-106, and PYX-102 and advance our other preclinical research and development programs. 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, 2022, we had approximately $247.1 million in cash and cash equivalents. Based on our current operating plan, our current cash and cash equivalents, we estimate that such funds will enable us to fund our operating expenses and capital expenditure requirements into the third quarter of 2024. 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, completion of our IND enabling studies and initiation of Phase 1 clinical trials for PYX-201, PYX-202, PYX-203, PYX-106, and PYX-102;
- 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, including due to the COVID-19 pandemic, that we experience in our preclinical studies, future 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 revenue from sales of products or 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 the COVID-19 pandemic 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 limited to organizing and staffing our company, business planning, raising capital, conducting discovery and research activities, engaging third parties for initiating manufacturing of drug product and preparing for preclinical toxicology studies, filing patent applications, identifying and obtaining rights to potential product candidates and advancing the FACT platform. All our product candidates are still in preclinical development. We have not yet demonstrated our ability to successfully submit INDs, initiate or complete any clinical trials, 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 preclinical 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.

Risks Related to the Discovery and Development of our Product Candidates

We are heavily dependent on the success of PYX-201, PYX-202, PYX-203, PYX-106 and PYX-102 all of which are in the early stages of development, and if PYX-201, PYX-202, PYX-203, PYX-106 and/or PYX-102 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, PYX-202, PYX-203, PYX-106 and PYX-102. 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-202, PYX-203, PYX-106 and PYX-102 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 PYX-201, PYX-202, PYX-203, PYX-106 and PYX-102 all of 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-202, PYX-203, PYX-106 and PYX-102 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-202, PYX-203, PYX-106 and PYX-102 in the United States until we receive licensure of a Biologics License Application, or BLA, from the FDA for such product candidates, as appropriate. Further, we are not permitted to market PYX-201, PYX-202, PYX-203, PYX-106 and PYX-102 in any foreign countries until we receive the requisite licensure or approvals from such countries. We have not submitted a BLA to the FDA or comparable applications to any other comparable regulatory authorities for PYX-201, PYX-202, PYX-203, PYX-106 and PYX-102. 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-202, PYX-203, PYX-106 and PYX-102 in a country, we will not be able to commercialize such product candidate in that country. As a result, our financial position will be materially adversely affected, and we may not be able to generate sufficient revenue to continue our business.

All of our product candidates are currently in preclinical development. 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 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 our product candidates are currently in preclinical development. In particular, none of our product candidates have ever been tested in a human subject. As a result, their risk of failure 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, four of our five product candidates are in-licensed 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, which may materially and adversely affect our business, results of operations and prospects.

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;
- delays in submitting INDs or comparable foreign applications or delays or 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 in completing IND-enabling preclinical studies or commencing and conducting clinical trials.

We have no experience as a company in completing IND-enabling preclinical studies or commencing and conducting clinical trials. In part because of this lack of experience, we cannot be certain that our preclinical studies will be completed on time or if our planned clinical trials will begin or be completed on time, if at all. 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, contract research organizations, or 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 plan to submit INDs for our product candidates, PYX-201 and PYX-106 in the second half of 2022, and PYX-203 and PYX-102 in the second half of 2023, but we may not be able to submit these planned INDs on the timelines we expect. For example, in case of PYX-202, in preparation for our IND filing and based on observation of our GLP studies to date, we have determined that we will need to conduct additional GLP and non-GLP toxicity studies to determine whether PYX-202 is a viable clinical candidate. We will continue to monitor the progress of our PYX-202 program and expect to provide an update about PYX-202 in mid-2022. Further, 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 licensure and commercialization.

Before obtaining regulatory licensure for the commercial sale of any of our product candidates, including PYX-201, PYX-202, PYX-203, PYX-106 and PYX-102 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 and have never been tested in humans, there is a high risk of failure. For example, in case of PYX-202, in preparation for our IND filing and based on observation of our GLP studies to date, we have determined that we will need to conduct additional GLP and non-GLP toxicity studies to determine whether PYX-202 is a viable clinical candidate. We will continue to monitor the progress of our PYX-202 program and expect to provide an update about PYX-202 in mid-2022. 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, we expect that the first clinical trials for our 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. 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. While we have not yet initiated clinical trials for any of our product candidates, 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. 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. 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 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 applications in foreign countries. Currently, all of our programs are in preclinical development. 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:

- inability to generate sufficient preclinical or other in vivo or in vitro data to support the initiation of clinical trials;
- the COVID-19 pandemic, which may result in delays; 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 pre-IND proposal, 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 or the inability to produce acceptable preclinical results to enable entry into human clinical trials;
- 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;
- delays in developing and validating any companion diagnostic to be used in the trial, to the extent we are required to do so; and
- disruptions caused by the evolving effects of the COVID-19 pandemic may increase the likelihood that we encounter these types of difficulties or delays in initiating, enrolling, conducting or completing our planned clinical trials.

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 risk evaluation and mitigation strategy, or REMS;
- be subject to additional postmarketing testing requirements or changes in the way the product is administered;
- the FDA or comparable foreign regulatory authorities may fail to approve any companion diagnostics that may be required in connection with approval of our therapeutic product candidates; or
- have our product removed from the market after obtaining marketing licensure.

Our product development costs also will increase if we experience delays in preclinical studies or clinical trials or in obtaining marketing licenses. We do not know whether any of our preclinical studies or clinical trials will begin as planned, 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 will be with patients who have received one or more prior treatments and we expect that we would initially seek regulatory licensure for use of these product candidates as second-line or third-line therapy. 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, including adverse events, could have a detrimental impact on our research pipeline and future success.

We use the FACT platform in two of our three ADC product candidates for cancer therapies. Any failures or setbacks involving the FACT 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 other issues that may be more problematic than we currently believe, which may prolong the period of observation required for obtaining, necessitate additional clinical testing or result in the failure to obtain, regulatory licensure. If the FACT platform is not safe in certain product candidates, we would be required to abandon or redesign certain product candidates, 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 to continue to build a pipeline of product candidates and develop marketable products.

We are using the FACT platform to develop three of our product candidates PYX-201, PYX-202 and PYX-203, as well as continuing to build our pipeline of product candidates. Our business depends not only on our ability to successfully develop, obtain regulatory licensure for, and commercialize the product candidates we currently have in preclinical development, but to continue to generate new product candidates through our platform. Even if we are successful in continuing to build our pipeline and further progress the development of our current product candidates, any additional product candidates may not be suitable for clinical development, including as a result of harmful side effects, manufacturing issues, limited potency or other characteristics that indicate that they are unlikely to be products that will succeed in clinical development, receive marketing licensure or achieve market acceptance. If we cannot validate our technology platform by successfully commercializing product candidates, we may not be able to obtain product, licensing or collaboration revenue in future periods, which would adversely affect our business, financial condition, results of operations and prospects.

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

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

Our estimated addressable markets and market opportunities for our product candidates are based on a variety of inputs, including data published by third parties, our own market insights and internal market intelligence, and internally generated data and assumptions. We have not independently verified any third-party information and cannot be assured of its accuracy or completeness. Market opportunity estimates, whether obtained or derived from third-party sources or developed internally, are subject to significant uncertainty and are based on assumptions and estimates that may prove not to be accurate. Although we believe our market opportunity estimates are reasonable, such information is inherently imprecise. In addition, our assumptions and estimates of market opportunities are necessarily subject to a high degree of uncertainty and risk due to a variety of factors, including but not limited to those described in this 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 our product candidates because they are based on our novel therapeutic modality, and we may not generate any future revenue from the sale or licensing of product candidates.

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

- educating medical personnel regarding the potential potency and safety benefits, as well as the challenges, of incorporating our product candidates, if approved, into treatment regimens; and
- establishing the sales and marketing capabilities to gain market acceptance, if approved.

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

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

- the timing of our receipt of any marketing and commercialization licensures;
- the terms of any licensures and the countries in which licensures are obtained;

- the safety, purity, and potency of our product candidates;
- the prevalence and severity of any adverse side effects associated with our product candidates;
- limitations or warnings contained in any labeling approved by the FDA, or other comparable foreign regulatory authorities;
- 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
- 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 have not tested any of our product candidates in clinical trials. 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 we commence in the future 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 Phase 1 clinical trials of our product candidates PYX-201, PYX-202, PYX-203, PYX-106 and PYX-102 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. For example, in case of PYX-202, in preparation for our IND filing and based on observation of our GLP studies to date, we have determined that we will need to conduct additional GLP and non-GLP toxicity studies to determine whether PYX-202 is a viable clinical candidate. We will continue to monitor the progress of our PYX-202 program and expect to provide an update about PYX-202 in mid-2022. Our future 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 planned 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 initiate 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 generally and during the COVID-19 pandemic, specifically. 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;
- competing clinical trials or approved therapies which present an attractive alternative to patients and their physicians;
- 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 impact of the current COVID-19 pandemic, which may affect the conduct of a clinical trial, including by slowing potential enrollment or reducing the number of eligible patients for clinical trials.
- the risk that enrolled subjects 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 planned 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 planned 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. While we have not yet initiated clinical trials for any of our product candidates, it is likely that there may be side effects associated with their use. Results of our trials could reveal a high and unacceptable severity and prevalence of these or other side effects. In such an event, our trials could be suspended or terminated, and the FDA or comparable foreign regulatory authorities could order us to cease further development of or deny licensure or approval of our product candidates for any or all targeted indications. Such side effects could also affect patient recruitment or the ability of enrolled patients to complete the trial or result in potential product liability claims. Any of these occurrences may materially and adversely affect our business, financial condition, results of operations and prospects.

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

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

- regulatory authorities may withdraw their licensure or approval of the product or seize the product;
- we may be required to recall the product or change the way the product is administered to patients;
- additional restrictions may be imposed on the marketing of the particular product or the manufacturing processes for the product or any component thereof;
- we may be subject to fines, injunctions or the imposition of civil or criminal penalties;
- regulatory authorities may require the addition of labeling statements, such as a “black box” warning or a contraindication;
- we may be required to create a medication guide outlining the risks of such side effects for distribution to patients;

- we could be sued and held liable for harm caused to patients;
- the product may become less competitive; and
- our reputation may suffer.

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

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

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

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

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

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. Indeed, 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 April 2021, there were approximately 275 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 marketing of ADC therapeutics and Immunotherapy which include, but are not limited to, ADC Therapeutics SA, Astellas Pharma, Inc., AstraZeneca plc, Daiichi Sankyo Company, Ltd., Genentech, Inc., Gilead Sciences, Inc, GlaxoSmithKline, plc, Pfizer, Inc., Rakuten Medical, Inc., Seagen, Inc., Nextcure, Inc. and Abcure, 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., the target of our PYX-202 candidate, DLK-1, from Chiome Bioscience, Inc., the target of our PYX-203 product candidate, CD123, from ImmunoGen, Inc., Vincerx Pharma, Inc., Macrogenics and Byondis B.V., the target of our PYX-106 product candidate, a Siglec-15 targeting antibody, from Nextcure, Inc. lead program - NC318 and the target of our PYX-102 product candidate, Anti-KLRG1, from Abcuro, Inc. 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 Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act, collectively the 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 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. 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 postmarketing 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 postmarketing studies, track and trace, serialization, postmarket 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 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 indicated uses for which the product may be marketed or to the conditions of licensure, or contain requirements for potentially costly postmarketing 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 postmarketing 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 receives 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 also may impose requirements for costly postmarketing 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 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 postmarketing 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 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 European Union and UK's 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 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 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. 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. In addition, 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. 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 when 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.

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 postmarketing trial does not verify clinical benefit, or if we do not comply with rigorous postmarketing requirements, the FDA may seek to withdraw accelerated approval.

We plan to seek accelerated approval of PYX-201, PYX-202, PYX-203, PYX-106 and PYX-102 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 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 postmarketing 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 postmarketing 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. These confirmatory trials must be completed with due diligence. If such confirmatory postmarketing trial fails 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. 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 its 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 postmarketing requirements, including the completion of one or more confirmatory postmarketing 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 postmarketing trial with due diligence, our confirmatory postmarketing 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 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 European Union 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, 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. Therefore, 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 IP 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 test 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 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 European Union 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 United Kingdom has left the EU, its regulatory legal framework provides for similar periods of protection (namely regulatory data exclusivity, marketing protection and market exclusivity).

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

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

In connection with the clinical development of our product candidates for certain indications, we may work with collaborators to develop or obtain access to companion diagnostic tests to identify appropriate patients for our product candidates. We may rely on third parties for the development, testing and manufacturing of these companion diagnostics, the application for and receipt of any required regulatory clearances or approvals, and the commercial supply of these companion diagnostics. The FDA and foreign regulatory authorities regulate companion diagnostics as medical devices that will likely be subject to clinical trials in conjunction with the clinical trials for product candidates, and which will require separate regulatory clearance or approval prior to commercialization. This process could include additional meetings with health authorities, such as a pre-submission meeting and the requirement to submit an investigational device exemption (IDE). In the case of a companion diagnostic that is designated as "significant risk device," approval of an IDE by the FDA and 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 require 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. If these parties are unable to successfully develop companion diagnostics for these therapeutic product candidates, 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 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, 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 the curtailment or restructuring of our operations.

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

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

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

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

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

Further, increasing efforts by third-party payors in the United States and abroad to cap or reduce healthcare costs may cause payor organizations to limit both coverage and the level of reimbursement for newly approved products and, as a result, they may not cover or provide adequate payment for our product candidates. In order to secure coverage and reimbursement for any product that might be approved for sale, we may need to conduct expensive pharmacoeconomic studies in order to demonstrate the medical necessity and cost-effectiveness of our products, in addition to the costs required to obtain FDA or comparable marketing authorizations or approvals. Additionally, we may also need to provide 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, countries in the European Union 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. A European Union 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 European Union 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, or CEPs. 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 European Union do not follow price structures of the United States and generally prices in the European Union 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, in March 2010, the ACA was enacted, which substantially changed the way healthcare is financed by both governmental and private payors. The ACA contained a number of provisions, including those governing the federal healthcare programs, provider reimbursement, and healthcare fraud and abuse laws. For example, the ACA:

- increased the minimum level of Medicaid rebates payable by manufacturers of brand name drugs from 15.1% to 23.1% of the average manufacturer price, or AMP;
- required collection of rebates for drugs paid by Medicaid managed care organizations;
- expanded beneficiary eligibility criteria for Medicaid programs by, among other things, allowing states to offer Medicaid coverage to certain individuals with income at or below 138% of the federal poverty level, thereby potentially increasing manufacturers' Medicaid rebate liability;
- extended manufacturers' Medicaid rebate liability to covered drugs dispensed to individuals who are enrolled in Medicaid managed care organizations;
- expanded the types of entities eligible for the 340B Drug Pricing Program;
- established a new methodology by which rebates owed by manufacturers under the Medicaid Drug and Rebate Program, or MDRP, are calculated for drugs that are inhaled, infused, instilled, implanted or injected;
- required manufacturers to participate in a coverage gap discount program, under which they must agree to offer 70 percent point-of-sale discounts off negotiated prices of applicable branded drugs to eligible beneficiaries during their coverage gap period, as a condition for the manufacturer's outpatient drugs to be covered under Medicare Part D;
- imposed a non-deductible annual fee on pharmaceutical manufacturers or importers who sell "branded prescription drugs" and biologic agents apportioned among these entities according to their market share in certain federal government programs;
- established the Center for Medicare and Medicaid Innovation within CMS to test innovative payment and service delivery models to lower Medicare and Medicaid spending, potentially including prescription drug spending;
- created the Patient-Centered Outcomes Research Institute to oversee, identify priorities in, and conduct comparative clinical effectiveness research, along with funding for such research;
- required reporting of certain financial arrangements between manufacturers of drugs, biological products, devices, and medical supplies and physicians and teaching hospitals under the federal Physician Payments Sunshine Act; and
- required annual reporting of certain information regarding drug samples that manufacturers and distributors provide to licensed practitioners.

Since its enactment, there have been judicial, legislative, and executive branch challenges to certain aspects of the ACA, and on June 17, 2021, the U.S. Supreme Court dismissed the most recent judicial challenge to the ACA brought by several states without specifically ruling on the constitutionality of the ACA. Prior to the Supreme Court's decision, President Biden had issued an executive order to initiate a special enrollment period from February 15, 2021, through August 15, 2021, for purposes of obtaining health insurance coverage through the ACA marketplace. The Executive Order also instructed certain governmental agencies to review and reconsider their existing policies and rules that limit access to healthcare, including among others, policies that create barriers to obtaining access to health insurance coverage through the ACA marketplaces. It is unclear how healthcare reform measures enacted by Congress or implemented by the Biden administration or other efforts to challenge, repeal or replace the ACA, if any, will impact the ACA.

Other legislative changes have been proposed and adopted in the U.S. since the ACA was enacted. These changes include the Budget Control Act of 2011, which, among other changes, led to aggregate reductions of Medicare payments to providers of up to 2% per fiscal year that started in April 2013 and, due to subsequent legislation, will continue into 2031, with the exception of a temporary suspension of the payment reduction from May 1, 2020 through March 31, 2022 due to the COVID-19 pandemic. Unless additional Congressional action is taken, sequestration will start again on April 1, 2022. From April 1 to June 30, 2022, payment for Medicare fee-for-service claims will be adjusted downwards by 1%; beginning July 1, 2022, the payment will be adjusted downwards by 2%.

The cost of prescription drugs has been the subject of considerable policy discussion and debate in the United States. This has resulted in several U.S. Congressional inquiries and proposed and enacted federal legislation designed to, among other things, bring more transparency to drug pricing, reduce the cost of prescription drugs under Medicare, and review the relationship between pricing and manufacturer patient programs. While several proposed reform measures will require Congress to pass legislation to become effective, Congress and the Biden administration have expressed support for legislative and/or administrative measures to address prescription drug costs. Since the Presidential inauguration, the Biden administration has taken several executive actions that signal changes in policy from the prior administration, including with respect to executive actions by the Trump administration related to prescription drug costs. Additionally, the American Rescue Plan Act of 2021 was recently signed into law, which, among other things, eliminated the statutory cap on drug manufacturers' MDRP rebate liability, effective January 1, 2024. Under current law enacted as part of the ACA, drug manufacturers' MDRP rebate liability is capped at 100% of AMP for a covered outpatient drug.

Individual states in the U.S. have also increasingly passed legislation and implemented regulations designed to control pharmaceutical and biological product pricing, including price or patient reimbursement constraints, discounts, restrictions on certain product access and marketing cost disclosure and transparency measures; and, in some cases, encourage importation from other countries and employ bulk purchasing. Legally mandated price controls on payment amounts by third-party payors or other restrictions could adversely affect our business prospects, financial condition, and results of operations. In addition, regional healthcare authorities and individual hospitals are increasingly using bidding procedures to determine what pharmaceutical products and which suppliers will be included in their prescription drug and other healthcare programs. This could reduce the ultimate demand for our product candidates or put pressure on our product pricing.

We expect that additional state and federal healthcare reform 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 change 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. It is possible that additional governmental action will be taken to address the COVID-19 pandemic. 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.

