UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 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 **September 30, 2022**

or

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

For the transition period from _____ to _____

Commission File Number: **001-36374**

ACTINIUM PHARMACEUTICALS, INC.
(Exact name of registrant as specified in its charter)

Delaware	**74-2963609**
(State or Other Jurisdiction of Incorporation or Organization)	(I.R.S. Employer Identification No.)
275 Madison Ave, 7th Floor New York, NY	**10016**
(Address of Principal Executive Offices)	(Zip Code)

(646) 677-3870
(Registrant's Telephone Number, Including Area Code)

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

Title of each class	Trading Symbol	Name of exchange on which registered
Common stock, par value $0.001	**ATNM**	**NYSE American**

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, a 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

Indicate the number of shares outstanding of each of the issuer's classes of common stock, as of November 11, 2022: 25,483,306

Actinium Pharmaceuticals, Inc.
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PART I - FINANCIAL INFORMATION

ITEM 1. FINANCIAL STATEMENTS

The accompanying consolidated financial statements have been prepared by the Company and are unaudited. In the opinion of management, all adjustments (which include only normal recurring adjustments) necessary to present fairly the financial position at September 30, 2022 and December 31, 2021, and the results of operations and cash flows for the three and nine months ended September 30, 2022 and 2021, respectively, have been made. Certain information and footnote disclosures normally included in financial statements prepared in accordance with accounting principles generally accepted in the United States of America have been condensed or omitted. It is suggested that these financial statements be read in conjunction with the financial statements and notes thereto included in the Company's audited financial statements for the year ended December 31, 2021 in the Company's Annual Report on Form 10-K. The results of operations for the three and nine months ended September 30, 2022 are not necessarily indicative of the operating results for the full year.

Actinium Pharmaceuticals, Inc.
Condensed Consolidated Balance Sheets
(amounts in thousands, except share and per share data)

	September 30, 2022 (Unaudited)	December 31, 2021 (Audited)
Assets		
Current Assets:		
Cash and cash equivalents	$ 111,815	$ 77,829
Restricted cash - current	394	392
Security deposit	-	50
Prepaid expenses and other current assets	1,214	1,478
Total Current Assets	113,423	79,749
Property and equipment, net of accumulated depreciation of $440 and $335	635	340
Restricted cash – long term	300	-
Operating leases right-of-use assets	2,454	241
Finance leases right-of-use assets	4	58
Total Assets	**$ 116,816**	**$ 80,388**
Liabilities and Stockholders' Equity		
Current Liabilities:		
Accounts payable and accrued expenses	$ 7,869	$ 5,535
Other revenue deferred– current liability	91	998
Operating leases current liability	386	245
Finance leases current liability	4	62
Total Current Liabilities	8,350	6,840
Long-term license revenue deferred	35,000	-
Long-term operating leases obligations	2,210	-
Long-term finance leases obligations	1	3
Total Liabilities	$ 45,561	$ 6,843
Commitments and contingencies		
Stockholders' Equity:		
Preferred stock, $0.001 par value; 50,000,000 shares authorized, 0 shares issued and outstanding	-	-
Common stock, $0.001 par value; 1,000,000,000 shares authorized; 25,212,072 and 22,143,974 shares issued and outstanding, respectively	25	22
Additional paid-in capital	349,348	329,271
Accumulated deficit	(278,118)	(255,748)
Total Stockholders' Equity	71,255	73,545
Total Liabilities and Stockholders' Equity	**$ 116,816**	**$ 80,388**

See accompanying notes to the condensed consolidated financial statements.

Actinium Pharmaceuticals, Inc.
Condensed Consolidated Statements of Operations
(Unaudited)
(amounts in thousands, except share and per share data)

	For the Three Months Ended September 30,		For the Nine Months Ended September 30,	
	2022	**2021**	**2022**	**2021**
Revenue				
Revenue	$ -	$ -	$ -	$ -
Other revenue	45	233	1,030	1,121
Total revenue	45	233	1,030	1,121
Operating expenses:				
Research and development, net of reimbursements	6,771	4,708	15,802	12,615
General and administrative	3,073	1,994	8,041	5,422
Total operating expenses	9,844	6,702	23,843	18,037
Loss from operations	(9,799)	(6,469)	(22,813)	(16,916)
Other income:				
Interest income - net	325	46	443	152
Total other income	325	46	443	152
Net loss	**$ (9,474)**	**$ (6,423)**	**$ (22,370)**	**$ (16,764)**
Net loss per common share – basic and diluted	$ (0.38)	$ (0.30)	$ (0.94)	$ (0.84)
Weighted average common shares outstanding – basic and diluted	25,164,599	21,539,455	23,691,218	20,060,315

See accompanying notes to the condensed consolidated financial statements.

Actinium Pharmaceuticals, Inc.
Condensed Consolidated Statement of Changes in Stockholders' Equity
For the Three and Nine Months Ended September 30, 2022
(Unaudited)
(amounts in thousands, except share amounts)

	Common Stock		Additional Paid-In	Accumulated	Stockholders'
	Shares	Amount	Capital	Deficit	Equity
Balance, January 1, 2022	**22,143,974**	**$ 22**	**$ 329,271**	**$ (255,748)**	**$ 73,545**
Stock-based compensation	-	-	421	-	421
Net loss	-	-	-	(5,129)	(5,129)
Balance, March 31, 2022	**22,143,974**	**$ 22**	**$ 329,692**	**$ (260,877)**	**$ 68,837**
Stock-based compensation	-	-	425	-	425
Sale of common stock, net of issuance costs	2,726,649	3	16,683	-	16,686
Net loss	-	-	-	(7,767)	(7,767)
Balance, June 30, 2022	**24,870,623**	**$ 25**	**$ 346,800**	**$ (268,644)**	**$ 78,181**
Stock-based compensation	19,639	-	970	-	970
Sale of common stock, net of issuance costs	321,810	-	1,578	-	1,578
Net loss	-	-	-	(9,474)	(9,474)
Balance, September 30, 2022	**25,212,072**	**$ 25**	**$ 349,348**	**$ (278,118)**	**$ 71,255**

See accompanying notes to the condensed consolidated financial statements.

Actinium Pharmaceuticals, Inc.
Condensed Consolidated Statement of Changes in Stockholders' Equity
For the Three and Nine Months Ended September 30, 2021
(Unaudited)
(amounts in thousands, except share amounts)

	Common Stock		Additional Paid-In	Accumulated	Stockholders'
	Shares	Amount	Capital	Deficit	Equity
Balance, January 1, 2021	**17,532,893**	**$ 18**	**$ 292,275**	**$ (230,974)**	**$ 61,319**
Stock-based compensation	-	-	376	-	376
Sale of common stock, net of costs	1,712,745	1	14,360	-	14,361
Net loss	-	-	-	(5,320)	(5,320)
Balance, March 31, 2021	**19,245,638**	**$ 19**	**$ 307,011**	**$ (236,294)**	**$ 70,736**
Stock-based compensation	8,705	-	459	-	459
Sale of common stock, net of issuance costs	1,835,688	2	14,317	-	14,319
Exercise of stock options	900	-	6	-	6
Net loss	-	-	-	(5,021)	(5,021)
Balance, June 30, 2021	**21,090,931**	**$ 21**	**$ 321,793**	**$ (241,315)**	**$ 80,499**
Stock-based compensation	12,601	-	412	-	412
Sale of common stock, net of issuance costs	927,306	1	5,796	-	5,797
Net loss	-	-	-	(6,423)	(6,423)
Balance, September 30, 2021	**22,030,838**	**$ 22**	**$ 328,001**	**$ (247,738)**	**$ 80,285**

See accompanying notes to the condensed consolidated financial statements.

Actinium Pharmaceuticals, Inc.
Condensed Consolidated Statements of Cash Flows
(Unaudited)
(amounts in thousands)

	For the Nine Months Ended September 30,	
	2022	**2021**
Cash Flows From Operating Activities:		
Net loss	$ (22,370)	$ (16,764)
Adjustments to reconcile net loss to net cash used in operating activities:		
Stock-based compensation expense	1,816	1,246
Depreciation and amortization expense	538	387
Changes in operating assets and liabilities:		
Prepaid expenses and other current assets	264	137
Accounts payable and accrued expenses	2,334	(566)
Other revenue deferred– current liability	(907)	-
Long-term license revenue deferred	35,000	-
Operating lease liabilities	(253)	(254)
Net Cash Provided By/Used In Operating Activities	**16,422**	**(15,814)**
Cash Flows Used In Investing Activities:		
Purchase of property and equipment	(350)	(133)
Net Cash Used In Investing Activities	**(350)**	**(133)**
Cash Flows From Financing Activities:		
Payments on finance leases	(48)	(63)
Sales of shares of common stock, net of costs	18,264	34,477
Proceeds from exercise of stock options	-	6
Net Cash Provided By Financing Activities	**18,216**	**34,420**
Net change in cash, cash equivalents, and restricted cash	34,288	18,473
Cash, cash equivalents, and restricted cash at beginning of period	78,221	63,999
Cash, cash equivalents, and restricted cash at end of period	**$ 112,509**	**$ 82,472**
Supplemental disclosure of cash flow information:		
Cash paid for interest	$ -	$ -
Cash paid for income taxes	$ -	$ -
Supplemental disclosure of non-cash investing and financing activity:		
Acquisition of equipment financed by security deposit	$ 50	$ -

See accompanying notes to the condensed consolidated financial statements.

Actinium Pharmaceuticals, Inc.
Notes to Condensed Consolidated Financial Statements
(Unaudited)

Note 1 - Description of Business and Summary of Significant Accounting Policies

Nature of Business - Actinium Pharmaceuticals, Inc. (the "Company" or "Actinium") is a clinical-stage, biopharmaceutical company focused on developing and potentially commercializing targeted radiotherapies for patients with unmet needs. The Company applies its proprietary technology platform consisting of over 195 patents, know-how and clinical experience in approximately 600 patients to develop novel therapies for blood cancer and solid tumor indications. Its clinical and preclinical development programs utilize multiple isotopes including Actinium-225, Iodine-131 and Lutetium-177 directed at multiple validated cancer targets including CD45, CD33, CD38, CD47, HER2 and HER3 for targeted conditioning prior to cell and gene therapies including bone marrow transplant and cancer therapeutics as single agents or in combination with other therapeutic modalities. Its lead drug candidate, Iomab-B, has met the primary endpoint of the pivotal Phase 3 SIERRA Trial with a high degree of statistical significance ($p<0.0001$) and the Company will report additional data from the SIERRA trial by the end of 2022. Its second most advanced drug candidate, Actimab-A, is being studied in a Phase 1 combination trial with the chemotherapy regimen CLAG-M and has reported median overall survival of 12 months, 53% 1-year overall survival and 32% 2-year overall survival in patients with relapsed or refractory AML who have adverse cytogenetics such as a TP53 mutation or have failed targeted therapies. Data from this trial will be presented in an oral presentation at the American Society of Hematology Annual Meeting & Symposium in December 2022.

Basis of Presentation - The accompanying unaudited condensed consolidated financial statements and related notes have been prepared in accordance with accounting principles generally accepted in the United States of America ("U.S. GAAP") for condensed financial information, and pursuant to the rules and regulations of the United States Securities and Exchange Commission (the "SEC") with respect to Form 10-Q and Article 10 of Regulation S-X. Accordingly, they do not include all of the information and footnotes required by U.S. GAAP for complete financial statements. The unaudited condensed consolidated financial statements reflect all adjustments (consisting of normal recurring adjustments) which are, in the opinion of management, necessary for a fair statement of the results for the condensed periods presented. Condensed results are not necessarily indicative of the results for the full year. These unaudited condensed consolidated financial statements should be read in conjunction with the audited consolidated financial statements and notes thereto contained in the Company's Annual Report on Form 10-K for the year ended December 31, 2021.

Principles of Consolidation - The basis of consolidation is unchanged from the disclosure in the Company's Notes to the Consolidated Financial Statements section in its Report on Form 10-K for the year ended December 31, 2021. The unaudited condensed consolidated financial statements include the Company's accounts and those of the Company's wholly owned subsidiaries.

Use of Estimates - The preparation of these unaudited condensed consolidated financial statements in conformity with U.S. GAAP requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities at the date of the consolidated financial statements and the reported amounts of expenses during the reporting period. Actual results could differ from those estimates.

Impact of COVID–19 Pandemic on Financial Statements - The global health crisis caused by the novel coronavirus ("COVID-19") pandemic and its resurgences has and may continue to negatively impact global economic activity, which, despite progress in vaccination efforts, remains uncertain and cannot be predicted with confidence. In addition, the Omicron variants of COVID-19, including subvariants BA.4 and BA.5, which appear to be the most transmissible variants to date, have spread globally. The full impact of the Omicron variants, or any subsequent variants, cannot be predicted at this time, and could depend on numerous factors, including vaccination rates among the population, the effectiveness of COVID-19 vaccines and boosters against the Omicron variants and subsequent variants and the response by governmental bodies and regulators.

Many countries around the world have continued to impose quarantines and restrictions on travel and mass gatherings to slow the spread of the virus. Accordingly, the Company's ability to continue to operate its business may also be limited. Such events may result in a period of business, supply and drug product manufacturing disruption, and in reduced operations, any of which could materially affect the Company's business, financial condition and results of operations. In response to COVID-19, the Company implemented hybrid working for its office-based staff, while its research staff has been actively working in its laboratory throughout the pandemic and thus far, has not experienced a significant disruption or delay in its operations as it relates to the clinical development, preclinical research or manufacturing of its drug candidates. Although the Company is adhering to health and safety protocols, an outbreak of COVID-19 at the Company's facilities could nonetheless cause shutdowns of facilities and a reduction in its workforce, which could cause a disruption or delay in such operations. A continuation or worsening of the levels of market disruption and volatility seen in the recent past could have an adverse effect on the Company's ability to access capital, which could in the future negatively affect the Company's liquidity. In addition, a recession or market correction resulting from the spread of COVID-19 could materially affect the Company's business and the value of the Company's common stock.