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, recently passed in California. The CPRA will impose 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 will also create 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 will go into effect on January 1, 2023, and additional compliance investment and potential business process changes may be required. In the event that we are subject to or affected by HIPAA, the CCPA, the CPRA or other domestic 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 General Data Protection Regulation, or GDPR, went into effect on May 2018 and imposes strict requirements for processing the personal data of individuals within the European Economic Area, or the EEA. Companies that must comply with the GDPR face increased compliance obligations and risk, including more robust regulatory enforcement of data protection requirements and potential fines for noncompliance of up to €20 million or 4% of the annual global revenues of the noncompliant company, whichever is greater. Among other requirements, the GDPR regulates transfers of personal data subject to the GDPR to third countries that have not been found to provide adequate protection to such personal data, including the United States, and the efficacy and longevity of current transfer mechanisms between the European Union and the United States remains uncertain. For example, in 2016, the European Union and United States agreed to a transfer framework for data transferred from the European Union to the United States, called the Privacy Shield, but the Privacy Shield was invalidated in July 2020 by the Court of Justice of the European Union. Further, from January 1, 2021, companies have to comply with the GDPR and also the United Kingdom GDPR, or the UK GDPR, which, together with the amended United Kingdom Data Protection Act 2018, retains the GDPR in United Kingdom national law. The UK GDPR mirrors the fines under the GDPR, i.e., fines up to the greater of €20 million (£17.5 million) or 4% of global turnover. The relationship between the United Kingdom and the European Union in relation to certain aspects of data protection law remains unclear, and it is unclear how United Kingdom data protection laws and regulations will develop in the medium to longer term. The European Commission has adopted an adequacy decision in favor of the UK, enabling data transfers from EU member states to the UK without additional safeguards. However, the UK adequacy decision will automatically expire in June 2025 unless the European Commission re-assesses and renews/extends that decision, and remains under review by the Commission during this period. These changes may lead to additional costs and increase our overall risk exposure.

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, 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 Chief Executive Officer, Pamela Connealy, our Chief Financial Officer, and Jay Feingold M.D., Ph.D., our Chief Medical 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 planned 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.

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

As of May 13, 2022, we had 64 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 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 development. If any of our product candidates complete clinical development and are approved, we intend to either establish a sales and marketing organization with technical expertise and supporting distribution capabilities to commercialize our product candidates in a legally compliant manner, or to outsource this function to a third party. There are risks involved if we decide to establish our own sales and marketing capabilities or enter into arrangements with third parties to perform these services. To the extent that we enter into collaboration agreements with respect to marketing, sales or distribution, our product revenue may be lower than if we directly marketed or sold any approved products. Such collaborative arrangements with partners may place the commercialization of our products outside of our control and would make us subject to a number of risks, including that we may not be able to control the amount or timing of resources that our collaborative partner devotes to our products or that 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 collaborator's business strategy.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

- production shortages resulting from any events affecting raw material supply or manufacturing capabilities abroad; and
- business interruptions resulting from geo-political actions, including war and terrorism.

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

We face risks related to health epidemics and outbreaks, including the COVID-19 pandemic, which could significantly disrupt our preclinical studies and clinical trials, and therefore our receipt of necessary regulatory licensure or approvals could be delayed or prevented.

In December 2019, the coronavirus disease, COVID-19, was identified in Wuhan, China. Since then, COVID-19 has spread globally. In March 2020, the World Health Organization declared COVID-19 a global pandemic and the United States declared a national emergency with respect to COVID-19. In response to the COVID-19 pandemic, "shelter in place" orders and other public health guidance measures have been implemented across much of the United States, including in the locations of our offices and those of key vendors and partners. As a result of the COVID-19 pandemic, or similar pandemics, and related "shelter in place" orders and other public health guidance measures, we have and may in the future experience disruptions that could materially and adversely impact our preclinical studies and development, any clinical trials we subsequently commence, and our business, financial condition, and results of operations. Potential disruptions to our preclinical development efforts include, but are not limited to:

- delays or disruptions in preclinical experiments and IND-enabling studies due to restrictions of on-site staff, limited or no access to animal facilities, and unforeseen circumstances at CROs and vendors;
- limitations on employee or other resources that would otherwise be focused on the conduct of our preclinical work and any clinical trials we subsequently commence, including because of sickness of employees or their families, the desire of employees to avoid travel or contact with large groups of people, an increased reliance on working from home, school closures, or mass transit disruptions;
- delays in necessary interactions with regulators, ethics committees, and other important agencies and contractors due to limitations in employee resources or forced furlough of government or contractor personnel; and
- limitations in maintaining our corporate culture that facilitates the transfer of institutional knowledge within our organization and fosters innovation, teamwork, and a focus on execution.
- We have not yet commenced clinical trial activities for any of our product candidates. If we commence clinical trials for one or more of our product candidates, potential disruptions of those clinical activities as a result of COVID-19 or similar pandemics include, but are not limited to:
- interruption of key clinical trial activities, such as clinical trial site data monitoring and efficacy, safety and translational data collection, processing and analyses, due to limitations on travel imposed or recommended by federal, state, or local governments, employers and others or interruption of clinical trial subject visits, which may impact the collection and integrity of subject data and preclinical study endpoints;
- delays or difficulties in initiating or expanding clinical trials, including delays or difficulties with clinical site initiation and recruiting clinical site investigators and clinical site staff;
- delays or difficulties in enrolling and retaining patients in our clinical trials;
- increased rates of patients withdrawing from our clinical trials following enrollment as a result of contracting COVID-19 or other health conditions or being forced to quarantine;
- interruption of, or delays in receiving, supplies of our product candidates from our contract manufacturing organizations due to staffing shortages, production slowdowns, or stoppages and disruptions in materials and reagents;
- diversion of healthcare resources away from the conduct of clinical trials, including the diversion of hospitals serving as our clinical trial sites and hospital staff supporting the conduct of our clinical trials;
- interruption or delays in the operations of the FDA and comparable foreign regulatory agencies;
- changes in regulations as part of a response to the COVID-19 pandemic which may require us to change the ways in which our clinical trials are conducted, which may result in unexpected costs, or to discontinue the clinical trials altogether;
- delays in receiving approval from local regulatory authorities to initiate our planned clinical trials;
- limitations on employee resources that would otherwise be focused on the conduct of our preclinical studies and clinical trials, including because of sickness of employees or their families or the desire of employees to avoid contact with large groups of people;
- interruption of, or delays in receiving, supplies of our product candidates from our contract manufacturing organizations due to staffing shortages, production slowdowns or stoppages and disruptions in delivery systems;

- refusal of the FDA or comparable regulatory authorities to accept data from clinical trials in affected geographies; and
- additional delays, difficulties or interruptions as a result of current or future shutdowns due to the COVID-19 pandemic in countries where we or our third-party service providers operate.

The COVID-19 global pandemic continues to rapidly evolve. Although many countries, including certain countries in Europe and the United States, have re-opened, rises in new cases have caused certain countries to re-initiate restrictions. The extent to which the outbreak may affect our preclinical studies, clinical trials, business, financial condition, and results of operations will depend on future developments, which are highly uncertain and cannot be predicted at this time, such as the ultimate geographic spread of the disease, the duration of the outbreak, travel restrictions, and actions to contain the outbreak or treat its impact, such as social distancing and quarantines or lock-downs in the United States and other countries, business closures, or business disruptions and the effectiveness of actions taken in the United States and other countries to contain and treat the disease. Additionally, we are unable to predict if a different pandemic could have similar or different impacts on our business, financial condition, or share price. Future developments in these and other areas present material uncertainty and risk with respect to our clinical trials, business, financial condition, and results of 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 Securities and Exchange Commission, or 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.

Separately, in response to the COVID-19 pandemic, on March 10, 2020, the FDA announced its intention to postpone most inspections of foreign manufacturing facilities, and on March 18, 2020, the FDA temporarily postponed routine surveillance inspections of domestic manufacturing facilities. On July 10, 2020, the FDA announced its intention to resume certain on-site inspections of domestic manufacturing facilities subject to a risk-based prioritization system. The FDA intends to use this risk-based assessment system to identify the categories of regulatory activity that can occur within a given geographic area, ranging from mission critical inspections to resumption of all regulatory activities. Additionally, on April 15, 2021, the FDA issued a guidance document in which the FDA described its plans to conduct voluntary remote interactive evaluations of certain drug manufacturing facilities and clinical research sites. According to the guidance, the FDA intends to request such remote interactive evaluations in situations where an in-person inspection would not be prioritized, deemed mission-critical, or where direct inspection is otherwise limited by travel restrictions, but where the FDA determines that remote evaluation would still be appropriate.

FDA has since adjusted its inspection activities in response to the ongoing COVID-19 pandemic. On December 29, 2021, the agency implemented temporary changes to its inspectional activities to ensure the safety of its employees and regulated firms. On February 2, 2022, FDA announced that it would resume domestic surveillance inspections across all product areas on February 7, 2022. We cannot predict whether, and when, FDA will decide to pause or resume inspections due to the COVID-19 pandemic.

Regulatory authorities outside the United States may adopt similar restrictions or other policy measures in response to the COVID-19 pandemic. If a prolonged government shutdown occurs, or if global health concerns continue to 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, Inc., or Pfizer, LegoChem Biosciences, Inc., or LegoChem, Biosion USA, Inc., or Biosion, and the University of Chicago, pursuant to which we in-license patents and technology for certain of our product candidates, and we are also party to a collaboration agreement with Alloy Therapeutics, Inc., or Alloy, 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 entered into a three-year collaboration with Alloy to finance and operate Voxall Therapeutics, LLC, or Voxall, a joint venture company formed in collaboration with Alloy to leverage our site-specific target catalog and Alloy's ATX-Gx platform and antibody discovery services. We additionally may seek other third-party collaborators for the research development and commercialization of our current or future product candidates. The collaboration with Alloy and any other collaboration agreements we enter into will likely limit our control over the amount and timing of resources that our collaborators dedicate to the development or commercialization of any product candidates we may seek to develop with them. Our ability to generate revenues from these arrangements will depend on our collaborators' abilities to successfully perform the functions assigned to them in these arrangements. We cannot predict the success of any collaboration in which we have entered or may enter.

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.

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

We rely on third parties to manufacture our product candidates. Any failure by a third-party manufacturer to produce acceptable raw materials or product candidates for us or to obtain authorization from the FDA or comparable foreign regulatory authorities 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 we expect to continue to do so in the future in relation to our clinical product supplies, and if we receive authorization to market our product candidates, 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. In particular, any replacement of our manufacturer could require significant effort and expertise because there may be a limited number of qualified replacements.

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 collaborators;
- 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 CMOs or to do so on acceptable terms. Even if we are able to establish agreements with CMOs, reliance on them entails additional risks, including:

- reliance on the CMO for regulatory, compliance and quality assurance;
- the possible breach of the manufacturing agreement by the CMO;
- 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 CMO 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 CMOs 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 CMOs, 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 European Union 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, European Union Member States and the EMA or other comparable regulatory authorities does not approve these facilities for the manufacture of our product candidates or if it withdraws 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 candidate, 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 CMOs 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.

Our CMOs 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 CMOs, 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 CMOs 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 CMOs 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.

Some of our suppliers may experience disruption to their respective supply chain due to the effects of the COVID-19 pandemic, which could delay, prevent or impair our development or commercialization efforts.

We obtain certain chemical or biological intermediates in the synthesis of our product candidates in countries affected by the COVID-19 pandemic. If we are unable to obtain these chemical or biological intermediates in sufficient quantity and in a timely manner, the development, 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 clinical research organizations, or 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, 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, LegoChem 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 our service providers or 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 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 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, PYX-202, PYX-203, PYX-106, and PYX-102, 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; 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. 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 antibody-drug conjugates and their therapeutic use. Some of these patent applications have already been allowed or issued, and others may issue in the future. While we may decide to initiate proceedings to challenge the validity of these or other patents in the future, we may be unsuccessful, and courts or patent offices in the United States and abroad could uphold the validity of any such patent. Furthermore, because patent applications can take many years to issue and may be confidential for 18 months or more after filing, and because pending patent claims can be revised before issuance, there may be applications now pending which may later result in issued patents that may be infringed by the manufacture, use or sale of our product candidates. Regardless of when filed, we may fail to identify relevant third-party patents or patent applications, or we may incorrectly conclude that a third-party patent is invalid or not infringed by our product candidates or activities. If a patent holder believes our product candidate infringes its patent, the patent holder may sue us even if we have received patent protection for our technology. Moreover, we may face patent infringement claims from non-practicing entities that have no relevant drug revenue and against whom our own patent portfolio may thus have no deterrent effect. If a patent infringement suit were threatened or brought against us, we could be forced to stop or delay research, development, manufacturing or sales of the therapeutic or product candidate that is the subject of the actual or threatened suit.

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

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, LegoChem 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.

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 our product candidates PYX-201 and PYX-203 are in-licensed from Pfizer, the rights to the intellectual property covering our product candidate PYX-202 is in-licensed from LegoChem, and the rights to the intellectual property covering our product candidate PYX-106 is 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 Pfizer License Agreement, the LegoChem License Agreement, or the Biosion License Agreement, 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. 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. 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.

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.

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.

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 to be subject to annual and quarterly fluctuations. Our net loss and other operating results will 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, 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 receives 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 Form 10-Q titled "Risk Factors" 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, 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, such as the COVID-19 pandemic, 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 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, 2022, 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 54.2% 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

At the time of our IPO, approximately 66% of our outstanding shares were prohibited or otherwise restricted from resale as a result of securities law provisions, market standoff agreements entered into by certain of our stockholders with us or lock-up agreements entered into by our stockholders with the underwriters in connection with our IPO. In April 2022, our lock up period of 180 days expired. As a result, majority of our current outstanding shares are free from any restrictions to resale. 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.

Certain holders of our outstanding shares have rights, subject to certain conditions, to require us to file registration statements covering the sale of their shares or to include their shares in registration statements that we may file for ourselves or our other stockholders. We also registered the offer and sale of all shares of common stock that we may issue under our equity compensation plans, which shares will be able to be sold in the public market upon issuance, subject to applicable securities laws.

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 IPO, (b) in which we have total annual gross revenue of at least $1.07 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 $700.0 million as of the prior June 30th and (ii) the date on which we have issued more than $1.0 billion in non-convertible debt during the prior three-year period.

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

- being permitted to present only two years of audited financial statements and only two years of related management's discussion and analysis of financial condition and results of operations in their annual report on Form 10-K;
- not being required to comply with the auditor attestation requirements of Section 404 of 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 of the 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 itself of this extended transition period, and, as a result, we will adopt new or revised accounting standards on the relevant dates on which adoption of such standards is required for other public companies.

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

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

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

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

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

We will incur increased costs as a result of operating as a public company, and our management 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 new public company, and particularly after we are no longer an emerging growth company or a smaller reporting company, we will 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 will need to 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. However, these rules and regulations are 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 will incur additional costs and obligations in order to comply with SEC rules that implement Section 404 of the Sarbanes-Oxley Act. Under these rules, beginning with our second annual report on Form 10-K, we will be 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 will be engaging 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. 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 limited in connection with our recent IPO or other ownership changes.

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, 2021, our federal and state net operating losses in the United States were $10.1 million ($48.0 million before tax) and $2.8 million ($45.9 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 state net operating loss carryforwards begin expiring in 2039. In addition, as of December 31, 2021, we had $1.0 million and $0.6 million of federal and state credit carryovers which begin to expire in 2039. These loss and credit carryforwards are subject to review and possible adjustment by the appropriate taxing authorities.

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

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

Use of Proceeds from Initial Public Offering

Our initial public offering of common stock, or the IPO, was affected 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. There has been no material change in our planned use of the net proceeds from the IPO as described in our final prospectus filed pursuant to Rule 424(b)(4) under the Securities Act with the SEC on October 8, 2021.

Item 3. Defaults Upon Senior Securities.

None

Item 4. Mine Safety Disclosures.

Not applicable

Item 5. Other Information.

None

Item 6. Exhibits.

Exhibit Number	Description	Form	File No.	Exhibit	Filing Date	Filed Here with
10.1†	License Agreement, dated March 28, 2022 between the registrant and Biosion USA, Inc.					X
31.1	Certification of Principal Executive Officer Pursuant to Rules 13a-14(a) and 15d-14(a) under the Securities Exchange Act of 1934, as Adopted Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.					X
31.2	Certification of Principal Financial Officer Pursuant to Rules 13a-14(a) and 15d-14(a) under the Securities Exchange Act of 1934, as Adopted Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.					X
32.1*	Certification of Principal Executive Officer Pursuant to 18 U.S.C. Section 1350, as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.					X
32.2*	Certification of Principal Financial Officer Pursuant to 18 U.S.C. Section 1350, as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.					X
101.INS	Inline XBRL Instance Document – the instance document does not appear in the Interactive Data File because XBRL tags are embedded within the Inline XBRL document.					X
101.SCH	Inline XBRL Taxonomy Extension Schema Document					X
101.CAL	Inline XBRL Taxonomy Extension Calculation Linkbase Document					X
101.DEF	Inline XBRL Taxonomy Extension Definition Linkbase Document					X
101.LAB	Inline XBRL Taxonomy Extension Label Linkbase Document					X
101.PRE	Inline XBRL Taxonomy Extension Presentation 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 13, 2022

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

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

CERTAIN INFORMATION CONTAINED IN THIS DOCUMENT, MARKED BY [***], HAS BEEN OMITTED BECAUSE IT IS NOT MATERIAL AND IS THE TYPE THAT THE REGISTRANT TREATS AS PRIVATE OR CONFIDENTIAL.

LICENSE AGREEMENT

This LICENSE AGREEMENT ("**Agreement**") is made effective as of March 28, 2022 (the "**Effective Date**"), by and between Pyxis Oncology, Inc., a Delaware corporation, having an address at 35 Cambridge Park Drive, Cambridge, Massachusetts 02140 ("**Licensee**"), and Biosion USA, Inc., a Delaware corporation, having an address at 1 Innovation Way, Suite 300, Newark, Delaware 19711 ("**Licensor**"). Licensee and Licensor may, from time-to-time, be individually referred to as a "**Party**" and collectively referred to as the "**Parties**".

RECITALS

WHEREAS, Licensor Controls certain Antibody compounds directed to Siglec-15, one of the Sialic acid-binding immunoglobulin-like lectins ("**Siglec-15**"), and the Licensed Technology (hereinafter defined) that covers the exploitation of those compounds; and

WHEREAS, Licensee wishes to obtain, and Licensor wishes to grant to Licensee, certain exclusive licenses under the Licensed Technology on the terms and conditions set forth herein to exploit those anti-Siglec-15 compounds.

NOW, THEREFORE, in consideration of the mutual agreements and covenants set forth herein and other good and valuable consideration, the receipt and sufficiency of which the Parties hereby acknowledge, the Parties, intending to be legally bound hereby, agree to the foregoing and as follows:

1. DEFINITIONS.

Unless the context otherwise requires, the terms in this Agreement with initial letters capitalized shall have the meanings set forth below or the meaning as designated in the indicated places throughout this Agreement.

1.1. "**Accelerated Approval**" means the granting of Regulatory Approval by FDA based on a surrogate endpoint or intermediate clinical endpoint, as permitted by applicable FDA rules, orders and guidances.

1.2. "**Acquiring Person**" is defined in Section 1.35.

1.3. "**Additional Information**" is defined in Section 14.2.

1.4. "**Adverse Event**" means any untoward medical occurrence in a human patient or subject who is administered a product, whether or not considered related to the product, including any undesirable sign (including abnormal laboratory findings of clinical concern), symptom, or disease associated with the use of such product.

1.5. "**Affiliate**" means, with respect to a Party, any other Person that, on the Effective Date or during the Term, controls, is controlled by, or is under common control with that Party. For the purpose of this definition, "control" refers to: (a) the possession, directly or indirectly, of the power to direct or cause the direction of the management or policies of an entity, whether through the ownership of voting securities or other ownership interest, by contract or otherwise; or (b) the ownership, directly or indirectly, of at least fifty percent (50%) of the combined voting power of the securities or other ownership interest of such entity. For clarity, a Person will be deemed an Affiliate of another Person only so long as it satisfies the foregoing definition.

1.6. "**Agreement**" is defined in the introduction to this Agreement.