Additionally, COVID-19 may result in delays in receiving approvals from local and foreign regulatory authorities, delays in necessary interactions with IRB's or Institutional Review Boards, local and foreign regulators, ethics committees and other important agencies and contractors due to limitations in employee resources or forced furlough of government employees.

To date, COVID-19 has not had a direct financial impact on the Company. The Company continues to monitor the impacts of COVID-19 on the global economy and on its business operations. However, at this time, it is difficult to predict how long the potential operational impacts of COVID-19 will last or to what degree further disruption might impact the Company's operations and financial results.

Cash, Cash Equivalents and Restricted Cash - The Company considers all highly liquid accounts with original maturities of three months or less to be cash equivalents. Balances held by the Company are typically in excess of Federal Deposit Insurance Corporation insured limits.

The following is a summary of cash, cash equivalents and restricted cash at September 30, 2022 and December 31, 2021:

(amounts in thousands)	**September 30, 2022**	**December 31, 2021**
Cash and cash equivalents	$ 111,815	$ 77,829
Restricted cash - current	394	392
Restricted cash – long-term	300	-
Cash, cash equivalents and restricted cash	$ 112,509	$ 78,221

Restricted cash relates to certificates of deposit held as collateral for letters of credit issued in connection with the Company's leases of corporate office spaces.

Leases – The Company has operating and finance leases for corporate office space, office equipment and furniture located at the corporate office space. Leases with an initial term of 12 months or less are not recorded on the balance sheet; lease expense for these leases is recognized on a straight-line basis over the lease term. The Company entered into a lease for corporate office space effective June 1, 2022 and paid a security deposit to the landlord. A certificate of deposit was provided as collateral for a letter of credit issued with this office space during 2022 and at that time, the security deposit was returned to the Company.

Revenue Recognition - The Company recognizes revenue in accordance with Accounting Standards Codification (ASC) Topic 606, *Revenue From Contracts With Customers* ("ASC 606"). Under ASC 606, an entity recognizes revenue when its customer obtains control of promised goods or services, in an amount that reflects the consideration that the entity expects to receive in exchange for those goods or services. To determine revenue recognition for arrangements within the scope of ASC 606, the entity performs the following five steps: (i) identify the contract(s) with a customer; (ii) identify the performance obligations in the contract; (iii) determine the transaction price, including variable consideration, if any; (iv) allocate the transaction price to the performance obligations in the contract; and (v) recognize revenue as the entity satisfies a performance obligation. The Company only applies the five-step model to contracts when it is probable that the entity will collect the consideration to which it is entitled in exchange for the goods or services it transfers to the customer.

At contract inception, once the contract is determined to be within the scope of ASC 606, the Company assesses whether the promised goods or services promised within each contract are distinct and, therefore, represent a separate performance obligation. Goods and services that are determined not to be distinct are combined with other promised goods and services until a distinct bundle is identified. In determining whether goods or services are distinct, the Company evaluates certain criteria, including whether (i) the customer can benefit from the good or service either on its own or together with other resources that are readily available to the customer (capable of being distinct) and (ii) the good or service is separately identifiable from other goods or services in the contract (distinct in the context of the contract).

The Company then determines the transaction price, which is the amount of consideration it expects to be entitled from a customer in exchange for the promised goods or services for each performance obligation and recognizes the associated revenue as each performance obligation is satisfied. The Company's estimate of the transaction price for each contract includes all variable consideration to which it expects to be entitled. Variable consideration includes payments in the form of collaboration milestone payments. If an arrangement includes collaboration milestone payments, the Company evaluates whether the milestones are considered probable of being reached and estimates the amount to be included in the transaction price using the most likely amount method. If it is probable that a significant revenue reversal would not occur, the associated milestone value is included in the transaction price.

ASC 606 requires the Company to allocate the arrangement consideration on a relative standalone selling price basis for each performance obligation after determining the transaction price of the contract and identifying the performance obligations to which that amount should be allocated. The relative standalone selling price is defined in the revenue standard as the price at which an entity would sell a promised good or service separately to a customer. The Company then recognizes as revenue the amount of the transaction price that is allocated to the respective performance obligation as each performance obligation is satisfied, either at a point in time or over time, and if over time, recognition is based on the use of an output or input method.

Collaborative Arrangements - The Company follows the accounting guidance for collaboration agreements with third parties, which requires that certain transactions between the Company and collaborators be recorded in its consolidated statements of operations and comprehensive loss on either a gross basis or net basis, depending on the characteristics of the collaborative relationship, and requires enhanced disclosure of collaborative relationships. The Company evaluates its collaboration agreements for proper classification in its consolidated statements of operations and comprehensive loss based on the nature of the underlying activity. When the Company has concluded that it has a customer relationship with one of its collaborators, the Company follows the guidance of ASC 606.

Grant Revenue – The Company has a grant from a government-sponsored entity for research and development related activities that provides for payments for reimbursed costs, which includes overhead and general and administrative costs as well as an administrative fee. The Company recognizes revenue from grants as it performs services and all conditions are met under this arrangement. Associated expenses are recognized when incurred as research and development expense. Revenue and related expenses are presented gross in the consolidated statements of operations.

License Revenue – The Company entered into a product licensing agreement whereby the Company allowed a third party to commercialize a certain product in specified territories using the Company's trademarks. The terms of this arrangement includes payment to the Company for a combination of one or more of the following: upfront license fees; development, regulatory and sales-based milestone payments; and royalties on net sales of licensed products. The Company uses its judgment to determine whether milestones or other variable consideration should be included in the transaction price.

Upfront license fees: If the license to the Company's intellectual property is determined to be distinct from the other performance obligations identified in the arrangement, the Company will recognize revenue from upfront license fees allocated to the license when the license is transferred to the licensee and the licensee is able to use and benefit from the license. For licenses that are bundled with other promises, the Company determines whether the combined performance obligation is satisfied over time or at a point in time.

Development, regulatory or commercial milestone payments: At the inception of each arrangement that includes payments based on the achievement of certain development, regulatory and sales-based or commercial events, the Company evaluates whether the milestones are considered probable of being achieved and estimates the amount to be included in the transaction price using the most likely amount method. If it is probable that a significant revenue reversal would not occur, the associated milestone value is included in the transaction price. Milestone payments that are not within the Company's or the licensee's control, such as regulatory approvals, are not considered probable of being achieved until regulatory approval is received. At the end of each subsequent reporting period, the Company will re-evaluate the probability of achieving such development and regulatory milestones and any related constraint, and if necessary, adjust the Company's estimate of the overall transaction price. Any such adjustments are recorded on a cumulative catch-up basis and recorded as part of license revenue during the period of adjustment.

Sales-based milestone payments and royalties: For arrangements that include sales-based royalties, including milestone payments based on the volume of sales, the Company will determine whether the license is deemed to be the predominant item to which the royalties or sales-based milestones relate and if such is the case, the Company will recognize revenue at the later of (i) when the related sales occur, or (ii) when the performance obligation to which some or all of the royalty has been allocated has been satisfied (or partially satisfied).

Upfront payments and fees may require deferral of revenue recognition to a future period until the Company performs its obligations under these arrangements or when it is probable that a significant reversal in the amount of cumulative revenue recognized will not occur or when the uncertainty associated with any variable consideration is subsequently resolved. Amounts payable to the Company are recorded as accounts receivable when the Company's right to consideration is unconditional.

Research and Development Costs - Research and development costs are expensed as incurred. These costs include the costs of manufacturing drug product, the costs of clinical trials, costs of employees and associated overhead, and depreciation and amortization costs related to facilities and equipment. Research and development reimbursements are recorded by the Company as a reduction of research and development costs.

Share-Based Payments - The Company estimates the fair value of each stock option award at the grant date by using the Black-Scholes option pricing model. The fair value determined represents the cost for the award and is recognized over the vesting period during which an employee is required to provide service in exchange for the award. The Company accounts for forfeitures of stock options as they occur.

Net Loss Per Common Share - Basic loss per common share is computed by dividing the net loss available to common stockholders by the weighted average number of shares of common stock outstanding during the reporting period. For periods of net loss, diluted loss per share is calculated similarly to basic loss per share because the impact of all potential dilutive common shares is anti-dilutive. For the three and nine months ended September 30, 2022 and 2021, the Company's potentially dilutive shares, which include outstanding common stock options, restricted stock units and warrants, have not been included in the computation of diluted net loss per share as the result would have been anti-dilutive.

(amounts in thousands)	**September 30, 2022**	**September 30, 2021**
Options	3,192	1,426
Restricted Stock Units	300	-
Warrants	1,443	2,114
Total	4,935	3,540

Recently Adopted Accounting Pronouncements – In May 2021, FASB issued ASU 2021-04, *Earnings Per Share (topic 260), Debt — Modifications and Extinguishments (Subtopic 470-50), Compensation – Stock Compensation (Topic 718) and Derivatives and Hedging – Contracts in an Entity's Own Equity (Subtopic 815-40) – Issuer's Accounting for Certain Modifications or Exchanges of Freestanding Equity-Classified Written Call Options*, which provides guidance of a modification or an exchange of a freestanding equity-classified written call option that remains equity classified after modification or exchange as (1) an adjustment to equity and, if so, the related earnings per share (EPS) effects, if any, or (2) an expense and, if so, the manner and pattern of recognition. The amendments in this ASU are effective January 1, 2022, including interim periods. The Company adopted this standard effective January 1, 2022 and the standard did not have a material effect on the Company's financial statements.

In November 2021, the FASB issued ASU 2021-10, *Government Assistance (Topic 832), Disclosures by Business Entities about Government Assistance*, which provides guidance on disclosure requirements to entities other than not-for-profit entities about transaction with a government that are accounted for by applying a grant or contribution accounting model by analogy. ASU 2021-10 requires an entity to make annual disclosures related to (1) the nature of the transactions and the related accounting policy used to account for the government transactions, (2) quantification and disclosure of amounts related to the government transactions included in balance sheet and income statement financial statement line items, and (3) significant terms and conditions of the government transactions, including commitments and contingencies. The amendments of ASU 2021-10 are effective January 1, 2022, including interim periods. The Company adopted this standard effective January 1, 2022, and the standard did not have a material impact on the Company's financial statements.

Recently Issued Accounting Pronouncements – In October 2021, FASB issued ASU 2021-08, *Business Combinations (Topic 805), Account for Contract Assets and Contract Liabilities from Contracts with Customers*, which provides guidance on accounting for contract assets and contract liabilities acquired in a business combination in accordance with ASC 606. To achieve this, an acquirer may assess how the acquiree applied ASC 606 to determine what to record for the acquired revenue contracts. Generally, this should result in an acquirer recognizing and measuring the acquired contract assets and contract liabilities consistent with how they were recognized and measured in the acquiree's financial statements. The amendments of ASU 2021-08 are effective January 1, 2023, including interim periods. Early adoption is permitted, including adoption in an interim period. The Company will evaluate the impact of ASU 2021-08 on any future business combinations the Company may enter in the future.

Note 2 - Commitments and Contingencies

On June 15, 2012, the Company entered into a license and sponsored research agreement with Fred Hutchinson Cancer Research Center ("FHCRC") to build upon previous and ongoing clinical trials with apamistamab (licensed antibody). FHCRC has completed both a Phase 1 and Phase 2 clinical trial with apamistamab. The Company has been granted exclusive rights to the antibody and related master cell bank developed by FHCRC. A milestone payment of $1 million will be due to FHCRC upon U.S. Food and Drug Administration ("FDA") approval of the first drug utilizing the licensed antibody. Upon commercial sale of the drug, royalty payments of 2% of net sales will be due to FHCRC.

Note 3 - Leases

The Company entered into a lease for corporate office space, effective June 1, 2022. The lease has a term of 5 years 2 months, with an expiration date of July 30, 2027, and a current annual rate of $0.6 million. The Company is also responsible for certain other costs, such as insurance, utilities and maintenance. As of September 30, 2022, the Company has two operating leases for corporate office space and two finance leases for office equipment and furniture located in one of the corporate office spaces. In addition, the Company has auxiliary corporate office space that it rents on a month-to-month basis; this rental is accounted for as an operating lease with the same term as the Company's main office.

The components of lease expense are as follows:

	Three months ended		Nine Months ended	
(amounts in thousands)	**September 30, 2022**	**September 30, 2021**	**September 30, 2022**	**September 30, 2021**
Operating lease expense	$ 206	$ 93	$ 440	$ 279
Finance lease cost				
Amortization of right-to-use assets	$ 14	$ 20	$ 54	$ 61
Interest on lease liabilities	$ -	$ 2	$ 2	$ 7
Total finance lease cost	$ 14	$ 22	$ 56	$ 68

Supplemental cash flow information related to leases are as follows:

Cash flow information:

(amounts in thousands)	Nine Months ended September 30, 2022	Nine Months ended September 30, 2021
Cash paid for amounts included in the measurement of lease liabilities:		
Operating cash flow use from operating leases	$ 302	$ 282
Operating cash flow use from finance leases	$ 2	$ 7
Financing cash flow use from finance leases	$ 48	$ 63
Non-cash activity:		
Right-of-use assets obtained in exchange for lease obligations:		
Operating leases	$ 2,605	$ -
Finance Leases	$ -	$ -