1.7. "**Alliance Manager**" is defined in Section 4.3.

1.1. "**Annual Net Sales**" means, with respect to a Calendar Year during the applicable Royalty Term, the aggregate Net Sales by Licensee, its Affiliates, and Sublicensees of all Products in the Field in the Licensed Territory during such Calendar Year.

1.2. "**Anti-Corruption Law**" means any applicable law, statute, rule, regulation, order, judgment, ordinance, or guideline of any governmental authority concerning bribery, corruption, or illegal payments and gratuities, including the United States Foreign Corrupt Practices Act, the Hong Kong Prevention of Bribery Ordinance, the UK Bribery Act 2010, the PRC Criminal Law, the PRC Unfair Competition Law, the Interim Regulations on Prohibition of Commercial Bribery issued by the SAIC, and any Applicable PRC Law similar to any of the foregoing.

1.3. "**Antibody**" means a molecule comprising or containing one (1) or more immunoglobulin variable domains or any fragments, derivatives, variants, or modifications thereof that bind to the same antigen.

1.4. "**Applicable Law**" means any applicable law, statute, rule, regulation, order, judgment, ordinance, or guideline of any governmental authority, including the US Federal Food, Drug and Cosmetic Act (21 U.S.C. 335a), the rules and regulations of the Securities Exchange Commission, any listing requirements of any securities exchange or market applicable to a Party, Applicable PRC Law, Anti-Corruption Law, cGCP, cGLP, and cGMP.

1.5. "**Applicable PRC Law**" means any applicable (including local- or national-level) law, statute, rule, regulation, order, judgment, ordinance, or guideline, and other legislative, executive, or judicial interpretation or normative documents of any governmental authority of the PRC, including any officially-announced policies of the PRC, which are publicly promulgated and available and in force from time to time.

1.6. "**Asian Market**" means the following countries: Japan; the Republic of Korea; Singapore and India.

1.7. "**Auditor**" is defined in Section 6.2.1.

1.8. "**Bankruptcy Code**" is defined in Section 1.16.

1.9. "**Bankruptcy Event**" means, with respect to a Party, the occurrence of any of the following: (a) the institution of any bankruptcy, receivership, insolvency, reorganization, or other similar proceedings by or against such Party under any bankruptcy, insolvency, or other similar law now or hereinafter in effect, including any section or chapter of the United States Bankruptcy Code or under any similar laws or statutes of the United States or any state thereof (the "**Bankruptcy Code**"), where, in the case of involuntary proceedings, such proceedings have not been dismissed or discharged within [***] days after they are instituted; (b) the insolvency or making of an assignment for the benefit of creditors or the admittance by such Party of any involuntary debts as they mature; (c) the institution of any reorganization, arrangement, or other readjustment of debt plan of such Party not involving the Bankruptcy Code; (d) appointment of a receiver for all or substantially all of such Party's assets; or (e) any corporate action taken by the board of directors of such Party in furtherance of any of the foregoing actions.

1.10. "**Biomarker Test**" means the predictive protein assay which is intended to be used to identify and select patients likely to respond to a Product containing a Compound, and any improved versions of such assay. [***].

1.11. "**Biosimilar Product**" means [***].

1.12. "**BLA**" means a biologics license application or an equivalent authorization to market a Product in a particular country or jurisdiction, as defined by Applicable Law and regulations and filed with the applicable Regulatory Authority.

1.13. "**Business Day**" means any day other than a Saturday, a Sunday, or a day on which commercial banks located in New York, New York, USA, are authorized or required by Applicable Law to remain closed.

1.14. "**Calendar Quarter**" means the respective periods of three (3) consecutive calendar months ending on March 31, June 30, September 30, and December 31; provided, that: (a) the first Calendar Quarter of the Term shall extend from the Effective Date to the end of the first such three (3)-month period thereafter; and (b) the final Calendar Quarter of the Term shall extend from the first day of the applicable three (3)-month period until the last day of the Term.

1.15. "**Calendar Year**" means any twelve (12)-month period commencing on January 1 and ending on December 31; provided, that: (a) the first Calendar Year of the Term shall extend from the Effective Date to December 31; and (b) the final Calendar Year of the Term shall extend from January 1 until the last day of the Term.

1.1. "**cGCP**" means the then-current good clinical practices as defined in Parts 50, 56 and 312 of Title 22 of the U.S. Code of Federal Regulations or any successor thereto or foreign equivalents thereof, including Good Clinical Practice for Drugs promulgated by FDA, together with any guidelines or implementation rules issued by FDA in connection therewith.

1.2. "**cGLP**" means the then-current good laboratory practices as required by the FDA under 21 C.F.R. Part 58 and all applicable FDA rules, regulations, orders, and guidances, and the requirements with respect to current good laboratory practices prescribed by the European Community, the OECD (Organization for Economic Cooperation and Development Council) and the ICH Guidelines.

1.1. "**cGMP**" means the then-current good manufacturing practices as defined in Parts 210 and 211 of Title 21 of the U.S. Code of Federal Regulations or any successor thereto and foreign equivalents thereof, including Good Manufacturing Practice for Drugs.

1.2. "**Change of Control**" means, with respect to a Party, that: (a) (i) any Third Party acquires directly or indirectly the beneficial ownership of any voting securities of such Party, or (ii) the percentage ownership by a Third Party of the voting securities of such Party is increased through stock redemption, cancellation, or other recapitalization, and, in each case ((i) and (ii)), immediately after such acquisition or increase such Third Party is, directly or indirectly, the beneficial owner of voting securities representing more than fifty percent (50%) of the total voting power of all of the then-outstanding voting securities of such Party; (b) any merger, consolidation, recapitalization, or reorganization of such Party is consummated that results in the shareholders or equity holders of such Party immediately prior to such transaction owning less than fifty percent (50%) of the outstanding voting securities of the surviving entity (or its parent entity) immediately following such transaction; (c) the shareholders or equity holders of such Party approve any plan of complete liquidation of such Party or an agreement for the sale or disposition by such Party of all or substantially all of such Party's assets, in each case, through one (1) or more related transactions, other than to an Affiliate or pursuant to one (1) or more related transactions that would result in shareholders or equity holders of such Party immediately prior to such transaction owning more than fifty percent (50%) of the outstanding voting securities of the surviving entity (or its parent entity) immediately following such transaction; or (d) the sale or transfer to any Third Party, in one (1) or more related transactions, of all or substantially all of such Party's consolidated assets taken as a whole.

1.3. "**Claims**" means, collectively, any and all demands, claims, actions, and proceedings (whether criminal or civil, in contract, tort, or otherwise) asserted or brought by any Third Party for losses, damages, liabilities, costs, or expenses (including attorneys' fees).

1.1. "**Clinical Supply Agreement**" is defined in Section 3.5.1.

1.2. "**Commercial Supply Agreement**" is defined in Section 3.5.2.

1.3. "**Commercialize**" or "**Commercialization**" means to market, promote, distribute, offer for sale, sell, import, have imported, export, have exported, or otherwise commercialize a compound or product. When used as a noun, "Commercialization" means any and all activities involved in Commercializing.

1.4. "**Commercially Reasonable Efforts**" means [***].

1.5. [***].

1.6. "**Compound"** means: (a) the monoclonal antibody directed to human Siglec-15 that exists as of the Effective Date, which is designated as "BSI-060T," the amino acid sequences of the variable region light chain and heavy chains of which are set forth on Schedule 1.33; or (b) any other Antibody directed to Siglec-15, [***], that is Controlled by either Party as of the Effective Date or during the Term. Compounds shall not include any ROFO Compounds.

1.7. "**Confidential Information**" means, with respect to a Party, all confidential or proprietary information and materials (whether or not patentable) regarding such Party's or any of its Affiliates' technology, products, or business that is communicated in any way or form by or on behalf of such Party or any of its Affiliates (in such capacity, the "**Disclosing Party**") to the other Party or any of its Affiliates (in such capacity, the "**Receiving Party**") or to any of the Receiving Party's employees, consultants, or advisors (collectively, "**Representatives**"), either prior to or after the Effective Date, and whether or not such information or material is identified as confidential at the time of disclosure. Notwithstanding the foregoing, the existence of, and the terms and conditions of, this Agreement shall be considered Confidential Information of each of Licensor and Licensee.

1.8. "**Control**" or "**Controlled**" means, with respect to any Intellectual Property Rights, data, or other information, the legal authority or right (whether by ownership, license, or otherwise) of a Party to grant a license or a sublicense of or under such Intellectual Property Rights (including in the case of the ROFO Product Technology if the ROFO if exercised) to the other Party on the terms and conditions set forth in this Agreement or provide such Intellectual Property Rights, data or other information to such other Party under this Agreement without breaching the terms of any agreement with a Third Party; provided, that a Party and its Affiliates will not be deemed to Control any Intellectual Property Rights, data, or other information to the extent that, prior to the consummation of a Change of Control of such Party, such Intellectual Property Rights, data, or other information are owned or in-licensed by a Third Party and its Affiliates that collectively become Affiliates of such acquired Party (or that merges or consolidates with such Party) after the Effective Date as a result of such Change of Control (each, an "**Acquiring Person**"), except: (a) with respect to any such Intellectual Property Right, data, or other information arising as a result of activities by or on behalf of the Acquiring Person who participate in activities under this Agreement, or have access to Confidential Information under this Agreement; or (b) to the extent that any such Intellectual Property Right, data, or other information is included in or used in furtherance of such Party's activities under this Agreement by or on behalf of the Acquiring Person after such Change of Control.

1.9. "**Cover**" means, with respect to a compound or product, that, but for a license granted to a Person under a claim included in a Patent Right, the Development, Manufacture, Commercialization, or other use of such compound or product in the Field in the Licensed Territory by such Person would infringe, or contribute to or induce the infringement of, such claim (or, with respect to a claim that has not yet issued, would infringe such claim if it were to issue as then being prosecuted).

1.10. "**Develop**" or "**Development**" means to conduct any and all research and development activities necessary to obtain Regulatory Approval, including toxicology, pharmacology, and other pre-clinical efforts, test method development and stability testing, statistical analysis, clinical studies, and regulatory activities.

1.11. "**Disclosing Party**" is defined in Section 1.34.

1.1. "**Dispute**" is defined in Section 15.1.

1.2. "**Effective Date**" is defined in the introduction to this Agreement.

1.3. "**Executive Officers**" means: (a) with respect to Licensor, its Chief Executive Officer or his/her designee; and (b) with respect to Licensee, its Chief Executive Officer or his/her designee.

1.4. "**Existing Upstream License Agreements**" is defined in Section 1.121.

1.5. "**FDA**" means the United States Food and Drug Administration, or a successor federal agency thereto.

1.6. "**Field**" means the treatment, prevention, diagnosis, control and maintenance of all human diseases and conditions.

1.7. "**Final Decision-Making Authority Matters**" is defined in Section 4.1.6.

1.8. "**First Commercial Sale**" means, with respect to a Product, the first sale of such Product by Licensee, any of its Affiliates, or any Sublicensee to a Third Party in a country or jurisdiction in the Licensed Territory following receipt of Regulatory Approval for such Product in such country or jurisdiction or, if no such Regulatory Approval or similar approval is required, the date on which the Product is first commercially launched in such country or jurisdiction; provided, that First Commercial Sale will not include: [***].

1.9. "**FPFD**" means, with respect to a human clinical study, the administration of the first dose of a biopharmaceutical product to the first patient (or volunteer, as relevant) participating in such human clinical study.

1.10. "**GAAP**" means generally accepted accounting principles in the United States, consistently applied.

1.12. "**Government Official**" means: (a) any elected or appointed government official (e.g., a member of a ministry of health); (b) any employee or person acting for or on behalf of a government official, agency, or enterprise performing a governmental function; (c) any political party officer, employee, or person acting for or on behalf of a political party or candidate for public office; (d) any employee or person acting for or on behalf of a public international organization; or (e) any person otherwise categorized as a government official under local law.

1.11. "**Greater China**" means (a) the PRC; (b) the Hong Kong Special Administrative Region ("**Hong Kong**"), (c) the Macau Special Administrative Region ("**Macau**"), and (d) Taiwan.

1.12. "**IND**" means an investigational new drug application or similar application or submission for approval to conduct human clinical studies filed with or submitted to a Regulatory Authority in a particular country or jurisdiction in conformance with the requirements of such Regulatory Authority, including, in each case, any amendments thereto.

1.1. "**Indemnified Party**" is defined in Section 11.3.

1.2. "**Indemnifying Party**" is defined in Section 11.3.

1.3. "**Intellectual Property Rights**" means all Patent Rights, Know-How, copyrights, trademarks, moral rights, and any and all other intellectual property or proprietary rights in any jurisdiction.

1.4. "**Intercompany License Agreement**" means the Intellectual Property Sharing Agreement, dated as of March 22, 2022, between Licensor and Biosion, Inc., a company duly incorporated and validly existing under the laws of People's Republic of China and the parent company of Licensor.

1.5. "**JSC**" is defined in Section 4.1.1.

1.6. "**Know-How**" means any proprietary information, including records, discoveries, inventions, improvements, modifications, processes, techniques, methods, assays, designs, protocols, formulas, data (including toxicology data, animal data, raw data, clinical data, and analytical and quality control data), dosage regimens, results in any form whatsoever, know-how, and trade secrets (in each case, patentable, copyrightable, or otherwise).

1.1. "**Last Patient Last Visit**" means with respect to the relevant clinical trial the final visit to the trial site, to the treating physician for the clinical trial subject or such other final requirement for the last patient on study drug in that clinical trial, required by the protocol for that clinical in order for the database to be locked.

1.2. "**Licensed Know-How**" means any and all Know-How Controlled by Licensor or any of its Affiliates as of the Effective Date or during the Term which is necessary or reasonably useful for the Development, Manufacture or Commercialization of the Compound or any Product or the Biomarker Test in the Field.

1.3. "**Licensed Materials**" means all materials and documents, including Regulatory Filings and all information contained in such documents or filings, (a) Controlled by Licensor or any of its Affiliates that are listed in Schedule 1.60, or (b) Controlled by Licensor or any of its Affiliates during the Term which are otherwise necessary for the Development, Manufacture or Commercialization of any Compound or Product or the Biomarker Test in the Field.

1.4. "**Licensed Patent Rights**" means, subject to Section 2.4, any and all Patent Rights Controlled by Licensor or any of its Affiliates as of the Effective Date or during the Term: (a) that claim the composition of matter, method of using or manufacturing or formulation of the Compound or any Product; or (b) which are otherwise necessary or reasonably useful for the Development, Manufacture, or Commercialization of the Compound or any Product or the Biomarker Test in the Field. The Licensed Patent Rights existing as of the Effective Date include the Patent Rights listed on Schedule 1.61, which schedule may be updated from time to time during the Term upon the request of Licensee.

1.5. "**Licensed Technology**" means, collectively, the Licensed Patent Rights, the Licensed Know-How, and the Licensed Material.

1.1. "**Licensed Territory**" means all of the countries of the world other than the Retained Territory.

1.2. "**Licensee**" is defined in the introduction to this Agreement.

1.3. "**Licensee Development Plan**" is defined in Section 3.2.2.

1.4. "**Licensee Foreground Patent Rights**" means any Patent Rights that are conceived, developed, generated or otherwise made by or on behalf of Licensee or its Affiliates or its or their Sublicensees under or in connection with this Agreement that constitute Licensee Patent Rights.

1.5. "**Licensee Indemnitees**" is defined in Section 11.2.

1.6. "**Licensee Know-How**" means any and all Know-How Controlled by Licensee or any of its Affiliates as of the Effective Date or during the Term which is necessary or reasonably useful for the Development, Manufacture or Commercialization of the Compound or any Product or the Biomarker Test in the Field.

1.7. "**Licensee Materials**" means all materials and documents, including Regulatory Filings and all information contained in such documents or filings, Controlled by Licensee or any of its Affiliates during the Term which are necessary or reasonably useful for the Development, Manufacture or Commercialization of any Compound or Product or the Biomarker Test in the Field.

1.8. "**Licensee Patent Rights**" means any and all Patent Rights Controlled by Licensee or any of its Affiliates as of the Effective Date or during the Term: (a) that claim the composition of matter, method of using or manufacturing or formulation of the Compound or any Product; or (b) which are otherwise necessary or reasonably useful for the Development, Manufacture, or Commercialization of the Compound or any Product or the Biomarker Test in the Field.

1.9. "**Licensee Technology**" means, collectively, the Licensee Patent Rights, the Licensee Know-How, and the Licensee Material.

1.10. "**Licensing Revenue**" means [***].

1.11. "**Licensor**" is defined in the introduction to this Agreement.

1.12. "**Licensor Indemnitees**" is defined in Section 11.1.

1.13. "**Loss of Market Share**" means [***].

1.14. "**Major European Country**" means the United Kingdom, Germany, France, Italy and Spain.

1.15. "**Manufacture**" or "**Manufacturing**" means: (a) to make, produce, manufacture, process, fill, finish, package, label, perform quality assurance testing, release, ship, or store a compound or product or any component thereof; or (b) to engage a Third Party to engage in any of the foregoing activities. When used as a noun, "Manufacture" or "Manufacturing" means any and all activities involved in Manufacturing a compound or product or any component thereof.

1.16. "**Marginal Royalty Rates**" is defined in Section 5.3.

1.17. "**Milestone**" is defined in Section 5.2.1.

1.18. "**Milestone Payment**" is defined in Section 5.2.1.

1.19. "**Net Sales**" means [***].

1.6. "**New Licensed Technology Agreement**" means an agreement with a Third Party entered into following the Effective Date, pursuant to which Licensor in-licenses or otherwise acquires Control of any Patent Rights or Know-How that would constitute Licensed Technology.

1.7. "**Notice of Dispute**" is defined in Section 15.1.1.

1.8. "**Party**" and "**Parties**" is defined in the introduction to this Agreement.

1.9. "**Patent Rights**" means any and all: (a) issued patents; (b) pending patent applications, including all provisional applications, divisions, continuations, substitutions, continuations-in-part, and renewals, and all patents granted thereon; (c) patents-of-addition, re-examinations, reissues, and extensions or restorations by existing or future extension or restoration mechanisms, including patent term adjustments, patent term extensions, supplementary protection certificates, or the equivalent thereof; (d) inventor's certificates; (e) other forms of government-issued rights substantially similar to any of the foregoing; and (f) United States and foreign counterparts of any of the foregoing.

1.10. "**Person**" means an individual, corporation, partnership, limited liability company, trust, business trust, association, joint stock company, joint venture, pool, syndicate, sole proprietorship, unincorporated organization, governmental authority, or any other form of entity not specifically listed herein.

1.11. "**Pharmacovigilance Agreement**" is defined in Section 3.4.

1.12. "**Phase 1 Clinical Trial**" means a clinical trial of a product that would satisfy the requirements of 21 CFR 312.21(a) or its equivalents outside the United States.

1.1. "**Phase 2 Clinical Trial**" means a clinical trial of a product that would satisfy the requirements of 21 CFR. 312.21(b) or its equivalents outside the United States.

1.2. "**Phase 3 Clinical Trial**" means a clinical trial of a product that would satisfy the requirements of 21 CFR 312.21(c) or its equivalents outside the United States.

1.13. "**Pivotal Clinical Trial**" means a human clinical study designed to be used as a pivotal study for purposes of seeking Regulatory Approval for a biopharmaceutical product, which study is conducted on sufficient numbers of human patients to establish that a biopharmaceutical product is safe and efficacious for its intended use, to define warnings, precautions, and adverse reactions that are associated with such product in the dosage range to be prescribed, and at a standard suitable to obtain Regulatory Approval of such product in any country or jurisdiction within the Licensed Territory or label expansion of such product.