Weighted average remaining lease terms are as follows at September 30, 2022:

Weighted average remaining lease term:	
Operating leases	4.8 years
Finance Leases	1.3 year

As the interest rate implicit in the leases was not readily determinable at the time that the leases were evaluated, the Company used its incremental borrowing rate based on the information available in determining the present value of lease payments. The Company's incremental borrowing rate was based on the term of the lease, the economic environment of the lease and reflect the rate the Company would have had to pay to borrow on a secured basis. Below is information on the weighted average discount rates used at the time that the leases were evaluated:

Weighted average discount rates:	
Operating leases	4.8%
Finance Leases	8.0%

Maturities of lease liabilities are as follows:

(amounts in thousands) Year ending December 31,	Operating Leases	Finance Leases
2022 (excluding nine months ended September 30, 2022)	$ 50	$ 1
2023	606	4
2024	618	-
2025	630	-
2026	643	-
2027	380	-
Total lease payments	$ 2,927	$ 5
Less imputed interest	(331)	-
Present value of lease liabilities	$ 2,596	$ 5

Note 4 – Other revenue

The Company determined that certain collaborations with a third party are within the scope of ASC 606. The collaboration agreement is made up of multiple modules related to various research activities. The Company identified a single performance obligation to provide research services within each module for which the Company receives monetary consideration. The third party can choose to proceed with each module or can terminate the agreement at any time. The Company recognizes revenue for each module on a straight-line basis over the expected module period. Revenue for succeeding modules is not recognized until all contingencies are resolved, inclusive of the third party's ability to terminate the module. Other revenue recognized during the three months and nine months ended September 30, 2022 was $0.0 million and $0.9 million, respectively, and for the three months and nine months ended September 30, 2021 was $0.0 million and $0.9 million, respectively.

The Company has a grant from a government-sponsored entity for research and development related activities that provide for payments for reimbursed costs, which includes overhead and general and administrative costs as well as an administrative fee. The Company recognizes revenue from grants as it performs services under this arrangement. Associated expenses are recognized when incurred as research and development expense. Other revenue recognized during the three months and nine months ended September 30, 2022 was $0.0 million and $0.1 million, respectively. Other revenue recognized during the three and nine months ended September 30, 2021 was $0.2 million.

On April 7, 2022, the Company entered into a license and supply agreement (the "License Agreement") with Immedica Pharma AB ("Immedica"), pursuant to which Immedica licensed the exclusive product rights for commercialization of Iomab-B (I-131 apamistamab) in the European Economic Area, Middle East and North Africa (EUMENA) including Algeria, Andorra, Bahrain, Cyprus, Egypt, Iran, Iraq, Israel, Jordan, Kuwait, Lebanon, Libya, Monaco, Morocco, Oman, Palestine, Qatar, San Marino, Saudi Arabia, Switzerland, Syria, Tunisia, Turkey, the United Arab Emirates, the United Kingdom, the Vatican City and Yemen. Upon signing, the Company was entitled to an upfront payment of $35 million from Immedica, which was received in May 2022. Under the terms of the License Agreement, the Company is eligible to receive regulatory and commercial milestone payments and is entitled to receive royalties in the mid-20 percent range on net sales of the product in certain countries that may result from the License Agreement. The Company will continue to be responsible for certain clinical development activities and the manufacturing of Iomab-B and will retain commercialization rights in the U.S. and rest of the world.

The Company's contract liabilities are recorded within Other revenue deferred – current liability or Long-term license revenue deferred in its condensed consolidated balance sheets depending on the short-term or long-term nature of the payments to be recognized. The Company's contract liabilities primarily consist of advanced payments from licensees. Other revenue deferred – current liability was $0.1 million at September 30, 2022 and $0.9 million at December 31, 2021. Long-term license revenue deferred was $35.0 million at September 30, 2022; there was no long-term license revenue deferred at December 31, 2021. This deferred revenue will be recognized upon European Union regulatory approval of Iomab B.

Note 5 - Equity

In August 2020 the Company entered into the Capital on Demand™ Sales Agreement with JonesTrading Institutional Services LLC, or JonesTrading, pursuant to which the Company may sell, from time to time, through or to JonesTrading, up to an aggregate of $200 million of its common stock. Shares of common stock are offered pursuant to a shelf registration statement on Form S-3 filed with the SEC on August 7, 2020. As of December 31, 2021, the Company had sold 6.7 million shares of common stock, resulting in gross proceeds of $59.1 million and net proceeds of $57.0 million. For the nine months ended September 30, 2022, the Company sold 3.0 million shares of common stock, resulting in gross proceeds of $18.9 million and net proceeds of $18.3 million. For the nine months ended September 30, 2021, the Company sold 4.5 million shares of common stock, resulting in gross proceeds of $35.6 million and net proceeds of $34.5 million.

On June 28, 2022, the Company entered into an Amendment and Restated Capital on Demand™ Sales Agreement (the "A&R Sales Agreement") with JonesTrading and B. Riley Securities, Inc. ("B. Riley Securities"). The A&R Sales Agreement modifies the original Capital on Demand™ Sales Agreement to include B. Riley Securities as an additional sales agent thereunder.

Stock Options

The following is a summary of stock option activity for the nine months ended September 30, 2022:

(amounts in thousands, except for per-share amounts)	Number of Shares	Weighted Average Exercise Price	Weighted Average Remaining Contractual Term (in years)	Aggregate Intrinsic Value
Outstanding, January 1, 2022	1,362	$ 12.45	8.69	$ -
Granted	1,885	4.99		
Cancelled	(55)	11.06		
Outstanding, September 30, 2022	3,192	8.06	9.03	5,377
Exercisable, September 30, 2022	638	17.94	7.43	397

During the nine months ended September 30, 2022, the Company granted options to purchase 1.9 million shares of common stock with an exercise price ranging from $4.96 to $8.46 per share, a term of 10 years, and a vesting period of 4 years. The options have an aggregated fair value of $6.6 million that was calculated using the Black-Scholes option-pricing model. Variables used in the Black-Scholes option-pricing model include: (1) discount rate range from 1.52% to 3.45% (2) expected life of 6 years, (3) expected volatility range from 78.8% to 80.2%, and (4) zero expected dividends.

The fair values of all options issued and outstanding are being amortized over their respective vesting periods. The unrecognized compensation expense at September 30, 2022 was $9.7 million related to unvested options, which is expected to be expensed over a weighted average of 3.5 years. During the nine months ended September 30, 2022 and 2021, the Company recorded compensation expense related to stock options of $1.6 million and $1.0 million, respectively.