1.14. "**PRC**" means the People's Republic of China, excluding, for purposes of this Agreement, Hong Kong, Macau, and Taiwan.

1.15. "**Product**" means any product that includes or incorporates the Compound in any and all dosage forms and formulations.

1.16. "**Prosecuting Party**" is defined in Section 7.5.1.

1.17. "**Prosecution and Maintenance**" means, with respect to a Patent Right, the preparation, filing, prosecution, and maintenance of such Patent Right, as well as re-examinations, reissues, appeals, and requests for patent term adjustments and patent term extensions with respect to such Patent Right, together with the initiation or defense of interferences, oppositions, post grant review, inter parties review, derivations, re-examinations, post-grant proceedings, and other similar proceedings (or other defense proceedings with respect to such Patent Right, but excluding the defense of challenges to such Patent Right as a counterclaim in an infringement proceeding) with respect to the particular Patent Right, and any appeals therefrom. For clarification, "Prosecution and Maintenance" shall not include any other enforcement actions taken with respect to a Patent Right.

1.18. "**Receiving Party**" is defined in Section 1.34.

1.20. "**Regulatory Approval**" means any technical, medical, scientific, or other license, registration, authorization, or approval of any Regulatory Authority in any regulatory jurisdiction (including any approval of a BLA) with respect to any biopharmaceutical product and any indication or intended use, necessary to market and sell such biopharmaceutical product for such indication or intended use, and in the United States, sufficient to make such biopharmaceutical product an available therapy under Applicable Law.

1.21. "**Regulatory Authority**" means any governmental agency or authority responsible for granting Regulatory Approvals for a biopharmaceutical product in the Licensed Territory, including the FDA.

1.22. "**Regulatory Exclusivity**" means, with respect to any Product in any country or jurisdiction in the Licensed Territory, the period of time during which: (a) Licensee, its Affiliate, or a Sublicensee has the exclusive legal right, pursuant to a grant by a Regulatory Authority, other than through a Patent Right, including orphan drug exclusivity, pediatric exclusivity, or rights similar thereto in such country or jurisdiction, or is otherwise entitled to the exclusive legal right by operation of Applicable Law in such country or jurisdiction to market and sell such Product, and such right precludes the receipt of Regulatory Approval of any Third Party product that is deemed to be the same or a similar drug, in each case, under applicable orphan drug legislation or regulations; or (b) the data and information submitted by Licensee, its Affiliate, or any Sublicensee to the relevant Regulatory Authority in such country or jurisdiction for purposes of obtaining Regulatory Approval of such Product may not be disclosed, referenced, or relied upon in any way by any Third Party or such Regulatory Authority to support the Regulatory Approval or marketing of any product by any Third Party in such country or jurisdiction, or if such data and information is disclosed, referenced, or relied upon to support a Regulatory Approval granted to any Third Party in such country or jurisdiction, then the product may not be placed on the market for any indication.

1.23. "**Regulatory Filings**" means, with respect to a Product, any submission to a Regulatory Authority of any appropriate regulatory application or approval, including any IND, BLA, any submission to a regulatory advisory board, any marketing authorization application, and any supplement or amendment thereto.

1.24. "**Regulatory Materials**" means the regulatory registrations, applications, authorizations, and approvals (including approvals of marketing authorization applications, supplements and amendments, pre- and post-approvals, pricing approvals, and labeling approvals), Regulatory Approvals, and other submissions made to or with any Regulatory Authority for research, development (including the conduct of clinical trials), manufacture, or commercialization of a pharmaceutical, biological, or diagnostic product in a regulatory jurisdiction, together with all related correspondence to or from any Regulatory Authority and all documents referenced in the complete regulatory chronology for each marketing authorization application, including all drug master files (if any), INDs, BLAs, and new drug applications, and equivalents outside the United States of any of the foregoing.

1.25. "**Relevant Records**" is defined in Section 6.1.

1.26. "**Representatives**" is defined in Section 1.34.

1.1. "**Requesting Party**" is defined in Section 3.3.3.

1.2. "**Research**" means any non-clinical research activities (including drug discovery, identification or synthesis).

1.3. "**Retained Territory**" means Greater China.

1.4. "**Review Period**" is defined in Section 14.3.

1.5. "**ROFO**" is defined in Section 2.7.

1.6. "**ROFO Compound**" means (a) any [***] Antibody, [***], that inhibits, modulates or binds to Siglec-15 and one or more other protein target(s) [***], or (b) any antibody-drug conjugate, [***], that inhibits, modulates or binds to Siglec-15 [***], in each case of (a) and (b) that is Controlled by a Party or its Affiliate during the Term.

1.27. "**ROFO Product**" means any product that includes or incorporates the applicable ROFO Compound in any and all dosage forms and formulations.

1.28. "**ROFO Product Technology**" means (a) any and all Know-How Controlled by a Party or any of its Affiliates which is necessary or reasonably useful for the Development, Manufacture or Commercialization of the applicable ROFO Compound or any corresponding ROFO Product in the Field, and (b) any and all Patents Rights Controlled by a Party or any of its Affiliates: (i) that claim the composition of matter, method of using or manufacturing or formulation of the applicable ROFO Compound or any corresponding ROFO Product; or (ii) which are otherwise necessary or reasonably useful for the Development, Manufacture, or Commercialization of the applicable ROFO Compound or corresponding ROFO Product in the Field.

1.29. "**Royalties**" is defined in Section 5.3.

1.30. "**Royalty Term**" means, on a Product-by-Product and country-by-country or jurisdiction-by-jurisdiction basis, the period of time from the First Commercial Sale of such Product in such country or jurisdiction until the latest of: (a) the expiration of the last Valid Claim of any Licensed Patent Right which Covers the composition of matter, method of use, Manufacture or sale of such Product in the Field in such country or jurisdiction; (b) the expiration of any applicable Regulatory Exclusivity obtained for such Product in such country or jurisdiction; or (c) the twelve (12)-year anniversary of the date of the First Commercial Sale of such Product in such country or jurisdiction.

1.31. "**Siglec-15**" is defined in the Recitals of this Agreement.

1.32. "**Sublicensee**" means, with respect to a Party, a Third Party (excluding distributors) to whom such Party or an Affiliate of such Party grants or has granted, directly or indirectly, a sublicense of rights licensed to such Party and its Affiliates by the other Party under this Agreement. For clarity, contract research organizations, contract manufacturing organizations, or similar vendors or service providers shall not be regarded as Sublicensees.

1.33. "**Term**" is defined in Section 13.1.

1.34. "**Third Party**" means any Person other than a Party or an Affiliate of a Party.

1.35. "**Third Party Infringement**" is defined in Section 8.1.

1.36. "**Third Party Payments**" is defined in Section 5.4.1.

1.37. "**Uncured Breach**" is defined in Section 13.2.

1.38. "**Upstream License Agreement**" means any agreement with a Third Party pursuant to which Licensor, any of its Affiliates, or any of their respective Third Party licensors in-licenses or otherwise maintains Control of Patent Rights or Know-How that constitute Licensed Technology for purposes of this Agreement, including the agreements set forth on Schedule 1.121 (the "**Existing Upstream License Agreements**") and any Upstream License Agreements which become such pursuant to Section 2.4.

1.39. "**Valid Claim**" means [***].

2. LICENSE GRANTS.

2.1. License Grants by Licensor.

2.1.1. Subject to the terms and conditions of this Agreement, Licensor (on behalf of itself and its Affiliates) hereby grants to Licensee and its Affiliates, during the Term, an exclusive, sublicensable (in accordance with Section 2.3.1), transferable (to the extent permitted in this Agreement), and royalty-bearing license, under the Licensed Technology, to Develop, Manufacture, and Commercialize the Compound and any Product in the Field within the Licensed Territory.

2.1.2. Subject to the terms and conditions of this Agreement, Licensor (on behalf of itself and its Affiliates) hereby grants to Licensee and its Affiliates, during the Term, an exclusive, sublicensable (in accordance with Section 2.3.1), transferable (to the extent permitted in this Agreement), and royalty-free license, under the Licensed Technology, to Develop, Manufacture, and Commercialize the Biomarker Test in the Field within the Licensed Territory, solely for use with a Product.

2.1.3. Subject to the terms and conditions of this Agreement, Licensor (on behalf of itself and its Affiliates) hereby grants to Licensee and its Affiliates, during the Term, a non-exclusive, sublicensable (in accordance with Section 2.3.1), transferable (to the extent permitted in this Agreement), and royalty-bearing license, under the Licensed Technology, solely to (a) Research and Manufacture the Compound, any Product and the Biomarker Test in the Retained Territory, to support the Development, Manufacture or Commercialization of the Compound, any Product or the Biomarker Test in the Licensed Territory in accordance with the terms of this Agreement, and (b) perform Licensee's obligations under this Agreement.

1.1. License Grants by Licensee.

1.1.1. Subject to the terms and conditions of this Agreement, Licensee (on behalf of itself and its Affiliates) hereby grants to Licensor and its Affiliates, during the Term, an exclusive, sublicensable (in accordance with Section 2.3.2), transferable (to the extent permitted in this Agreement), [***] license, under the Licensee Technology, to Develop, Manufacture, and Commercialize the Compound and any Product in the Field within the Retained Territory.

1.7.1. Subject to the terms and conditions of this Agreement, Licensee (on behalf of itself and its Affiliates) hereby grants to Licensor and its Affiliates, during the Term, an exclusive, sublicensable (in accordance with Section 2.3.2), transferable (to the extent permitted in this Agreement), [***] license, under the Licensee Technology, to Develop, Manufacture, and Commercialize the Biomarker Test in the Field within the Retained Territory, solely for use with a Product.

1.7.2. Subject to the terms and conditions of this Agreement, Licensee (on behalf of itself and its Affiliates) hereby grants to Licensor and its Affiliates, during the Term, a non-exclusive, sublicensable (in accordance with Section 2.3.2), transferable (to the extent permitted in this Agreement), [***] license, under the Licensee Technology, solely to (a) Research and Manufacture the Compound, any Product and the Biomarker Test in the Licensed Territory, to support the Development, Manufacture or Commercialization of the Compound, any Product or the Biomarker Test in the Retained Territory in accordance with the terms of this Agreement, and (b) perform Licensor's obligations under this Agreement.

1.8. Sublicense Rights.

1.8.1. Licensee and each of its Affiliates shall have the right to grant sublicenses under the rights granted under Section 2.1 to any Sublicensees provided, that: (a) each such sublicense agreement will be consistent with the terms and conditions of this Agreement; (b) Licensee will provide Licensor with a true and complete copy of each sublicense agreement with a Sublicensee and each amendment thereto (which sublicense agreement and amendments may be redacted except to the extent necessary for Licensor to determine Licensee's compliance with this Agreement) within [***] days after such sublicense agreement or amendment has been executed; (c) Licensee or its Affiliate will require each Sublicensee to comply with Licensee's obligations under this Agreement applicable to such sublicense and will be responsible and directly liable to Licensor for any failure by any Sublicensee to comply with the terms and conditions of this Agreement; and (d) Licensee will remain responsible for the payment to Licensor of all Milestone Payments and Royalties payable with respect to the activities and Net Sales of any Sublicensee.

1.8.2. Licensor and each of its Affiliates shall have the right to grant sublicenses under the rights granted under Section 2.2 to any Sublicensee; provided, that: (a) each such sublicense agreement will be consistent with the terms and conditions of this Agreement; (b) Licensor will provide Licensee with a true and complete copy of each sublicense agreement with a Sublicensee and each amendment thereto (which sublicense agreement and amendments may be redacted except to the extent necessary for Licensee to determine Licensor's compliance with this Agreement) within [***] days after such sublicense agreement or amendment has been executed; and (c) Licensor or its Affiliate will require each Sublicensee to comply with Licensor's obligations under this Agreement applicable to such sublicense and will be responsible and directly liable to Licensee for any failure by any Sublicensee to comply with the terms and conditions of this Agreement.

1.1. Upstream License Agreements. In the event that, after the Effective Date, Licensor enters into a New Licensed Technology Agreement, which agreement permits Licensor to grant a sublicense thereunder to Licensee as Licensed Technology licensed under this Agreement, then Licensor shall promptly provide Licensee with notice and, to the extent permitted under the New Licensed Technology Agreement, a copy of the applicable agreement (which sublicense agreement may be redacted except to the extent necessary for Licensee to determine its potential rights and obligations in relation to such agreement). [***].

1.9. Transfer of Licensed Materials and Licensed Know-How.

1.1.2. Promptly [***] following the Effective Date, Licensor shall provide the Licensed Materials in existence as of the Effective Date and the Licensed Know-How as set forth in the virtual data room to Licensee. Thereafter, from time to time during the Term, Licensor shall, upon Licensee's request or in accordance with procedures to be established by the JSC, provide to Licensee any Licensed Materials consisting of documents (including Regulatory Filings) and Licensed Know-How which have not yet been provided to Licensee hereunder. Licensed Materials and Licensed Know-How are provided by Licensor on an "as-is" basis without representation or warranty of any type, express or implied, including any representation or warranty of merchantability, non-infringement, title or fitness for a particular purpose, each of which is hereby disclaimed by Licensor, except as specifically set forth in Section 10.2 below. The Parties shall work together through the JSC to establish procedures and timelines for the sharing of data (including clinical data) generated in the Development of the Compound, Products or the Biomarker Test that constitutes Licensed Know-How or Licensed Materials.

1.1.3. Licensee agrees that: (a) it will use Licensed Materials in compliance with all Applicable Laws; and (b) upon termination (but not expiration) of this Agreement for any reason, Licensee will, if and as instructed by Licensor, either destroy or return the Licensed Materials and the Licensed Know-How provided under this Agreement that are not the subject of a continuing license hereunder.

1.1.4. Licensee may transfer Licensed Materials to any Affiliate or Sublicensee under terms obligating such Affiliate or Sublicensee not to use or transfer such Licensed Materials except in compliance with this Agreement.

1.1.5. In the event that, and to the extent that, Applicable Law (including Applicable PRC Law) prevents the transfer of Licensed Know-How (including data associated with clinical trials or individual patients) or Licensed Materials to, or the processing of such Know-How or materials by, Licensee, then the Parties shall negotiate in good faith to put in place arrangements that will allow Licensee to, except to the extent prohibited by Applicable Law, obtain the same rights and economic benefits as it would have been entitled to had such transfer to Licensee been permitted.

1.10. Transfer of Licensee Materials and Licensee Know-How.

1.1.6. From time to time during the Term, Licensee shall, upon Licensor's request or in accordance with procedures to be established by the JSC, provide to Licensor any Licensee Materials consisting of documents (including Regulatory Filings) and Licensee Know-How which have not yet been provided to Licensor hereunder. Licensee Materials and Licensee Know-How are provided by Licensee on an "as-is" basis without representation or warranty of any type, express or implied, including any representation or warranty of merchantability, non-infringement, title or fitness for a particular purpose, each of which is hereby disclaimed by Licensee. The Parties shall work together through the JSC to establish procedures and timelines for the sharing of data (including clinical data) generated in the Development of the Compound, Products or the Biomarker Test that constitutes Licensee Know-How or Licensee Materials.

1.1.7. Licensor agrees that: (a) it will use Licensee Materials in compliance with all Applicable Laws; and (b) upon termination (but not expiration) of this Agreement for any reason, Licensor will, if and as instructed by Licensee, either destroy or return the Licensee Materials and the Licensee Know-How provided under this Agreement that are not the subject of a continuing license hereunder.

1.1.8. Licensor may transfer Licensee Materials to any Affiliate or Sublicensee under terms obligating such Affiliate or Sublicensee not to use or transfer such Licensee Materials except in compliance with this Agreement.

1.1.9. In the event that, and to the extent that, Applicable Law prevents the transfer of Licensee Know-How (including data associated with clinical trials or individual patients) or Licensee Materials to, or the processing of such Know-How or materials by, Licensor, then the Parties shall negotiate in good faith to put in place arrangements that will allow Licensor to, except to the extent prohibited by Applicable Law, obtain the same rights and economic benefits as it would have been entitled to had such transfer to Licensor been permitted.

1.1. Right of First Offer. Within [***] days following the Effective Date, the Parties shall execute an amendment to this Agreement setting forth mutually agreeable and customary terms and conditions for a right of first offer ("**ROFO**") to be granted by each Party to the other Party to obtain an exclusive, sublicensable (through multiple tiers), transferable, and royalty-bearing license under the ROFO Product Technology to Develop, Manufacture, and Commercialize each ROFO Compound and any corresponding ROFO Products in the Field within the other Party's territory (i.e., the Licensed Territory for Licensee and the Retained Territory for Licensor). [***].

1.2. **No Implied Rights.** Except as expressly provided in this Agreement, neither Party will be deemed, by estoppel, implication, or otherwise, to have granted the other Party any license or other right with respect to any Intellectual Property Rights of such Party. Each Party retains all rights under Patent Rights, Know-How, other intellectual property rights, or materials Controlled by such Party that are not expressly granted to the other Party pursuant to this Agreement.

1.3. [***]**.**

1.3.1. [***].

1.3.2. [***].

1.3.3. [***].

1.3. **Retained Rights.**

1.3.1. Notwithstanding the license grants under Section 2.1.3, Licensor expressly retains all rights under the Licensed Technology to (a) Research and Manufacture the Compound, any Product and the Biomarker Test in the Licensed Territory, to support the Development, Manufacture or Commercialization of the Compound, any Product or the Biomarker Test in the Retained Territory in accordance with the terms of this Agreement, and (b) perform Licensor's obligations under this Agreement.

1.3.2. Notwithstanding the license grants under Section 2.2.3, Licensee expressly retains all rights under the Licensee Technology to (a) Research and Manufacture the Compound, any Product and the Biomarker Test in the Retained Territory, to support the Development, Manufacture or Commercialization of the Compound, any Product or the Biomarker Test in the Licensed Territory in accordance with the terms of this Agreement, and (b) perform Licensee's obligations under this Agreement.

3. DEVELOPMENT; MANUFACTURE; COMMERCIALIZATION; COMPANION DIAGNOSTIC.

3.1. **General.** From and after the Effective Date, as between the Parties and subject to Section 3.2.1, Section 3.5, Section 3.6, Section 3.9 and Article 4, Licensee, itself or with and through its Affiliates, Sublicensees, and other Third Parties, will have sole authority over, responsibility for, and control of the Development, Manufacture, and Commercialization of the Compound, Products and Biomarker Test in the Field in the Licensed Territory, and will bear all costs associated with such Development, Manufacture, and Commercialization. From and after the Effective Date, as between the Parties and subject to Section 3.5, Section 3.9 and Article 4, Licensor, itself or with and through its Affiliates, Sublicensees, and other Third Parties, will have sole authority over, responsibility for, and control of the Development, Manufacture, and Commercialization of the Compound, Products and Biomarker Test in the Field in the Retained Territory, and will bear all costs associated with such Development, Manufacture, and Commercialization.

3.2. **Development.**

1.3.3. **Development Diligence.** Licensee will use Commercially Reasonable Efforts to clinically Develop at least one (1) Product and obtain Regulatory Approval for at least one (1) Product in the Licensed Territory. For clarity, any actions taken by Licensee's Affiliates, Sublicensees, or other Third Parties under this Agreement performing obligations on behalf of Licensee will be treated as actions taken by Licensee with

respect to satisfaction of the requirements of this Section 3.2.1.

3.2.1. **Development Plan; Responsibility.** Within [***] days after the Effective Date, Licensee will provide Licensor its development plan for Development of the Product and Biomarker Test, to the extent applicable, in the Licensed Territory (the "**Licensee Development Plan**"). The Parties shall thereafter, through the JSC, discuss the Licensee Development Plan and Licensee shall consider [***] any comments from Licensor with respect thereto, including with respect to the activities and timelines in the Licensee Development Plan. At least [***] days prior to the end of each Calendar Year during the Term when Development activities of Products or the Biomarker Test are ongoing, or from time to time if a material amendment to the Licensee Development Plan is required, Licensee shall provide the JSC an updated version of the Licensee Development Plan.

3.2.2. **Development Reporting.** On a [***] basis until the JSC has been disbanded in accordance with Section 4.1.8, Licensee will provide the JSC with a [***] written report that summarizes Licensee's, its Affiliates, and Sublicensees' [***] efforts and achievements with respect to the Development of Products and the Biomarker Test in the Field in the Licensed Territory, which report will identify the applications for Regulatory Approval that Licensee or its Affiliates or Sublicensees have filed, sought, or attempted to obtain in the prior [***]-month period, and any that they reasonably expect to file, seek, or attempt to obtain in the following [***]-month period. On a [***] basis until the JSC has been disbanded in accordance with Section 4.1.8, Licensor will keep the JSC [***] apprised of its material efforts and achievements with respect to the Development of Products and the Biomarker Test in the Field in the Retained Territory, which appraisal will identify the applications for Regulatory Approval that Licensee or its Affiliates or Sublicensees have filed, sought, or attempted to obtain in the prior [***]-month period, and any that they reasonably expect to file, seek, or attempt to obtain in the following [***]-month period.

1.1. **Regulatory Matters.**

1.1.1. **Responsibility.** Subject to the terms and conditions of this Agreement (including Article 4), (a) Licensor will have the sole and exclusive right, in its sole discretion and at its sole expense, itself or with or through its Affiliates, Sublicensees or other Third Parties, to: (i) prepare and submit to applicable Regulatory Authorities all Regulatory Materials (including BLAs, new drug applications and INDs) for the Products and Biomarker Test in the Retained Territory, and (ii) obtain and maintain all Regulatory Approvals for the Products and Biomarker Test in the Retained Territory; and (b) Licensee will have the sole and exclusive right, in its sole discretion and at its sole expense, itself or with or through its Affiliates, Sublicensees or other Third Parties, to: (i) prepare and submit to applicable Regulatory Authorities all Regulatory Materials (including BLAs, new drug applications and INDs) for the Products and Biomarker Test in the Licensed Territory, and (ii) obtain and maintain all Regulatory Approvals for the Products and Biomarker Test in the Licensed Territory. Additionally, each Party shall promptly notify the JSC in writing, including a brief description in English of the principal issues raised, of all material communications from Regulatory Authorities regarding Products or the Biomarker Test.

1.1.2. **Communications with Regulatory Authorities.** For clarity and without limiting Section 3.3.1, each Party will have the exclusive right to correspond or communicate with Regulatory Authorities regarding the Products and the Biomarker Test in its respective territory (i.e., for Licensor, the Retained Territory, and for Licensee, the Licensed Territory). Unless required by Applicable Law, each Party, its Affiliates, its Sublicensees, and its permitted subcontractors will not correspond or communicate with Regulatory Authorities having jurisdiction in the other Party's respective territory regarding any Product or the Biomarker Test without first obtaining the other Party's prior written consent. At the invitation of Licensor, Licensee shall have the right to attend and observe (but not participate in) all substantive meetings or discussions with any Regulatory Authorities in the Retained Territory relating to a Product or the Biomarker Test to the extent that such meetings or discussions could be reasonably expected to have a material effect on the Development or Commercialization of Products or the Biomarker Test in the Licensed Territory. At the invitation of Licensee, Licensor shall have the right to attend and observe (but not participate in) all substantive meetings or discussions with any Regulatory Authorities in the Licensed Territory relating to a Product or the Biomarker Test to the extent that such meetings or discussions could be reasonably expected to have a material effect on the Development or Commercialization of Products or the Biomarker Test in the Retained Territory.

1.1.3. **Right of Reference.** Each Party and its Affiliates and Sublicensees (the "**Requesting Party**") will have, and the other Party (on behalf of itself and its Affiliates) hereby grants to the Requesting Party, access and a right of reference (without any further action required on the part of the Requesting Party, whose authorization to file this consent with any Regulatory Authority is hereby granted) to any and all Regulatory Materials concerning each Product or the Biomarker Test Controlled by such Party, and all data contained or referenced in all such Regulatory Materials, for the Requesting Party to exercise its rights and perform its obligations under this Agreement. In all cases, each Party will ensure that the Requesting Party is afforded access to all such Regulatory Materials and all data contained or referenced in all such Regulatory Materials, including by providing copies thereof to the Requesting Party in a mutually agreed format.

1.3.4. Review and Comment.

(a) Licensee shall promptly share with Licensor any material correspondence received from a Regulatory Authority with respect to any Product or the Biomarker Test in the Field in the Licensed Territory, and any related Regulatory Materials, in each case, that could be reasonably expected to have a material effect on the Development or Commercialization of Products or the Biomarker Test in the Retained Territory. With respect to any proposed submissions to, or filing with, any Regulatory Authority relating to any Product or the Biomarker Test in the Field in the Licensed Territory, Licensee shall provide such proposed submission or filing to Licensor reasonably in advance of submission or filing and consider [***] any comments provided by Licensor with respect thereto; provided that Licensee may take such steps as it reasonably considers necessary where urgent or emergency action is required with respect to a relevant submission or filing. In the event of a disagreement between the Parties with respect to such comments and any proposed revisions, such disagreement shall be referred to the JSC for resolution in accordance with Section 4.1.6. Licensee will keep Licensor reasonably informed of the status of all material Regulatory Materials (including the status of its preparation, review by any Regulatory Authority and granting of any Regulatory Approvals) relating to any Product or the Biomarker Test in the Field in the Licensed Territory. Without limiting the foregoing, unless otherwise agreed by the Parties in writing, Licensee will provide Licensor with electronic copies of all final Regulatory Materials submitted by it or any of its Affiliates or Sublicensees to a Regulatory Authority relating to any Product or the Biomarker Test within [***] Business Days after submission.

(b) Licensor shall promptly share with Licensee any material correspondence received from a Regulatory Authority with respect to any Product or the Biomarker Test in the Field in the Retained Territory, and any related Regulatory Materials, in each case, that could be reasonably expected to have a material effect on the Development or Commercialization of Products or the Biomarker Test in the Licensed Territory. With respect to any proposed submissions to, or filing with, any Regulatory Authority relating to any Product or the Biomarker Test in the Field in the Retained Territory, Licensor shall provide such proposed submission or filing to Licensee reasonably in advance of submission or filing and consider [***] any comments provided by Licensee with respect thereto; provided that Licensor may take such steps as it reasonably considers necessary where urgent or emergency action is required with respect to a relevant submission or filing. In the event of a disagreement between the Parties with respect to such comments and any proposed revisions, such disagreement shall be referred to the JSC for resolution in accordance with Section 4.1.6. Licensor will keep Licensee reasonably informed of the status of all material Regulatory Materials (including the status of its preparation, review by any Regulatory Authority and granting of any Regulatory Approvals) relating to any Product or the Biomarker Test in the Field in the Retained Territory. Without limiting the foregoing, unless otherwise agreed by the Parties in writing, Licensor will provide Licensee with electronic copies of all final Regulatory Materials submitted by it or any of its Affiliates or Sublicensees to a Regulatory Authority relating to any Product or the Biomarker Test within [***] Business Days after submission.

1.2. **Complaints; Adverse Event Reporting Procedures.** Each Party will maintain a record of any and all complaints it receives with respect to each Product and the Biomarker Test. Each Party will notify the other Party in reasonable detail of any complaint received by it with respect to each Product or the Biomarker Test within sufficient time to allow the other Party to comply with any and all Applicable Law in any jurisdiction in which each Product or the Biomarker Test is being marketed or tested in clinical trials. Licensee will maintain a global adverse event database for each Product and the Biomarker Test, at its cost and expense, and Licensor will have access thereto. Each Party will provide the other Party with all adverse event information and safety data relating to each Product or Biomarker Test in its control within sufficient time to allow the other Party to comply with any and all Applicable Law in any jurisdiction in which each Product or the Biomarker Test is being marketed or tested in clinical trials. Following entry into the Pharmacovigilance Agreement, each Party will report to the other Party the details around any adverse events and serious adverse events relating to each Product or Biomarker Test in its control within the time periods for such reporting as specified in the Pharmacovigilance Agreement. Each Party shall be responsible, at its own expense, for submitting adverse event reports with respect to a Product and the Biomarker Test to the applicable Regulatory Authorities in its respective territory. Within [***] after the Effective Date, the Parties will develop and agree in writing upon a pharmacovigilance agreement ("**Pharmacovigilance Agreement**") that will include safety data exchange procedures governing the coordination of collection, investigation, reporting, and exchange of information concerning any adverse experiences, and any product quality and product complaints involving adverse experiences, related to each Product and the Biomarker Test, sufficient to enable each Party to comply with its respective legal and regulatory obligations. The Pharmacovigilance Agreement may supersede the reporting provisions of this Section 3.4.

1.4. **Manufacturing.**

1.4.1. Upon execution of the Clinical Supply Agreement, notwithstanding the provisions of Section 2.2 and Section 2.10 (but subject to the terms of the Clinical Supply Agreement), as between the Parties, Licensee shall have the first and primary right to have Manufactured by a Third Party contract manufacturer the Compound and Products for Development in the Field within the Licensed Territory and the Retained Territory. Within [***] days after the Effective Date (or such later date mutually agreed by the Parties based on timing of identification of a Third Party contract manufacturer meeting the requirements set forth in this Section 3.5.1), the Parties shall negotiate in good faith the terms and conditions of a clinical supply agreement and corresponding quality agreement on customary terms, pursuant to which Licensee would Manufacture and supply, itself or through an Affiliate or one (1) or more Third Party contract manufacturers, the Compound and Products to Licensor to support Licensor's Development of the Compound and Products in the Field in the Retained Territory (the "**Clinical Supply Agreement**"). [***].

1.4.2. Upon execution of the Commercial Supply Agreement, notwithstanding the provisions of Section 2.2 and Section 2.10 (but subject to the terms of the Commercial Supply Agreement), as between the Parties, Licensee shall have the first and primary right to have Manufactured by a Third Party contract manufacturer any Compound and Product for Commercialization in the Field within the Licensed Territory and the Retained Territory. Upon the request of either Party following Licensee's finalization of arrangements for the commercial manufacture of the Compound and Products, the Parties shall negotiate in good faith the terms and conditions of a commercial supply agreement and corresponding quality agreement on customary terms, pursuant to which Licensee would Manufacture and supply, itself or through an Affiliate or one (1) or more Third Party contract manufacturers, the Compound and Products to Licensor to support Licensor's Commercialization of the Compound and Products in the Field in the Retained Territory (the "**Commercial Supply Agreement**"). [***].

1.2.1. Licensee may, at any time during the Term, notify Licensor that Licensee desires Licensor to procure its own supply of Compound and Products for use in the Retained Territory, and if Licensee makes such notification, the Parties shall cooperate in good faith to agree upon a process and timeline for, and to conduct, a technology transfer [***] of the manufacturing process for the Compound and Products to Licensor or its designee. [***].

1.3. **Commercialization Diligence.** Licensee will use Commercially Reasonable Efforts to Commercialize at least one (1) Product in the Licensed Territory following Licensee's or its designated Affiliate's or Sublicensee's receipt of Regulatory Approval for such Product in the Licensed Territory.

1.4. **Commercialization Plan and Reports**. [***], Licensee shall submit a high-level commercialization plan to the JSC or Licensor (after disbandment of the JSC) for review, including [***]. With respect to each Product, [***], at least once each [***], Licensee shall provide the JSC or Licensor (after disbandment of the JSC) a high-level summary of its Commercialization activities with respect to such Product conducted since the last such summary was provided hereunder (or since Licensee commenced its Commercialization activities hereunder with respect to the first such report).

1.5. **Licensor Assistance.** Licensor shall provide reasonable assistance to Licensee, at Licensee's cost and as Licensee may reasonably request, for the Development, Manufacture, and Commercialization of Compounds and Products in the Field in the Licensed Territory, subject to reasonable limitations to be determined by the JSC.

1.6. **Biomarker Test.** The Parties intend to collaborate on the development of the Biomarker Test and plan to engage in good faith negotiation in the future to execute a collaboration agreement on such development. [***].

1. GOVERNANCE.

1.11. Joint Steering Committee.

1.1.10. **Establishment; Responsibilities**. Within [***] days after the Effective Date, the Parties shall establish a joint steering committee (the "**JSC**") as more fully described in this Section 4.1.

1.1.11. **Representatives.** The JSC shall be comprised of [***] representatives (or such other number of representatives as the Parties may mutually agree) from each of Licensor and Licensee. Each representative of a Party shall have sufficient seniority and expertise to participate on the JSC as determined in such Party's reasonable judgment. Licensee shall have the right to designate the chairperson of the JSC. Each Party may replace any or all of its representatives on the JSC at any time upon written notice to the other Party. Each Party may, upon receiving the other Party's prior written consent (not to be unreasonably withheld, conditioned, or delayed), invite non-JSC representatives of such Party and any Third Party to attend meetings of the JSC; provided, that any such non-JSC representative or Third Party is bound by obligations of confidentiality, non-disclosure, and non-use no less restrictive than those set forth in Article 9 prior to attending any such meeting.

1.1.12. **JSC Responsibilities**. Subject to this Section 4.1, the JSC's responsibilities are as follows:

(a) Discuss and coordinate activities with respect to the particular therapeutic indications for which the Products and the Biomarker Test will be Developed and Commercialized;

(b) Develop, review and coordinate activities conducted under, the Licensee Development Plan, and modifications thereto;

(c) Review the Development activities of the Product(s) and Biomarker Test conducted by each Party and its respective Affiliates and Sublicensees in their respective territories;

(d) Coordinate pharmacovigilance activities in connection with the Products and Biomarker Test;

(e) Coordinate the development of a strategy for cost effective production of the Product for Development and Commercialization both inside and outside the Licensed Territory; and

(f) Fulfill such other responsibilities as may be allocated to the JSC under this Agreement or by mutual written agreement of the Parties.

1.1.13. **Meetings.** [***]. After the first scheduled meeting of the JSC until the time at which the JSC is disbanded in accordance with Section 4.1.8, the JSC shall meet by videoconference or other electronic means at least [***], or more or less frequently as the Parties agree, on such dates and at such places and times as provided herein or as the Parties shall agree. The representatives of the JSC may also convene or be consulted from time to time by means of telecommunications, video conferences, electronic mail, or correspondence, in each case, as deemed necessary or appropriate. Each Party shall bear all costs and expenses it incurs in connection with participating in all meetings of the JSC, including all travel expenses.

1.1.14. **Minutes.** Licensee shall be responsible for preparing and circulating minutes of each meeting of the JSC, setting forth, *inter alia*, an overview of the discussions at the meeting. A draft of such minutes shall be circulated by Licensee to all representatives of the JSC within [***] days after the applicable meeting. Such minutes shall be effective only after such minutes have been approved by both Parties in writing. Definitive minutes of all JSC meetings shall be finalized no later than [***] days after the meeting to which the minutes pertain.

1.1.15. **Final Decision-Making Authority.** In all matters under the JSC's responsibilities, the JSC will strive to make decisions by consensus. If the JSC cannot reach consensus on any matter within [***] days of such matter being brought to the JSC's attention, then [***].

1.1.16. **Limitation of JSC Authority.** For clarity and notwithstanding the creation of the JSC, (a) each Party will retain the rights, powers and discretion granted to it hereunder, and neither the JSC nor any member of the JSC will be delegated or vested with such rights, powers or discretion, and (b) the JSC shall have no authority to make decisions that bind the Parties except as provided in Section 4.1.6. Neither the JSC nor any member of the JSC will have the power to amend, waive or modify any term of this Agreement.

1.1.17. **Disbanding.** The JSC shall be disbanded upon [***].

1.12. **Sub-Committees.** The JSC may, at any time that it deems necessary or appropriate, establish joint sub-committees and delegate such of its responsibilities as it determines appropriate to such joint sub-committees.

1.13. **Alliance Managers**. Each Party shall appoint a person(s) who shall oversee contact between the Parties for all matters between meetings of the JSC, shall be the primary contacts between the Parties after disbandment of the JSC, and shall have such other responsibilities as the Parties may agree in writing after the Effective Date, which person(s) may be replaced at any time by notice in writing to the other Party (each such person, an "**Alliance Manager**"). The Alliance Managers shall work together to manage and facilitate the communication between the Parties under this Agreement, including the resolution (in accordance with the terms of this Agreement) of issues between the Parties that arise in connection with this Agreement. The Alliance Managers shall not have final decision-making authority with respect to any matter under this Agreement.

2. PAYMENT TERMS.

1.14. **Upfront Payment.** As partial consideration for the licenses and rights granted to Licensee hereunder, within [***] days after the Effective Date, Licensee shall pay to Licensor a one-time non-refundable non-creditable upfront payment in the amount of ten million dollars ($10,000,000) in immediately available funds.

1.15. **Milestone Payments.**

1.1.18. Subject to this Section 5.2, in further consideration of the licenses and rights granted to Licensee hereunder, upon the first achievement by Licensee, any of its Affiliates, or any Sublicensee of each of the milestone events set forth in the table below (each, a "**Milestone**"), the corresponding one (1)-time milestone payment (each, a "**Milestone Payment**") shall be payable by Licensee to Licensor:

MILESTONE	MILESTONE PAYMENT
[***]	[***]
[***]	[***]
[***]	[***]
[***]	[***]
[***]	[***]
[***]	[***]
[***]	[***]
[***]	[***]
[***]	[***]
[***]	[***]
[***]	[***]
[***]	[***]

[***].

1.1.19. [***]. For clarity: [***] the aggregate total of all Milestone Payments shall not exceed Two Hundred Twenty Two Million Five Hundred Thousand Dollars ($222,500,000).

1.1.20. Licensee shall provide Licensor with written notice of the achievement of each Milestone within [***] days after such Milestone is achieved by Licensee, any of its Affiliates, or a Sublicensee. After receipt of a notice of the achievement of a Milestone, Licensor shall submit an invoice to Licensee with respect to the corresponding Milestone Payment. Licensee shall make such Milestone Payment within [***] days after receipt of such invoice.

1.16. **Royalty Payments**. Subject to this Section 5.3 and Section 5.4, in further consideration of the licenses and rights granted to Licensee hereunder, Licensee will pay Licensor royalties in the amount of the applicable rates ("**Marginal Royalty Rates**") set forth below of Annual Net Sales during the Royalty Term (collectively, "**Royalties**"):

PORTION OF ANNUAL NET SALES	MARGINAL ROYALTY RATE
[***]	[***]
[***]	[***]
[***]	[***]
[***]	[***]
[***]	[***]
[***]	[***]

Each Marginal Royalty Rate set forth above will apply only to that portion of the Annual Net Sales during a given Calendar Year that falls within the indicated range.

1.16. Royalty Adjustments.

1.1.1. [***].

1.1.1. [***].

1.1.2. [***].

1.1.3. [***].

1.1. Net Sales Reports. Commencing with the Calendar Quarter during which the First Commercial Sale of a Product is made anywhere in the Field in the Licensed Territory, Licensee will provide Licensor with Net Sales reports as follows:

1.1.1. [***].

1.1.2. Within [***] days after the end of each Calendar Quarter, Licensee will deliver to Licensor a written report setting forth for such Calendar Quarter the following information, on a Product-by-Product and country-by-country or jurisdiction-by-jurisdiction basis: [***]. The total Royalty due for the sale of Products during such Calendar Quarter will be remitted [***].