Restricted Stock Units

The Company issued 300 thousand restricted stock units ("RSUs") in August 2022 to an employee. These RSUs were immediately vested on the date of the grant, however, shares under the RSUs will not be issued until the earlier of a change of control event, the termination of the recipient's continuous service status for any reason other than by the Company for cause, or the third anniversary of the date of the grant. The fair value of the RSUs, $1.8 million, was determined based on the stock price of $5.85 on the date of the grant and is being recognized over three years. The unrecognized compensation expense at September 30, 2022 of $1.7 million is expected to be expensed over 2.9 years. During the three months and nine months ended September 30, 2022, the Company recorded compensation expense related to RSUs of $0.1 million.

Warrants

Following is a summary of warrant activity for the nine months ended September 30, 2022:

(in thousands, except for per-share amounts)	Number of Shares	Weighted Average Exercise Price	Weighted Average Remaining Contractual Term (in years)	Aggregate Intrinsic Value
Outstanding, January 1, 2022	2,112	$ 20.52	1.76	$ 276
Granted	-	-		
Exercised	-	-		
Cancelled/Expired	(669)	29.01		
Outstanding, September 30, 2022	1,443	$ 16.58	1.58	$ -
Exercisable, September 30, 2022	1,440	$ 15.95	1.58	$ -

On August 2, 2022, warrants to purchase an aggregate of 0.6 million shares of common stock expired. These warrants were issued on August 2, 2017, when the Company completed an underwritten offering of 0.7 million shares of common stock and warrants to purchase 0.6 million shares of common stock at a price of $22.50 per share and related warrant. The warrants were exercisable for a period of 5 years at an exercise price of $31.50 per share.

Note 6 – Subsequent Event

Since September 30, 2022, the Company has sold 0.3 million shares of common stock under its A&R Sales Agreement, resulting in net proceeds of $2.7 million.

ITEM 2. MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATION

FORWARD-LOOKING STATEMENT NOTICE

This Form 10-Q contains certain forward-looking statements. For this purpose, any statements contained in this Form 10-Q that are not statements of historical fact may be deemed to be forward-looking statements. Without limiting the foregoing, words such as "may," "will," "expect," "believe," "anticipate," "estimate" or "continue" or comparable terminology are intended to identify forward-looking statements. These statements by their nature involve substantial risks and uncertainties, and actual results may differ materially depending on a variety of factors, many of which are not within our control. These factors include but are not limited to economic conditions generally and in the industries in which we may participate; competition within our chosen industry, including competition from much larger competitors; technological advances and failure to successfully develop business relationships.

Description of Business

Actinium Pharmaceuticals, Inc. is a clinical-stage, biopharmaceutical company applying its proprietary platform technology and clinical experience to develop novel targeted radiotherapies for patients with unmet needs. Our targeted radiotherapies combine the cell-killing ability of radiation via a radioisotope payload with a targeting agent, such as a monoclonal antibody, to deliver radiation in a precise manner inside the body to specific, targeted cells such as cancer cells, to potentially achieve greater efficacy with lower toxicity than with cytotoxic chemotherapy or external beam radiation. Targeted radiotherapies also enable broader application of radiation than external beam radiation as they can be used in the treatment of both solid tumors and blood cancers, which generally cannot be treated with external radiation given their diffuse nature.

CD45 and CD33 are both expressed in multiple hematologic cancers, which are known to be highly sensitive to radiation. Our clinical programs against these targets are focused on two primary areas: (1) targeted conditioning prior to a bone marrow transplant ("BMT"), adoptive cell therapy ("ACT") such as CAR-T or gene therapy with Iomab-B and (2) targeted radiotherapy combinations with Actimab-A and other therapeutic agents.

Our most advanced clinical development program is Iomab-B, a CD45 targeting radiotherapy being developed to enable patients with blood cancers and other conditions to receive cellular and gene therapies. Iomab-B is being studied in the pivotal Phase SIERRA trial to enable a bone marrow transplant ("BMT") in patients with active, relapsed or refractory acute myeloid leukemia ("r/r AML") age 55 and above, a patient population not considerable eligible for BMT, which is the only potentially curative treatment option, with current approaches.

On October 31, 2022, we announced that Iomab-B met the primary endpoint of the SIERRA trial with a high degree of statistical significance ($p<0.0001$). Additional data from the SIERRA trial will be reported by year end 2022 including survival data. The trial was conducted in patients 55 years of age or older with r/r AML who typically cannot access a potentially lifesaving BMT as they are deemed unfit and thus unable to tolerate standard chemotherapy-based conditioning. Trial results showed that with Iomab-B conditioning, these patients have increased access to a BMT with a clinically meaningful duration of complete remission, along with a favorable safety profile, potentially establishing a new treatment option for the majority of the 10,000 r/r AML patients in the U.S. who are deemed unfit for BMT with current approaches.

Our second most advanced clinical program is Actimab-A, a CD33 targeting radiotherapy that we are developing as a therapeutic to be used in combination with our treatment modalities to leverage the potential synergistic mechanism of targeted radiation. Actimab-A is being studied in a Phase 1/2 combination trial with the salvage regimen CLAG-M in patients with r/r AML fit for intensive therapy and in a Phase 1/2 combination trial with Venetoclax, a targeted therapy, in patients with r/r AML who are both fit and unfit for intensive therapy.

On November 3, 2022, we announced that Phase 1 results from the Actimab-A CLAG-M trial were accepted for oral presentation at the American Society of Hematology ("ASH") Annual Meeting & Symposium on December 10, 2022. The study enrolled patients with r/r AML with a median age of 63, 2 lines of prior therapies (range: 1- 5), and 67% had adverse cytogenetics with 52% having a TP53 mutation. Prior treatment included BMT in 57% and prior Venetoclax therapy in 57% of patients. This patient population has dismal survival outcomes and outside of this novel combination clinical trial, would not be treated with CLAG-M. There was a 67% overall response rate ("ORR") across all dose cohorts and an 83% ORR at the recommended Phase 2 dose ("RP2D"). Overall, 72% of patients achieving a Complete Remission ("CR") or Complete Remission with incomplete count recovery ("CRi") were minimal residual disease ("MRD") negative and 83% of patients receiving the RP2D were MRD negative. Median overall survival was 12-months with a 53% 1-year overall survival rate and 32% 2-year overall survival rate. To provide context for this analysis, the median OS in patients who relapse post Venetoclax is less than 3 months and the median OS in patients who relapse with a TP53 mutation is less than 2 months. More detailed information will be presented in an oral presentation at ASH in December.