1.2. Cumulative Royalties. The obligation to pay Royalties under Section 5.3 will be imposed only once with respect to a single unit of a Product regardless of how many Valid Claims in the Licensed Patent Rights would, but for this Agreement, be infringed by the use or sale of such Product in the country or jurisdiction in which such Product is used or sold.

1.3. Licensing Revenue Payments.

1.3.1. In further consideration of the licenses and rights granted to Licensee hereunder, Licensee shall pay to Licensor the percentages set forth below of all Licensing Revenue received from any Third Party.

[***]	[***]
[***]	[***]
[***]	[***]

1.3.2. Licensee shall make Licensing Revenue payments based on Licensing Revenue received during each Calendar Quarter within [***] days following the end of each such Calendar Quarter. All payments shall be accompanied by a report that includes a calculation of all Licensing Revenue payments payable to Licensor for the applicable Calendar Quarter and the Product subject to such sublicense.

1.4. **Late Payments**. Subject to the other terms of this Agreement, any payments hereunder not paid within the applicable time period set forth herein will bear interest from the due date until paid in full, at a rate per annum equal to [***]. Such payments when made will be accompanied by all interest so accrued. Such interest and the payment and acceptance thereof will not negate or waive the right of Licensor to any other remedy, legal or equitable, to which it may be entitled because of the delinquency of the payment.

1.5. **Currency**. Any payments under this Article 5 that are recorded in currencies other than the United States Dollar will be converted into United States Dollars at the average of the daily foreign exchange rates published in the *Wall Street Journal* (or any other qualified source that is acceptable to both Parties) for the Calendar Quarter in which such payments or expenses occurred, or for periods less than a Calendar Quarter, the average of the daily rates published in the *Wall Street Journal* for such period.

1.5. Taxes.

1.5.1. The Milestone Payments, payments of Royalties and Licensing Revenue payments payable by Licensee to Licensor pursuant to this Agreement (each, a "**Payment**") will be made subject to and reduced by any required taxes, duties, levies, fees, or charges. If Licensor is entitled under applicable tax law, including any applicable tax treaty, to a reduction of the rate of, or exemption from, applicable withholding tax, Licensor and the Licensee shall cooperate in obtaining such reduction or exemption, including the delivery of any statement or certification by Licensor to Licensee or the appropriate governmental authority required for that purpose. Upon request by Licensor, Licensee shall provide any reasonable assistance to Licensor that is required for obtaining such reduction or exemption or preparing or delivering such statement or certification. If Licensee withholds any amount of tax in connection with any Payment, Licensee shall timely remit the withheld amount to the proper taxing authority and send to Licensor proof of such payment within [***] days following such payment. Licensor shall furnish to Licensee a properly completed and validly executed Internal Revenue Service Form W-9.

1.5.2. Except as otherwise provided in this Section 5.10, each of Licensee and Licensor shall be solely responsible for its own tax liability levied on account of, or measured in whole or in part by reference to, any Payments it receives. Any information provided by one Party to the other Party in connection with tax pursuant to this Section 5.10 shall be treated as Confidential Information under this Agreement; provided that each Party shall be entitled to disclose such information to the extent required by any applicable tax law or as conducive to the conduct of any tax contest or administrative or judicial proceeding in relation to the taxes described in Section 5.10.1 with any taxing authority, as determined in the reasonable discretion of such Party or its tax advisors.

1. REPORTING; RECORDS; AUDIT RIGHTS.

1.17. Relevant Records. Licensee will keep and maintain, and require its Affiliates and Sublicensees to keep and maintain, accurate books of account and records in connection with the sale of Products, in sufficient detail to permit accurate determination of all figures necessary for verification of payments to be paid hereunder consistent with GAAP, including any records required to calculate any Royalty adjustments hereunder ("**Relevant Records**"). Licensee will maintain, and require its Affiliates and Sublicensees to maintain, such records for a period of [***].

1.18. Audit; Fees and Expenses.

1.18.1. Upon [***] days' prior written notice from Licensor, Licensee will permit an independent certified public accounting firm of internationally recognized standing selected by Licensor and reasonably acceptable to Licensee (an "**Auditor**") to examine, at Licensor's sole expense, the Relevant Records of Licensee, its Affiliates, and Sublicensees during the period covered by such examination, as may be reasonably necessary to verify the accuracy of the reports submitted by Licensee in accordance with Article 5 and the payment of amounts hereunder. An examination by Auditor under this Section 6.2 will occur not more than [***] and will be limited to [***]. The Auditor will be provided access to such books and records at the facilities where such books and records are kept and such examination will be conducted during normal business hours. Licensee may require the Auditor and its personnel involved in such audit to sign a reasonable and customary non-disclosure agreement as to any confidential information which is to be provided to such Auditor or to which such Auditor will have access while conducting the audit under this Section 6.2 before providing the Auditor access to Licensee's facilities or records.

1.18.2. Upon completion of the audit, the Auditor will provide both Licensor and Licensee a written report disclosing solely whether the reports submitted by Licensee are correct or incorrect, whether the amounts paid are correct or incorrect, and, in each case, the specific details concerning any discrepancies. Such Auditor may not reveal to Licensor any information learned in the course of such audit other than the amount of any such discrepancies. [***].

1.19. Payment of Deficiency. If an Auditor concludes that additional amounts were due to Licensor, Licensee will pay the additional amounts ([***]) within [***] days of the date Licensee receives such Auditor's written report so concluding. If such underpayment exceeds [***] of the amounts that were to be paid, Licensee also will reimburse Licensor for all reasonable charges of such Auditor for conducting the audit. If such Auditor concludes that Licensee overpaid amounts, Licensor will repay such amount in full within [***] days of the receipt of such Auditor's report.

3. INTELLECTUAL PROPERTY RIGHTS.

1.17. Ownership of Pre-Existing IP. Subject only to the rights expressly granted to the other Party under this Agreement, each Party will retain all rights, title, and interests in and to any Intellectual Property Rights that are Controlled by such Party: (a) prior to the Effective Date; or (b) independent of this Agreement.

1.18. **Ownership of Foreground IP**. Subject to the license grants and other rights herein, as between the Parties, each Party (including through or by its Affiliates) shall own and retain all right, title and interest in and to any and all Intellectual Property Rights that are conceived, developed, generated or otherwise made solely by or on behalf of such Party or its Affiliates or its or their Sublicensees under or in connection with this Agreement, whether or not patented or patentable. For clarity, and for the purpose of this Article 7, Licensee, its Affiliates and its and their Sublicensees shall not be considered a Sublicensee of Licensor or its Affiliates, and Licensor, its Affiliates and its and their Sublicensees shall not be considered a Sublicensee of Licensee or its Affiliates.

1.19. **Disclosure.** Each Party shall promptly disclose to the other Party in writing the conception, development, generation or other making by or on behalf of such first Party or any of its Affiliates or Sublicensees of any potentially patentable invention under or in connection with this Agreement.

1.20. **United States Law.** The determination of whether any Intellectual Property Rights is conceived, developed, generated or otherwise made by or on behalf of a Party or its Affiliates under or in connection with this Agreement shall, for purposes of this Agreement, be made in accordance with Applicable Law in the United States (including United States patent laws) irrespective of where such conception, development, generation or other making occurs.

1.21. **Patent Prosecution.**

1.1.2. **First Right.** As between the Parties, (a) with respect to the Licensed Territory, Licensee, or (b) with respect to the Retained Territory, Licensor, will have the first right to Prosecute and Maintain the Licensed Patent Rights and Licensee Foreground Patent Rights (each such Party, a "**Prosecuting Party**"). The Prosecuting Party shall keep the Non-Prosecuting Party reasonably informed of the status of the Licensed Patent Rights and Licensee Foreground Patent Rights in its respective territory and, prior to making any material filings or submissions to any governmental authority with respect to any Licensed Patent Right or Licensee Foreground Patent Right, shall provide a copy thereof to the Non-Prosecuting Party for its review and comment. The Prosecuting Party shall: (a) provide the Non-Prosecuting Party with a reasonable opportunity to comment substantively on the Prosecution and Maintenance with respect to the Licensed Patent Rights and Licensee Foreground Patent Rights in the Prosecuting Party's respective territory before taking material action; and (b) incorporate into the relevant filing or submission all reasonable comments provided by the Non-Prosecuting Party.

1.1.1. **Back-Up Right.** Licensee will provide Licensor with written notice in the event that Licensee has decided to abandon any Licensed Patent Rights or Licensee Foreground Patent Right in the Licensed Territory, which notice shall be provided reasonably in advance of any applicable deadline. In such event, Licensor may, by written notice to Licensee, elect to continue the Prosecution and Maintenance of such Patent Right in the Licensed Territory at Licensor's sole expense, and with respect to any Licensed Patent Right Licensor elects to continue Prosecution and Maintenance thereof, such Patent Right will no longer be within the Licensed Patent Rights for the purposes of this Agreement following Licensee's receipt of Licensor's written notice indicating such election. Licensor will provide Licensee with written notice in the event Licensor has decided to abandon any Licensee Foreground Patent Right in the Retained Territory, which notice shall be provided reasonably in advance of any applicable deadline. In such event, Licensee may, by written notice to Licensor, elect to continue the Prosecution and Maintenance of such Patent Right in the Retained Territory at Licensee's sole expense.

1.1.2. **Costs.** Each Party will be solely responsible for all costs and expenses it incurred following the Effective Date with respect to its Prosecution and Maintenance relating to the Licensed Patent Rights and Licensee Foreground Patent Rights.

4. INFRINGEMENT; MISAPPROPRIATION.

1.20. **Notification.** Each Party will promptly notify the other Party in writing of any actual or threatened infringement, misappropriation, other violation or challenge to the validity, scope, or enforceability by a Third Party of any Licensed Technology or Licensee Technology in the Field (but, with respect to Licensed Patent Rights and Licensee Patent Rights, solely to the extent such rights Cover any Compound, Product, or the Development, Manufacture, Commercialization, or other use of any Compound or Product) of which it becomes aware ("**Third Party Infringement**").

1.21. **Infringement Action.**

1.1.21. **Right of Enforcement.**

(a) Licensee will have the first right (but not the obligation), at its own expense, to control enforcement of the Licensed Patent Rights and Licensee Patent Rights against any Third Party Infringement in the Field in the Licensed Territory. Licensor shall, if requested by Licensee, join Licensee as a party for standing purposes (at Licensee's expense); provided, that if Licensor is represented by independent counsel in such action (as determined by Licensor in its sole discretion), each Party will bear the expense of its own counsel. Prior to commencing any such action, Licensee will consult with Licensor and will give due consideration to Licensor's recommendations regarding the proposed action. Licensee will give Licensor timely notice of any proposed settlement of any such action instituted by Licensee and will not, without the prior written consent of Licensor, enter into any settlement that would: (i) adversely affect the validity, enforceability, or scope of any of the Licensed Patent Rights or Licensee Patent Rights; (ii) give rise to liability of Licensor or any of its Affiliates; or (iii) otherwise impair Licensor's rights in any Licensed Technology, Licensee Technology or this Agreement.

(a) If Licensee does not, with respect to its first right of enforcement under Section 8.2.1(a), obtain agreement from the alleged infringer to desist or fails or refuses to initiate an infringement action by the earlier of: (i) [***] days following Licensee's receipt of notice of the alleged infringement; or (ii) [***] days before the expiration date for filing such actions, then Licensor will have the right, but not the obligation, at its sole discretion and expense, to control such enforcement of the Licensed Patent Rights or Licensee Patent Rights and may, at its expense, join Licensee as a party for standing purposes; provided, that if Licensee is represented by independent counsel in such action, each Party will bear the expense of its own counsel. Prior to commencing any such action, Licensor will consult with Licensee and will give due consideration to Licensee's recommendations regarding the proposed action. Licensor will give Licensee timely notice of any proposed settlement of any such action instituted by Licensor and will not, without the prior written consent of Licensee, enter into any settlement that would: (i) adversely affect the validity, enforceability, or scope of any claim within the Licensed Patent Rights or Licensee Patent Rights which Covers any Compound or Product, or the Development, Manufacture, or Commercialization, or other use thereof, in the Field in the Licensed Territory; (ii) give rise to liability of Licensee or any of its Affiliates or Sublicensees; (iii) admit non-infringement of any claim within the Licensed Patent Rights or Licensee Patent Rights which Covers any Compound or Product in the Field in the Licensed Territory; or (iv) otherwise impair Licensee's, any of its Affiliates', or any Sublicensee's rights in any Licensed Technology, Licensee Technology or this Agreement.

(b) Licensor will have the first right (but not the obligation), at its own expense, to control enforcement of the Licensed Patent Rights and Licensee Patent Rights against any Third Party Infringement in the Field in the Retained Territory. Licensee shall, if requested by Licensor, join Licensor as a party for standing purposes (at Licensor's expense); provided, that if Licensee is represented by independent counsel in such action (as determined by Licensee in its sole discretion), each Party will bear the expense of its own counsel. Prior to commencing any such action, Licensor will consult with Licensee and will give due consideration to Licensee's recommendations regarding the proposed action. Licensor will give Licensee timely notice of any proposed settlement of any such action instituted by Licensor and will not, without the prior written consent of Licensee, enter into any settlement that would: (i) adversely affect the validity, enforceability, or scope of any of the Licensed Patent Rights or Licensee Patent Rights; (ii) give rise to liability of Licensee or any of its Affiliates; or (iii) otherwise impair Licensee's rights in any Licensed Technology, Licensee Technology or this Agreement.

1.1.22. **Recoveries.** Any recoveries resulting from an action relating to a claim of Third Party Infringement in the Field in the Licensed Territory will first be applied to reimburse each Party's costs and expenses incurred in connection therewith. Any remaining recoveries will be retained by (or, to the extent received by Licensor, paid to) Licensee; provided, however, that such remaining recoveries will be apportioned [***]. Notwithstanding the foregoing, if Licensee fails to institute an action or proceeding and Licensor exercises its right to prosecute such infringement pursuant to Section 8.2.1(b), any remaining recoveries will be apportioned [***], resulting from an action brought by Licensor relating to any other claim of Third Party Infringement. Notwithstanding the foregoing in this Section 8.2.2, Licensor would retain [***] of any recoveries solely attributable to a claim of Third Party Infringement in the Retained Territory.

5. CONFIDENTIALITY.

1.22. **Obligations.** Except to the extent expressly authorized by this Agreement, the Parties agree that, during the Term and for [***] years thereafter, each Party, in its capacity as the Receiving Party, will: (a) keep the Disclosing Party's Confidential Information confidential; (b) not disclose, or permit the disclosure of, the Disclosing Party's Confidential Information; and (c) not use, or permit to be used, the Disclosing Party's Confidential Information for any purpose, in each case, except for the performance of its obligations or exercise of its rights under this Agreement; provided, however, that the foregoing obligations will not apply, or will cease to apply, to any Confidential Information to the extent that such information, as demonstrated by documentary evidence: (a) was already known by the Receiving Party (other than under an obligation of confidentiality to the Disclosing Party) at the time of disclosure by the Disclosing Party; (b) was generally available to the public or otherwise part of the public domain at the time of its disclosure to the Receiving Party; (c) became generally available to the public or otherwise part of the public domain after its disclosure to the Receiving Party, other than through any act or omission of the Receiving Party or any of its Representatives in breach of its obligations under this Agreement; (d) was disclosed to the Receiving Party, other than under an obligation of confidentiality, by a Third Party who had no obligation to the Disclosing Party not to disclose such information to the Receiving Party; or (e) was independently developed by or on behalf of the Receiving Party without reference to or reliance upon any Confidential Information of the Disclosing Party.

1.23. **Exceptions.**

1.1.3. **Disclosure to Party Representatives**. Notwithstanding the foregoing provisions of Section 9.1, the Receiving Party may disclose Confidential Information belonging to the Disclosing Party to the Receiving Party's Representatives who: (a) have a need to know such Confidential Information in connection with the performance of the Receiving Party's obligations or the exercise of the Receiving Party's rights under this Agreement; and (b) have agreed in writing to non-disclosure and non-use provisions with respect to such Confidential Information that are at least as restrictive as those set forth in this Article 9.

1.1.4. **Disclosure to Third Parties**.

(a) Notwithstanding the foregoing in Section 9.1, a Receiving Party may disclose the Disclosing Party's Confidential Information without obtaining the prior written consent of the Disclosing Party:

(i) to governmental authorities to the extent reasonably necessary to obtain or maintain INDs or Regulatory Approvals for any Compound, Product or Biomarker Test and in order to respond to inquiries, requests, investigations, orders, or subpoenas of governmental authorities relating to this Agreement;

(i) to the extent reasonably necessary in connection with Prosecution and Maintenance or prosecuting or defending litigation, in each case, as permitted by this Agreement; and

(ii) regarding the existence of this Agreement, this Agreement itself or the material and financial terms of this Agreement, to: (A) its accountants, lawyers, and other advisers; and (B) actual or potential investors, lenders, licensors, (sub)licensees, subcontractors, acquirers, investment bankers, or agents of the foregoing in connection with a financing, licensing transaction, merger, or acquisition, in each case ((A)-(B)) under confidentiality obligations no less restrictive than those set forth in this Agreement.

(b) In the event a Party deems it reasonably necessary to disclose Confidential Information belonging to the other Party in order to respond to inquiries, requests, investigations, orders, or subpoenas of governmental authorities relating to this Agreement pursuant to Section 9.2.2(a)(i), the disclosing Party will give reasonable advance written notice of such disclosure to the other Party and take all reasonable measures to ensure confidential treatment of such information.

1.1.5. **SEC Filings and Other Disclosures**. Notwithstanding any provision of this Agreement to the contrary, either Party may disclose the existence or terms of this Agreement or information regarding the Compounds or Products to the extent required, in the reasonable opinion of such Party's outside legal counsel, to comply with Applicable Law. Notwithstanding the foregoing, before disclosing this Agreement or any of the terms hereof pursuant to this Section 9.2.3, the Parties will consult with one another on the terms of this Agreement to be redacted in making any such disclosure. Further, if a Party discloses this Agreement or any of the terms hereof in accordance with this Section 9.2.3, such Party will, at its own expense, use reasonable efforts to seek confidential treatment of confidential portions of this Agreement and such other terms as may be reasonably requested by the other Party.

1.24. **Right to Injunctive Relief.** Each Party agrees that breaches of this Article 9 may cause irreparable harm to the Disclosing Party and will entitle the Disclosing Party, in addition to any other remedies available to it (subject to the terms of this Agreement), the right to seek injunctive relief enjoining such action.

1.25. **Ongoing Obligation for Confidentiality.** Upon expiration or termination of this Agreement, the Receiving Party will, and will cause any recipients of Confidential Information from the Receiving Party to, destroy, delete, or return (as requested by the Disclosing Party) any Confidential Information of the Disclosing Party, except that the Receiving Party: (a) may retain a single copy of Confidential Information for the sole purpose of ascertaining its rights and responsibilities with respect to such information; (b) will not be required to destroy any computer files stored securely by the Receiving Party that are created by automatic system back up and (c) may retain such Confidential Information to the extent necessary to exercise any surviving rights or perform any surviving obligations of the Receiving Party under this Agreement.