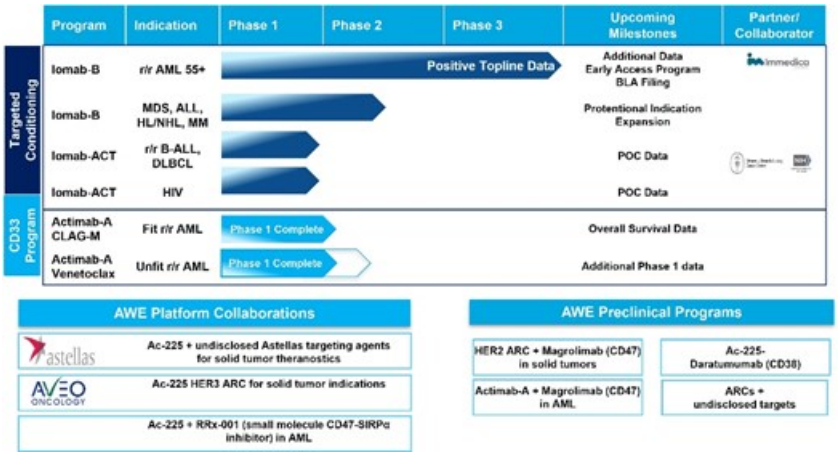
Data from our Actimab-A Venetoclax combination trial has been accepted for poster presentation at ASH. This trial is exploring the potential mechanistic synergy we elucidated in preclinical models, that depleting Mcl-1 via targeted radiation from Actimab-A can re-sensitize or reduce resistance to Venetoclax. We have observed responses including a CR in early-dose cohorts. This trial is ongoing with dose escalation and scheduling optimization ongoing. We expect to present proof of concept from the Phase 1 portion of this study in 2023.

We are studying Iomab-ACT, a low dose version of Iomab-B, for conditioning prior to CAR-T cellular therapy in collaboration with Memorial Sloan Kettering Cancer Center, which is funded by a National Institutes of Health ("NIH") grant. We have completed treatment of an initial cohort of 3 patients and will expand to a second cohort. We expect to present proof of concept data from this study in 2023.

Our clinical pipeline has emanated from our Antibody Warhead Enabling ("AWE") technology platform, which is protected by over 195 issued and pending patents, trade secrets and know-how that we are applying to the development of targeted radiotherapies for blood and solid tumor indications, independently and with collaborators. We are also utilizing our AWE technology platform to advance our research objectives focused on developing next-generation targeted radiotherapies with our expanded research and development organization and research laboratories leveraging our drug development experience.

Our Pipeline

We are advancing a pipeline of clinical-stage development programs that we believe can improve patient access to potentially curative treatments and improve patient outcomes. To the best of our knowledge, we are developing the most advanced multi-indication, clinical-stage radiotherapy pipeline for targeted conditioning. In addition, we believe we have the most experience with Actinium-225 based alpha therapies with approximately 150 patients treated across six Phase 1 and Phase 2 clinical trials.



Our product development strategy is actively informed by clinical data with our drug candidates Iomab-B, Actimab-A and Iomab-ACT in approximately 600 patients and 19 clinical trials, including the Pivotal Phase 3 SIERRA trial for Iomab-B, 12 prior clinical trials with Iomab-B at the Fred Hutchinson Cancer Research Center, 6 trials with Actimab-A and the MSKCC/NIH trial with Iomab-ACT. We are applying our clinical experience to address unmet patient needs with our programs:

Targeted Conditioning Programs for Cell and Gene Therapy: Iomab-B and Iomab-ACT are intended to potentially enable improved access and outcomes to cell-based therapies with curative potential, including BMT, ACT and gene therapy. Conditioning in the context of BMT, ACT or gene therapy is the act of depleting certain blood and immune-forming cells, including bone marrow stem cells and, in some cases, cancer cells prior to transplanting new cells into a patient. Currently, conditioning is accomplished using a combination of cytotoxic chemotherapeutic agents and external radiation. These non-targeted conditioning regimens are highly toxic and may prevent a patient from receiving a potentially curative therapy and hinder outcomes. We believe our targeted conditioning agents have the potential to increase patient access and outcomes by way of their ability to selectively deplete targeted cells while sparing normal healthy cells, resulting in potentially lower systemic and off-target toxicities. We intend to develop our targeted conditioning programs for BMT, ACT and gene therapy applications for malignant and non-malignant diseases and believe that multiple radioisotopes may be utilized including alpha and beta emitters.

Actinium-225 Based Therapeutic Backbone Therapy Program in AML: Our Actimab-A program demonstrates our leadership in the clinical development of Ac-225 therapeutics, as we focus this industry leading alpha-isotope based radiotherapy program as a backbone therapy for novel combinations in r/r AML. Actimab-A is the first radiotherapeutic for r/r AML and has the unique value proposition of broad applicability, a differentiated mechanism of action, and targeted precision that is well-tolerated with minimal toxicity. Specifically, Actimab-A targets CD33, which is expressed in virtually all AML patients regardless of cytogenetics or mutations and enables potent alpha radiation to be directed against radiosensitive AML cells that have no known resistance or repair mechanism when hit with the Ac-225 isotope payload that causes double stranded breaks in DNA. We believe that Actimab-A in combination with chemotherapy, targeted agents or immunotherapy, in r/r AML as a backbone therapy, represents a significant opportunity to improve patient outcomes in AML and are developing our product candidates according to this strategy.

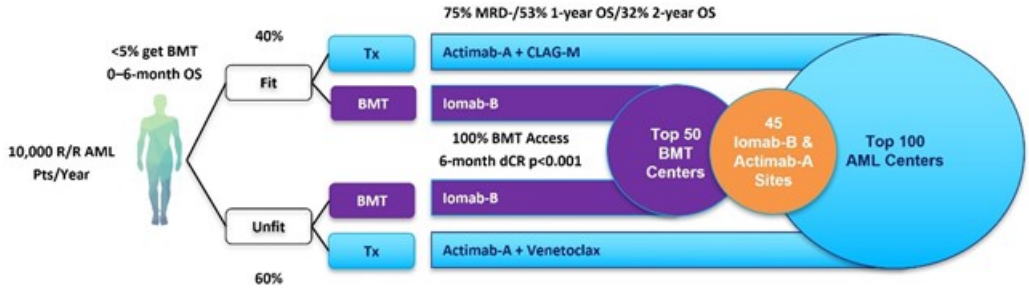
Platform Collaborations and Preclinical Programs: We are leveraging our clinical experience, robust intellectual property and radiotherapy know-how through research collaborations and our own preclinical development programs. Through our research collaborations, such as with Astellas, we are advancing into solid tumors indications. Here we can utilize the ability of radioisotopes to be used for diagnostic purposes as well as therapeutics, which is referred to as theranostics. We are also exploring novel targeted radiotherapies in solid tumors and blood cancers such as HER3 expressing solid tumors in collaboration with AVEO and combinations with immunotherapies such as CD47 immune checkpoint inhibitors with EpicentRx.