6. REPRESENTATIONS AND WARRANTIES; COVENANTS.

1.22. Representations and Warranties by Each Party. Each Party represents and warrants to the other Party, as of the Effective Date, that:

1.1.23. it is a corporation duly organized, validly existing, and in good standing (or equivalent status in the relevant jurisdiction) under the laws of its jurisdiction of formation or establishment;

1.1.24. it has full corporate power and authority to execute, deliver, and perform its obligations under this Agreement, and has taken all corporate action required by Applicable Law and its organizational documents to authorize the execution and delivery of this Agreement and the consummation of the transactions contemplated by this Agreement;

1.1.25. this Agreement has been duly executed and constitutes a valid and binding agreement enforceable against it in accordance with its terms;

1.1.26. all consents, approvals, and authorizations from all governmental authorities or other Third Parties required to be obtained by such Party in connection with this Agreement have been obtained; and

1.1.27. the execution and delivery of this Agreement and compliance with the terms and provisions hereof and all other instruments and documents required to be executed pursuant to this Agreement, and the consummation of the transactions contemplated hereby, do not and will not: (a) conflict with or result in a breach of any provision of its organizational documents; (b) result in a breach of any agreement to which it is a party that would impair the performance of its obligations hereunder; or (c) violate any Applicable Law.

1.23. Representations and Warranties by Licensor. Licensor represents and warrants to Licensee, as of the Effective Date, that:

1.1.1. Licensor Controls the Licensed Technology and Licensor has the right to grant all rights and licenses it purports to grant to Licensee and its Affiliates with respect to the Licensed Technology under this Agreement;

1.1.1. There is no ongoing or, to Licensor's knowledge, threatened (in writing) litigation, arbitration, or other proceedings against Licensor involving the Licensed Technology, or any Existing Upstream License Agreement;

1.1.2. Licensor and its Affiliates have not granted any license or other right under the Licensed Technology that is inconsistent with the licenses it purposes to grant to Licensee with respect to the Licensed Technology under this Agreement;

1.1.3. There is no pending litigation, nor has Licensor received any written notice from any Third Party, asserting or alleging that the use, Development, Manufacture, or Commercialization of any Compound or Product prior to the Effective Date infringed upon, violated, or constituted a misappropriation of any Intellectual Property Rights of any Third Party;

1.1.4. To Licensor's actual knowledge, the use, Development, Manufacture or Commercialization of any Compound or Product prior to the Effective Date has not infringed upon, violated, or constituted a misappropriation of any Intellectual Property Rights of any Third Party;

1.1.5. Licensor has not utilized, in connection with any Compound or Product, any Person that, to Licensor's knowledge, has been or is debarred or disqualified by any Regulatory Authority pursuant to the provisions of the Generic Drug Enforcement Act of 1992 (21 U.S.C. §335) or any equivalent Applicable Law;

1.1.6. Licensor has not received any written notice of violations of Applicable Law from the FDA or any other Regulatory Authority with respect to any past use, Development, Manufacture, or Commercialization of any Compound or Product that could reasonably be deemed to adversely affect the use, Development, Manufacture, or Commercialization of such Compound or Product;

1.1.7. Licensor has obtained assignments from all inventors of the inventions claimed in the Licensed Patent Rights of each such inventor's entire right, title, and interest in and to the Licensed Patent Rights and to Licensor's knowledge, all such assignments are valid and enforceable;

1.1.8. Schedule 1.61 sets forth a complete and accurate list of all Licensed Patent Rights Controlled by Licensor as of the Effective Date;

1.1.9. the Licensed Technology existing as of the Effective Date constitutes all of the Intellectual Property Rights owned or controlled by the Licensor and its Affiliates that is necessary or, to Licensor's reasonable belief as of the Effective Date, reasonably useful to Develop, Manufacture and Commercialize the Compound and Products in the Field within the Licensed Territory;

1.1.10. Licensor has provided Licensee with a complete and accurate copy of (a) each Existing Upstream License Agreement set forth on Schedule 1.121, and (b) the Intercompany License Agreement, and each such agreement is in full force and effect as of the Effective Date;

1.1.1. Neither Licensor nor any of its Affiliates own or otherwise Controls any cell lines or other biologic material that are material to the Development, Manufacture, or Commercialization of any Compound or Product, other than the Licensed Materials; and

1.1.2. To the extent that the Licensed Materials are intended to be used for human clinical trials, those Licensed Materials have been made in compliance with and, to the knowledge of Licensor, remain in compliance with Applicable Law for their intended purpose.

1.24. Representations and Warranties and Covenants by Licensee.

1.1.28. Licensee will not utilize, in connection with any Compound, Product or Biomarker Test, any Person that has been or is debarred or disqualified by the FDA or any Regulatory Authority outside the United States; and

1.1.29. Licensee will comply with all Applicable Law with respect to the performance of its obligations hereunder.

1.25. Additional Covenants of Licensor.

1.1.30. Licensor will not amend, modify, or terminate any Upstream License Agreement, the Intercompany License Agreement or any other agreement with any Third Party, or take (or fail to take) any other action with respect thereto, in a manner that would have material adverse effect on Licensee or Licensee's rights hereunder.

1.1.31. Licensor shall immediately notify Licensee in writing of any notice it receives from any Third Party licensor which is party to an Upstream License Agreement that it is in material breach of the applicable Upstream License Agreement in a manner that would have material adverse effect on Licensee and the plan to cure such material breach.

1.1.32. Licensor will not utilize, in connection with any Compound or Product, any Person that, to Licensor's knowledge, has been or is debarred or disqualified by any Regulatory Authority pursuant to the provisions of the Generic Drug Enforcement Act of 1992 (21 U.S.C. §335) or any equivalent Applicable Law.

1.26. Mutual Covenants.

1.26.1. Without limiting the generality of Section 10.3.2, each Party will comply with Anti-Corruption Laws. Each Party represents and warrants to the other Party that neither such Party, nor its respective Affiliates, nor, to such Party's knowledge, any director, officer, employee, consultant, agent, or representative or other person acting on its or their behalf has taken or will take any action, directly or indirectly, to pay, offer, promise or authorize the payment, or giving of anything of value to any Government Official, or to any person, and has not accepted and will not accept a payment for any item of value: (a) for the purpose of (i) influencing any act or decision of such Government Official(s) in their official capacity, including the failure to perform an official function, in order to assist such Party or any of its Affiliates or any beneficiary of such Party in obtaining or retaining business, or directing business to any Third Party, (ii) securing an improper advantage in connection with a Government Official, (iii) inducing such Government Official(s) to use their influence to affect or influence any act or decision of a government entity in order to assist such Party, its Affiliates, or any beneficiary of such Party in obtaining or retaining business, or directing business to any Third Party, or (iv) providing an unlawful personal gain or benefit, of financial or other value, to such Government Official(s); or (b) otherwise for the benefit of such Party or any of its Affiliates in violation of any Applicable Law.

1.26.2. Each Party shall (a) promptly notify the other Party of any efforts undertaken by such Party to obtain a license under Intellectual Property Rights controlled by a Third Party that are necessary or reasonably useful for Developing, Manufacturing or Commercializing any Compound or Product in the Field, and (b) use reasonable efforts to facilitate the other Party to be able to obtain a license under such Intellectual Property Rights to the extent relevant to the other Party's territory.

1.27. No Action Required Which Would Violate Law. In no event will either Party be obligated under this Agreement to take any action or omit to take any action that such Party believes, in good faith, would cause such Party to violate any Applicable Law, including Anti-Corruption Laws.

1.28. **No Other Warranties.** EXCEPT AS OTHERWISE EXPRESSLY PROVIDED IN THIS AGREEMENT, NEITHER PARTY MAKES ANY REPRESENTATION OR EXTENDS ANY WARRANTY OF ANY KIND, EXPRESS OR IMPLIED, WITH RESPECT TO ANY TECHNOLOGY, GOODS, SERVICES, RIGHTS, OR OTHER SUBJECT MATTER OF THIS AGREEMENT, INCLUDING WARRANTIES OF TITLE, MERCHANTABILITY, FITNESS FOR A PARTICULAR PURPOSE, AND NON-INFRINGEMENT.

7. INDEMNIFICATION.

1.29. **Indemnification by Licensee.** Licensee agrees to indemnify, hold harmless, and defend Licensor and its Affiliates, contractors, and distributors, and each of its and their respective officers, directors, employees, agents, and assigns (collectively, "**Licensor Indemnitees**"), from and against any Claims to the extent arising or resulting from: (a) the Development, Manufacture, Commercialization, or use (including the production, manufacture, promotion, import, sale, or use by any Person) of any Product by, on behalf of, or under the authority of, Licensee or any of its Affiliates, Sublicensees, subcontractors, distributors, or agents (other than by any Licensor Indemnitees) in the Field in the Licensed Territory; (b) the negligence, recklessness, or wrongful intentional acts or omissions of Licensee, its Affiliates, subcontractors, or Sublicensees, except to the extent caused by a breach by Licensor or any of its Affiliates of any of Licensor's obligations, representations, warranties, or covenants set forth in this Agreement, or Licensor's, or its Affiliates' negligence, recklessness, or intentional acts, or the negligence, recklessness, or intentional acts of any Third Party direct licensee (other than Licensee's Sublicensees or subcontractors under this Agreement) of the Licensed Technology acting within the scope of such license with Licensor; (c) breach by Licensee of any representation and warranty, obligation or covenant as set forth in this Agreement; or (d) breach by Licensee of the scope of the licenses set forth in Section 2.1, in each case ((a) through (d)), except to the extent caused by a breach by Licensor, its Affiliates, subcontractors, or sublicensees of any of Licensor's obligations, representations, warranties, or covenants set forth in this Agreement, or Licensor's or its Affiliates', subcontractors' or sublicensees', negligence, recklessness, or intentional acts.

1.30. **Indemnification by Licensor.** Licensor agrees to indemnify, hold harmless, and defend Licensee and its Affiliates, contractors, and distributors, and each of its and their respective officers, directors, employees, agents, and assigns (collectively, "**Licensee Indemnitees**"), from and against any Claims to the extent arising or resulting from: (a) the actions undertaken by Licensor, its Affiliates, sublicensees or subcontractors during the Development, manufacture, or use of any Compound or Product (i) prior to the Effective Date or from and after the termination of this Agreement within the Licensed Territory, and (ii) in all events outside of the Licensed Territory; (b) the negligence, recklessness, or wrongful intentional acts or omissions of Licensor or its Affiliates, or the negligence, recklessness, or intentional acts of any Third Party direct licensees (other than Licensee's Sublicensees or subcontractors under this Agreement) of the Licensed Technology acting within the scope of such direct licensees' license with Licensor; (c) breach by Licensor of any representation, warranty, obligation, or covenant as set forth in this Agreement; or (d) breach by Licensor of the scope of the licenses set forth in Section 2.2, in each case ((a) through (d)), except to the extent caused by a breach by Licensee, its Affiliates, subcontractors, or Sublicensees of any of Licensee's obligations, representations, warranties, or covenants set forth in this Agreement, or Licensee's or its Affiliates', subcontractors' or Sublicensees', negligence, recklessness, or intentional acts.

1.31. **Indemnification Procedure.** In connection with any Claim for which a Party (the "**Indemnified Party**") seeks indemnification from the other Party (the "**Indemnifying Party**") pursuant to this Agreement, the Indemnified Party will: (a) give the Indemnifying Party prompt written notice of the Claim (provided, however, that failure to promptly provide such notice will not relieve the Indemnifying Party from its indemnification obligations hereunder, except to the extent of any material prejudice as a direct result of such failure); (b) cooperate with the Indemnifying Party, at the Indemnifying Party's expense, in connection with the defense and settlement of the Claim; and (c) permit the Indemnifying Party to control the defense and settlement of the Claim; provided, however, that the Indemnifying Party may not settle the Claim without the Indemnified Party's prior written consent, which will not be unreasonably withheld or delayed, in the event that such settlement materially adversely impacts the Indemnified Party's rights or obligations. Further, the Indemnified Party will have the right to participate (but not control) and be represented in any suit or action by advisory counsel of its selection and at its own expense.

1.32. **Insurance**. During the Term and for a period of [***] years thereafter, Licensee shall maintain at its sole cost and expense, liability and other insurance in amounts which are [***]. Such insurance shall insure against liability arising out of the discovery and development of pharmaceutical products. Upon request, Licensee shall provide written proof of the existence of such insurance to Licensor. Licensee hereby specifically acknowledges and agrees that the insurance coverage limits set forth in this Section 11.4 shall not be construed to create any limit on Licensee's liability or indemnification obligations under this Agreement.

8. LIMITATION OF LIABILITY.

1.33. **Consequential Damages Waiver.** EXCEPT FOR A BREACH OF ARTICLE 9, A BREACH BY EITHER PARTY OF THE LICENSES GRANTED TO IT UNDER SECTION 2.1 OR SECTION 2.2, AS APPLICABLE, A BREACH OF SECTION 2.9, A PARTY'S GROSS NEGLIGENCE OR WILLFUL MISCONDUCT, OR OBLIGATIONS ARISING UNDER ARTICLE 11, NEITHER PARTY WILL BE LIABLE TO THE OTHER PARTY UNDER THIS AGREEMENT FOR ANY INDIRECT, CONSEQUENTIAL, SPECIAL, EXEMPLARY, OR PUNITIVE DAMAGES, INCLUDING DAMAGES FOR LOST PROFITS OR LOST REVENUES, REGARDLESS OF WHETHER IT HAS BEEN INFORMED OF THE POSSIBILITY OR LIKELIHOOD OF SUCH DAMAGES OR THE TYPE OF CLAIM, CONTRACT OR TORT (INCLUDING NEGLIGENCE) AND EVEN IF THE REMEDIES PROVIDED FOR IN THIS AGREEMENT FAIL OF THEIR ESSENTIAL PURPOSE.

9. TERM; TERMINATION.

1.34. **Term.** The term of this Agreement ("**Term**") will commence as of the Effective Date and, unless earlier terminated as expressly provided herein, will extend on a Product-by-Product and country-by-country or jurisdiction-by-jurisdiction basis, until such time as the Royalty Term with respect to the sale of such Product in such country or jurisdiction expires. Following the expiration (but not termination) of the Term applicable to a Product in a country or jurisdiction, Licensee will have a fully paid-up, irrevocable, freely transferable, sublicensable, and non-exclusive license, under the relevant Licensed Technology, to Develop, Manufacture, and Commercialize such Product and the applicable Compound contained in such Product in such country or jurisdiction.

1.35. **Termination for Cause.** Each Party will have the right to terminate this Agreement in the event the other Party materially breaches its obligations hereunder and fails to cure such breach within [***] days of receiving notice thereof (an "**Uncured Breach**"); provided, however, that if such breach is capable of being cured but cannot be cured within such [***]-day period and the breaching Party initiates actions to cure such breach within such period and thereafter diligently pursues such actions, the breaching Party will have such additional period as is reasonable to cure such breach, but in no event will such additional period exceed [***] days. Any termination by a Party under this Section 13.2 will be without prejudice to any damages or other legal or equitable remedies to which it may be entitled from the other Party. The foregoing cure periods shall be tolled during the pendency of any Dispute as to whether a material breach has occurred.

1.36. **Termination for a Bankruptcy Event.** Each Party will have the right to terminate this Agreement in the event of a Bankruptcy Event with respect to the other Party. For clarity, the Licensed Technology shall be regarded as intellectual property under Section 365(n) of the Bankruptcy Code.

1.37. **Termination for Convenience.** [***], Licensee may terminate this Agreement for convenience upon [***] days' prior written notice to Licensor.

1.38. **Termination for Safety Issue.** [***], if Licensee [***] has determined that the Development of the Product should be terminated for scientific or safety reasons [***], then Licensee may terminate this Agreement at any time upon [***] days' prior written notice to Licensor.

1.39. **Termination for Pyxis Cessation of Development and Commercialization**. If at any time during the Term, Licensee has ceased Development and Commercialization of all Compounds and Products throughout the Licensed Territory for [***], then, notwithstanding anything to the contrary herein, Licensor may terminate this Agreement in its entirety [***] upon written notice to Licensee.

1.40. **Effects of Termination.**

1.1.33. **Termination by Licensee for Cause or Bankruptcy Event**. In the event that Licensee terminates this Agreement pursuant to Section 13.2 or Section 13.3, the following will apply:

(a) **Rights and Obligations**. Except as otherwise provided herein, all rights and obligations of each Party hereunder will cease, including, subject to Section 13.7.1(b), the licenses granted to Licensee pursuant to Section 2.1; provided, that Licensor will remain entitled to receive payments that accrued before the effective date of such termination. Notwithstanding the foregoing, if this Agreement is terminated by Licensor pursuant to Section 13.2 or Section 13.3, at the request of any Sublicensee, Licensor will grant such Sublicensee a direct license under the Licensed Patent Rights, Licensed Know-How, and Licensed Materials on substantially the same terms as are set forth in the sublicense agreement between Licensee and such Sublicensee, so that the Sublicensee is put in the same position as it was prior to this Agreement being terminated; provided, however, that: (i) Licensor would not have any increased obligations as a result of such direct license to the Sublicensee; (ii) as consideration for such direct license, Sublicensee would be required to pay Licensor the same amount as Licensor would have received from Licensee had this Agreement survived as a result of (x) the applicable sublicense and (y) the exploitation of the applicable Compound(s) and Product(s); and (iii) any such direct license may be conditioned upon the Sublicensee being in good standing under the terms of the applicable sublicense agreement and applicable terms of this Agreement.

(b) **Licensee Inventory**. Licensee will have the right to sell its remaining inventory of Product as of the termination date so long as Licensee has fully paid, and continues to pay when due, all Royalties and Milestone Payments owed to Licensor, and Licensee is otherwise not in material breach of this Agreement. Except with respect to the offering for sale, sale, and import of the remaining inventory of Product described above, Licensee will immediately cease, and will cause its Affiliates and Sublicensees to cease, all Development, Manufacture, use, and Commercialization of Compounds and Products in the Field in the Licensed Territory.

1.1.34. **Termination by Licensor for Cause or Bankruptcy Event; Termination by Licensee for Convenience**. In the event that Licensor terminates this Agreement pursuant to Section 13.2, Section 13.3 or Section 13.6 or Licensee terminates this Agreement pursuant to Section 13.4 or Section 13.5, the following will apply:

(c) **Rights and Obligations**. Except as otherwise provided herein, all rights and obligations of each Party hereunder will cease, and, except as expressly provided in this Agreement, Licensee will cease all Development, Manufacture, and Commercialization of the Compounds and Products in the Field in the Licensed Territory.

(d) **Transition**. Within [***] days of termination of this Agreement, at Licensor's sole option, the Parties will prepare and negotiate a transition plan that will include, at a minimum, a plan for accomplishing the activities described in this Section 13.7.2(b).

(i) **Continued Development**. At Licensor's request and expense, Licensee will continue on-going Development for a mutually agreed-upon period following the termination of this Agreement, which period will be [***], unless otherwise agreed to by the Parties or unless Licensee terminates this Agreement pursuant to Section 13.5. [***].

(ii) **Technology Transfer and Supply**. At Licensor's request [***], Licensee will make available to Licensor all currently-available records and data which exist and are Controlled by Licensee as of the effective date of termination and are necessary or useful for Licensor to continue using, Developing, Manufacturing, and Commercializing the Compounds and Products. Licensee shall, and shall cause its Affiliates and its or their Sublicensees to, perform a manufacturing technology transfer to Licensor or its designee, including facilitating any transfer from Licensor's (or any of its Affiliate's or its or their Sublicensee's) contract manufacturers. The Parties agree that the Clinical Supply Agreement and Commercial Supply Agreement will set forth in more details the manufacturing technology transfer and supply obligations by the Licensee during the transition period.

(iii) **Regulatory Matters**. To the extent permitted by Applicable Law or any applicable Regulatory Authority, at Licensor's request [***], Licensee will transfer and assign to Licensor (or its designee) all Regulatory Approvals, pricing approvals, and Regulatory Filings held by Licensee with respect to the Product; provided, that if such transfer and assignment is not permitted by Applicable Law or any applicable Regulatory Authority, Licensee will permit Licensor to cross-reference and rely upon such Regulatory Approvals, pricing approvals and Regulatory Filings solely for the purposes of Developing, Manufacturing, and Commercializing the Compounds and Products. Licensee will make available to Licensor copies of all regulatory documentation and records related to the Product, including information contained in the regulatory and safety databases. The Parties will cooperate to ensure the prompt transition of regulatory responsibilities for the Product from Licensee to Licensor.

(iv) **Trademarks**. Licensee shall, [***], transfer and assign, and shall ensure that its Affiliates and its or their Sublicensees transfer and assign, to Licensor, [***], all trademarks associated with a Product and any applications therefor (excluding any such marks that include, in whole or part, any corporate name or logos of Licensee or its Affiliates or its or their Sublicensees).

(v) **Inventory**. At Licensor's request and expense, Licensee will, to the extent permitted by Applicable Law, transfer to Licensor (or its designee) all Products, components (including Compounds), and in-process inventory produced or held by Licensee with respect to the Manufacture of Products.

(vi) **Third Party Agreements**. At Licensor's request [***], to the extent Licensee is reasonably able to do so in accordance with Applicable Law and the applicable agreements, Licensee will assign to Licensor (or its designee) any agreements with Third Parties with respect to the Development, Commercialization, and Manufacture of the Products (including any sublicense agreements with a Sublicensee). With respect to Third Party agreements that Licensee is not able to assign to Licensor, Licensee will use reasonable efforts (at the expense of Licensor) to give Licensor the benefit of such contracts for a reasonable transitional period.

(vii) [***].

(e) **Licensee Inventory**. In the event that Licensee terminates this Agreement pursuant to Section 13.4 and Licensor elects not to initiate transition activities pursuant to Section 13.7.2(b), Licensee will have the right to sell its remaining inventory of Product so long as Licensee has fully paid, and continues to pay when due, all Royalties and Milestone Payments owed to Licensor[***]. Except with respect to the offering for sale, sale, and import of the remaining inventory of Product described above, Licensee will immediately cease, and will cause its Affiliates and Sublicensees to cease, all Development, Manufacture, use and Commercialization, of Compounds and Products in the Field in the Licensed Territory.

1.41. **Reduction of Payments in Lieu of Termination.** If there exists an Uncured Breach by Licensor, Licensee may, in lieu of terminating this Agreement, reduce any payments due under this Agreement by [***], and this Agreement shall continue in full force and effect notwithstanding such Uncured Breach.

1.42. **Survival.** Any expiration or termination of this Agreement will not preclude the terminating Party from exercising any other of those remedies to which it may be entitled under this Agreement or Applicable Law, or terminate any right to obtain performance of any obligation provided for in this Agreement that will survive termination. Expiration or termination of this Agreement will not relieve the Parties of any obligation accruing hereunder prior to such expiration or termination. Without limiting the foregoing, the provisions of this Section 13.9, Articles 1, 5 (to the extent relating to any accrued payments), 6 (to the extent relating to any accrued payments), 9, 11, 12, 14, 15 and 16 and Sections 7.1, 7.2, 8.2.2, 10.7 and 13.7 will survive expiration or termination of this Agreement.

10. PUBLICITY; PUBLICATIONS.

1.43. **Use of Names.** Subject to Licensor's rights pursuant to Section 13.7.2(b)(iv) and except as required by Applicable Law, neither Party (nor any of its Affiliates or agents) will use the registered or unregistered trademarks, service marks, trade dress, trade names, logos, insignia, domain names, symbols, or designs of the other Party or any of its Affiliates in any press release, publication, or other form of promotional disclosure without the prior written consent of the other Party in each instance.

1.26. **Press Releases**. Except as may be expressly permitted under Section 9.2.3, neither Party will make any public announcement regarding the existence or terms of this Agreement without the prior written approval of the other Party, such approval not to be unreasonably withheld. For clarity, nothing in this Agreement will prevent either Party from making any public disclosure relating to this Agreement if the contents of such public disclosure have previously been made public other than through a breach of this Agreement by the issuing Party or any of its Affiliates. The Parties agree that each Party may issue future announcements concerning Licensee's achievement of any significant milestones, including the selection of a clinical candidate, under this Agreement; provided, that the content of any such announcement by Licensor has been mutually agreed upon by the Parties or contains only information that has been previously publicly announced by Licensee. Notwithstanding the foregoing, Licensor may publicly announce the achievement of any Milestone entitling Licensor to receive a payment pursuant to Section 5.2; provided, that Licensor will submit to Licensee for prior review a draft of the proposed announcement to the extent including information that is not covered in the second sentence of this Section 14.2 ("**Additional Information**"), consider in good faith any reasonable comments made by Licensee on Additional Information, and cooperate with Licensee on the timing of such announcement where required for Licensee to comply with Applicable Law.

1.44. **Publications**. Subject to Section 9.2.3, during the Term, each Party will submit to the other Party for review any proposed material academic, scientific, or medical public presentation or publication that refers to, derives from, contains, or otherwise relates to the Compound, the Products, the Licensed Technology, the Licensee Technology or the other Party's Confidential Information. Such review will be conducted for the purposes of preserving the value of the Licensed Technology and the Licensee Technology, as applicable, and determining whether any portion of the proposed publication or presentation containing a Party's Confidential Information should be modified or deleted. Written copies of such proposed publication or presentation required to be submitted hereunder will be submitted to the non-publishing Party no later than [***] Business Days before the relevant submission date for such publication or presentation (the "**Review Period**"). The non-publishing Party will provide its comments with respect to such publications and presentations within [***] Business Days of its receipt of such written copy, and the publishing Party will incorporate all appropriate changes proposed by the non-publishing Party regarding its Confidential Information and will delete all Confidential Information of the non-publishing Party as the non-publishing Party may request. The publishing Party will, upon the request of the non-publishing Party, delay such publication or presentation for up to [***] days to permit the non-publishing Party to obtain patent protection for information included in the proposed publication or presentation. Each Party will comply with standard academic practice regarding authorship of scientific publications and recognition of contribution of other parties in any publication governed by this Section 14.3, including International Committee of Medical Journal Editors standards regarding authorship and contributions.

11. DISPUTE RESOLUTION.

1.27. **Arbitration.** The Parties recognize that a *bona fide* dispute as to certain matters may arise from time to time during the Term relating to either Party's rights or obligations hereunder or otherwise relating to the validity, enforceability, or performance of this Agreement, including disputes relating to alleged breach or termination of this Agreement but excluding any disputes relating to Final Decision-Making Authority Matters or to the determination of the validity, scope, infringement, enforceability, inventorship, or ownership of the Parties' respective Patent Rights (hereinafter, a "**Dispute**"). In the event of the occurrence of any Dispute, the Parties will follow the following procedures in an attempt to resolve the Dispute:

1.1.6. The Party claiming that such a Dispute exists will give notice in writing (a "**Notice of Dispute**") to the other Party of the nature of the Dispute.

1.1.7. The Dispute will be referred to the Executive Officer of Licensor and the Executive Officer of Licensee, who will meet no later than [***] days following the initial receipt of the Notice of Dispute and use reasonable endeavors to resolve the Dispute.

1.1.8. If, within [***] days of initial receipt of the Notice of Dispute, the Dispute has not been resolved or if, for any reason, the meeting described in Section 15.1.2 has not been held within [***] days of initial receipt of the Notice of Dispute, then the Parties agree that such Dispute will be finally resolved through binding arbitration to be administered by JAMS pursuant to its Comprehensive Arbitration Rules and Procedures and in accordance with the expedited procedures in those Rules, as specifically modified by the provisions of this Section 15.1.3.

(c) **Arbitration Panel**. The arbitration will be conducted by a panel of three (3) arbitrators. Within [***] days after the initiation of the arbitration, each Party will nominate one (1) person to act as arbitrator, and the two (2) arbitrators so named will then jointly appoint the third (3rd) arbitrator within [***] days of their appointment, who will serve as chairman of the panel. All three (3) arbitrators must be independent Third Parties having at least [***] years of dispute resolution experience (which may include judicial experience) or legal or business experience in the biotech or pharmaceutical industry. If either Party fails to nominate its arbitrator, or if the arbitrators nominated by the Parties cannot agree on a person to be named as chairman within such [***]-day period, JAMS will make the necessary appointments for such arbitrator(s) or the chairman. Once a Party appoints an arbitrator, such Party will have no *ex parte* communication with such appointed arbitrator.

(d) **Location and Proceedings**. The place of arbitration will be in Wilmington, Delaware, or such other venue as the Parties may mutually agree. The arbitration proceedings and all communications with respect thereto will be in English. Any written evidence originally in another language will be submitted in English translation accompanied by the original or a true copy thereof. The arbitrators have the power to decide all matters in Dispute, including any questions of whether or not such matters are subject to arbitration hereunder. The arbitration will be governed by the Federal Arbitration Act, 9 U.S.C. §§1 *et seq.*, and judgment upon the award rendered by the arbitrators may be entered in any court having competent jurisdiction thereof.

(e) **Limitation on Awards**. Except as permitted under Section 12.1, the arbitrators will have no authority to award any SPECIAL, INDIRECT, INCIDENTAL, CONSEQUENTIAL, PUNITIVE, EXEMPLARY, OR OTHER SIMILAR DAMAGES. Each Party will bear its own costs and expenses (including attorneys' fees and expert or consulting fees) incurred in connection with the arbitration. [***].

(f) **Confidentiality**. The existence, content, and results of any arbitration proceedings pursuant to this Section 15.1.3 will be deemed the Confidential Information of both Parties.

1.1.9. Notwithstanding any provision of this Agreement to the contrary, either Party may immediately initiate litigation in any court of competent jurisdiction seeking any remedy at law or in equity, including the issuance of a preliminary, temporary, or permanent injunction, to preserve or enforce its rights under this Agreement.

1.28. Disputes Relating to Inventorship under Article 7. Any dispute, controversy, or claim between the Parties involving the inventorship of any Patent Rights that are conceived, developed, generated or otherwise made solely by or on behalf of either Party or its Affiliates or its or their Sublicensees under or in connection with this Agreement that is not resolved by mutual agreement of the Party's respective chief patent counsels (or persons with similar responsibilities) within [***] days after the date the dispute, controversy, or claim is raised by one (1) or both of the Parties will be submitted to an independent patent counsel mutually selected by each Party's respective chief patent counsels (or persons with similar responsibilities) for resolution. Such independent patent counsel's determination of inventorship, absent manifest error, will be final and binding on the Parties. The Party whose position such independent patent counsel determines against shall bear [***] of the independent patent counsel's fees and expenses related to the independent patent counsel's resolution of any such dispute, controversy, or claim.

12. GENERAL PROVISIONS.

1.29. **Assignment.** Neither Party may assign this Agreement without the prior written consent of the other Party, which consent will not be unreasonably withheld, conditioned, or delayed, except that such consent will not be required in connection with any assignment to an Affiliate of the assigning Party, or to a Third Party in connection with a sale or transfer of all or substantially all the business to which this Agreement relates, or to any successor Person resulting from any merger or consolidation of such Party with or into such Person; provided, that: (a) the assignee will have agreed in writing to assume all of the assignor's obligations hereunder; and (b) the other Party is notified promptly after such assignment has been effected. Any such assignment will not relieve the assigning Party of any liabilities or obligations owed to the other Party, including, in the case of Licensee, the payment of any amounts described in Article 5. Any purported assignment of this Agreement in violation of this Section 16.1 will be null and void.

1.30. **Severability.** If any clause or portion thereof in this Agreement is for any reason held to be invalid, illegal, or unenforceable, the same will not affect any other portion of this Agreement, as it is the intent of the Parties that this Agreement will be construed in such fashion as to maintain its existence, validity, and enforceability to the greatest extent possible. In any such event, this Agreement will be construed as if such clause or portion thereof had never been contained in this Agreement, and there will be deemed substituted therefor such provision as will most nearly carry out the intent of the Parties as expressed in this Agreement to the fullest extent permitted by Applicable Law.

1.31. **Governing Law.** This Agreement, and all disputes and claims arising under or in connection therewith, will be governed by and interpreted in accordance with the laws of the State of New York, without regard to conflict of law principles thereof *provided* that all questions concerning inventorship and ownership of Patent Rights under this Agreement shall be determined in accordance with Section 15.2.

1.32. **Waiver.** No provision of this Agreement will be waived by any act, omission, or knowledge of a Party or its agents or employees except by an instrument in writing expressly waiving such provision and signed by a duly authorized officer of the waiving Party. The waiver by either of the Parties of any breach of any provision hereof by the other Party will not be construed to be a waiver of any succeeding breach of such provision or a waiver of the provision itself.

1.33. **Amendment.** No amendment, modification, or supplement of any provision of this Agreement will be valid or effective unless made in writing and signed by a duly authorized officer of the Party against whom enforcement of any such amendment, modification, amendment or supplement is sought.

1.34. **Relationship of the Parties.** The Parties understand and agree that this Agreement is limited to the activities, rights, and obligations as expressly set forth herein. Nothing herein contained will be deemed to create an employment, agency, joint venture, or partnership relationship between the Parties or any of their agents or employees, or any other legal arrangement that would impose liability upon one Party for the act or failure to act of the other Party. Neither Party will have any express or implied power to enter into any contracts or commitments or to incur any liabilities in the name of, or on behalf of, the other Party, or to bind the other Party in any respect whatsoever.

1.35. **Successors and Assigns.** This Agreement will be binding upon and inure to the benefit of the Parties and their respective successors and permitted assigns.

1.36. **Notices.** Any notice or notification required or permitted to be provided pursuant to the terms and conditions of this Agreement will be in writing and will be deemed given upon receipt if delivered personally or by e-mail transmission (receipt verified), five (5) Business Days after deposited in the mail if mailed by certified mail (return receipt requested) postage prepaid, or on the next Business Day if sent by overnight delivery using a nationally recognized express courier service and specifying next Business Day delivery (receipt verified), to the Parties at the following addresses (or at such other address for a Party as will be specified by like notice, provided, however, that notices of a change of address will be effective only upon receipt thereof):

If to Licensor:

Biosion USA, Inc.
1 Innovation Way, Suite 300
Newark, Delaware, USA 19711
Attention: President
Email: [***]

If to Licensee:

Pyxis Oncology, Inc.
35 Cambridge Park Drive
Cambridge, Massachusetts, USA 02140
Attention: Chief Executive Officer
Email: [***]

with a copy to:

Sidley Austin LLP
2850 Quarry Lake Drive
Baltimore, Maryland 21209
Attention: Asher Rubin and Adriana Tibbitts
Email: [***]

To help expedite the other Party's awareness and response, copies of notices may be provided to the other Party by email but must be supplemented by one of the following methods: (a) personal delivery; (b) first class certified mail with return receipt requested; or (c) next-day delivery by major international courier, with confirmation of delivery. Electronic copies may be sent via email to the email addresses provided above.

1.37. **Further Assurances.** Licensee and Licensor hereby covenant and agree, without the necessity of any further consideration, to execute, acknowledge, and deliver any and all such other documents and take any such other action as may be reasonably necessary or appropriate to carry out the intent and purposes of this Agreement.

1.38. **No Third Party Beneficiary Rights.** No provision of this Agreement will be deemed or construed in any way to result in the creation of any rights or obligation in any Person not a Party to this Agreement. However, either Party may decide, in its sole discretion, to use one (1) or more of its Affiliates to perform its obligations and duties hereunder; provided, that such Party will remain liable hereunder for the performance by any such Affiliates of any such obligations.

1.39. **Entire Agreement.** This Agreement, including its Schedules, constitutes and contains the complete, final, and exclusive understanding and agreement of the Parties and cancels and supersedes any and all prior negotiations, correspondence, understandings, and agreements, whether oral or written, between the Parties respecting the subject matter hereof and thereof.

1.40. **Cumulative Remedies.** No remedy referred to in this Agreement is intended to be exclusive, but each will be cumulative and in addition to any other remedy referred to in this Agreement or otherwise available under law.

1.41. **Waiver of Rule of Construction**. Each Party has had the opportunity to consult with counsel in connection with the review, drafting, and negotiation of this Agreement. Accordingly, any rule of construction that any ambiguity in this Agreement will be construed against the drafting Party will not apply.

1.42. **Interpretation**. Except where the context expressly requires otherwise: (a) the use of any gender herein will be deemed to encompass references to either or both genders, and the use of the singular will be deemed to include the plural (and vice versa); (b) the words "include", "includes", and "including" will be deemed to be followed by the phrase "without limitation"; (c) the word "shall" will be construed to have the same meaning and effect as the word "will" and vice versa; (d) any definition of or reference to any agreement, instrument, or other document herein will be construed as referring to such agreement, instrument, or other document as from time to time amended, supplemented, or otherwise modified (subject to any restrictions on such amendments, supplements, or modifications set forth herein); (e) any reference herein to any Person will be construed to include the Person's successors and permitted assigns; (f) the words "herein", "hereof", and "hereunder", and words of similar import, will be construed to refer to this Agreement in its entirety and not to any particular provision hereof; (g) all references herein to Sections or Schedules will be construed to refer to Sections or Schedules of this Agreement, and references to this Agreement include all Schedules hereto; (h) the word "notice" means notice in writing (whether or not specifically stated) and will include notices, consents, approvals, and other written communications contemplated under this Agreement; (i) provisions that require that a Party, the Parties, or any committee hereunder "agree," "consent," or "approve" or the like will require that such agreement, consent, or approval be specific and in writing, whether by written agreement, letter, approved minutes, or otherwise (but excluding email and instant messaging); (j) references to any specific law, rule, or regulation, or article, section, or other division thereof, will be deemed to include the then-current amendments thereto or any replacement or successor law, rule, or regulation thereof; and (k) the term "or" will be interpreted in the inclusive sense commonly associated with the term "and/or".

1.43. **Descriptive Headings**. The descriptive headings of this Agreement are for convenience only and will be of no force or effect in construing or interpreting any of the provisions of this Agreement.

1.44. **Fees and Expenses.** Except as otherwise specified in this Agreement, each of the Parties shall bear its own costs and expenses (including investment banking and legal fees and expenses) incurred in connection with this Agreement and the transactions contemplated hereby.

1.45. Counterparts. This Agreement may be executed in two (2) or more counterparts, each of which will be deemed an original, but all of which together will constitute one and the same instrument. If any signature is delivered by email delivery of a "pdf" format data file, such signature will create a valid and binding obligation of the Party executing (or on whose behalf such signature is executed) with the same force and effect as if such "pdf" signature page were an original thereof.

[*Signature Pages Follow*]

IN WITNESS WHEREOF, the Parties intending to be bound have caused this Agreement to be executed by their duly authorized representatives as of the Effective Date.

PYXIS ONCOLOGY, INC.

By:_____

Name: Lara S. Sullivan, M.D.

Title: Chief Executive Officer

By:_____

Name: Pam Connealy

Title: Chief Financial Officer

BIOSION USA, INC.

By:_____

Name: Hugh M. Davis, Ph.D.

Title: President

SCHEDULE 1.33

[***]

SCHEDULE 1.60

[***]

SCHEDULE 1.61

[***]

SCHEDULE 1.121

[***]

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)) 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. 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

   c. 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 13, 2022

By: /s/ Lara Sullivan
Lara Sullivan, M.D.
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)) 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. 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

   c. 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 13, 2022

By: /s/ Pamela Connealy
Pamela Connealy
Chief Financial 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 ending March 31, 2022 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 13, 2022

By: /s/ Lara Sullivan
Lara Sullivan, M.D.
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 ending March 31, 2022 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 13, 2022

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