Acute Myeloid Leukemia and Relapsed or Refractory Disease

AML is a blood cancer that arises when hematopoietic progenitor cells fail to differentiate into functioning mature cells and begin to proliferate rapidly, crowding functional mature cells out of the bone marrow. AML is the most common acute leukemia with approximately 21,000 patients expected to be diagnosed in the U.S. this year. It is also one of the most lethal blood cancers with the lowest 5-year survival. The median age of diagnosis is 68 years of age and more than 50% of patients are over the age of 50. Treatment for AML is determined by a patient's fitness or ability to tolerate treatment intensity. Initial treatment is classified as intensive therapy with curative intent or lower intensity conditioning with non-curative intent. Chemotherapy regimens such as cytarabine and daunorubicin known as "7+3" are examples of intensive regimens, while azacytidine or other hypomethylating agents ("HMAs") are examples of lower intensity treatment. Multiple targeted agents have been approved since 2017, including Venetoclax, FLT3 inhibitors, IDH inhibitors, hedgehog pathway inhibitors and mylotarg. An estimated 60% of patients are fit and able to tolerate intensive therapy while 40% are unfit and can only receive less intensive therapy that does not have curative intent. Approximately 50% of patients ultimately relapse or develop refractory disease including primary induction failure, where a patient never achieves a remission. The only curative treatment option for relapsed or refractory AML is a BMT.

Development Strategy for Relapsed and Refractory AML

We are developing Iomab-B and Actimab-A to holistically address the unmet needs of both fit and unfit patients with AML, initially targeting the estimated 10,000 patients with relapsed or refractory disease. These patients are largely treated in approximately 100 centers and a majority of the BMTs are done in the top 50 centers. There is virtually total overlap between the top 50 BMT centers and top 100 AML treatment centers. By developing two targeted radiotherapies for this indication, we believe we can address a significant number of patients at various stages of their disease and treatment journey. We also believe we can produce operating leverage through synergies in supply chain and commercialization across both drug candidates. In addition, we believe both Iomab-B and Actimab-A have potential to be used in other blood cancer indications.



Iomab-B enables patients with r/rr AML with active disease, who cannot tolerate intensive therapy and who otherwise would not be considered for BMT, to receive a potentially curative BMT. The SIERRA trial demonstrated the ability of Iomab-B conditioning to enable 100% of patients to proceed to BMT and achieve rapid engraftment resulting in significantly higher rates of patients with Complete Remissions and durable Complete Remissions. The tolerable safety profile of Iomab-B and efficacy as shown in SIERRA trial could transform the treatment paradigm for r/r AML.

For r/r AML patients requiring salvage therapy, we believe combinations based on our Actimab-A alpha therapy have the potential to improve patient outcomes. We are combining Actimab-A with CLAG-M for patients fit for intensive therapy in a Phase 1 trial conducted at the Medical College of Wisconsin ("MCW"). This novel combination trial enrolled patients who otherwise would not be considered for CLAG-M and added Actimab-A to precisely target and kill any residual AML cells following treatment with CLAG-M. The Actimab-A CLAG-M combination has a manageable safety profile and produced high response rates, high rates of MRD negativity and 53% 1-year and 32% 2-year median overall survival in a cohort of heavily pretreated patients with adverse cytogenetics, including 52% of patients who had a TP53 mutation. These survival outcomes represent a significant improvement over current dismal survival rates in these very hard to treat patients and support continued development.

We are also studying Actimab in combination with Venetoclax for patients who are both unfit and fit for intensive therapy. Venetoclax is approved in combination with HMAs, and we believe Actimab-A has a more synergistic mechanism and that its targeted nature can produce better patient outcomes than Venetoclax HMA combinations. We are currently conducting a multi-center Phase 1/2 trial of this novel combination and are optimizing the dosing regimen for the anticipated Phase 2 portion of the trial.

Iomab-B

Iomab-B (I-131 apamistamab), our lead candidate and targeted conditioning agent is comprised of the anti-CD45 monoclonal antibody known as apamistamab (formerly BC8) and the radioisotope Iodine-131 ("I-131"). Iomab-B is a first-in-class targeted radiotherapy intended to improve patient access to potentially curative BMT by simultaneously and rapidly depleting blood cancer, immune and bone marrow stem cells that uniquely express CD45. CD45 is an antigen expressed on leukemia, lymphoma and myeloma cancer cells, but is not expressed outside of the hematopoietic, or blood-forming system. This unique expression on blood cancer and immune cells enables simultaneous depletion of both cell types, making CD45 an optimal antigen for targeted conditioning applications. CD45 is a cell surface antigen with an average expression of 200,000 copies per cell, however, it only internalizes at a rate of 10-15%. We believe our targeted radiotherapy approach is the most effective method to target CD45 positive cells, as the radioisotope payload linear energy transfer can readily ablate a targeted cell without requiring payload internalization like an antibody drug conjugate or without relying on biological effector function processes like a naked antibody. Developed at the Fred Hutchinson Cancer Research Center, a pioneer in the field of BMT, Iomab-B is supported by data in six disease indications including leukemias, lymphomas and multiple myeloma, which afflict over 100,000 patients annually. Studied in over 400 patients, prior studies with Iomab-B have demonstrated nearly universal access to BMT, increased survival and tolerability in multiple clinical trials including the recently completed pivotal Phase 3 SIERRA trial in patients with active leukemic blasts >5%, relapsed or refractory acute myeloid leukemia age 55 and above.

Pivotal Phase 3 SIERRA Trial

The pivotal Phase 3 SIERRA (Study of Iomab-B in Elderly relapsed or refractory AML) is a 153-patient, randomized, multi-center clinical trial, studying Iomab-B compared to the control arm of physician's choice of salvage therapy. Patients with active, r/r AML are not considered eligible for BMT with current approaches and the SIERRA trial is the only randomized Phase 3 trial to offer BMT as a treatment option for this patient population. The SIERRA trial compares outcomes of patients randomized to receive Iomab-B and a BMT (the "study arm") to those patients randomized to receive physician's choice of salvage therapy (the "control arm"). The control arm is also defined as conventional care, as no standard of care exists for this patient population and includes over 20 agents that may be used as single agents or in combination including Venetoclax, a targeted Bcl-2 inhibitor, Midostaurin and Sorafenib, targeted FLT3 inhibitors, hypomethylating agents and cytotoxic chemotherapies. Patients who fail to achieve a Complete Remission ("CR") on the control arm are ineligible to proceed to a BMT, but the trial design permits these patients to "cross over" to receive the study arm treatment if they meet the eligibility criteria. The primary endpoint of the SIERRA trial is durable Complete Remission ("dCR") of 180 days and the secondary endpoints are Overall Survival ("OS") and Event Free Survival ("EFS").

On October 31, 2022, we announced positive topline results from the SIERRA trial that Iomab-B met the study's dCR primary endpoint with a high degree of statistical significance ($p<0.0001$). Additional data from the SIERRA trial is expected to be presented by year-end 2022. Data from full patient enrollment in the SIERRA trial (153 patients), was previously presented at the Transplantation & Cellular Therapy (TCT) Tandem Meetings of ASTCT and CIBMTR, the combined annual meetings of the American Society for Transplantation and Cellular Therapy (ASTCT) and the Center for International Blood & Marrow Transplant Research (CIBMTR) in April 2022 and at ASH highlighting that 100% of patients (66/66) on the study arm that received a therapeutic dose of Iomab-B received a BMT, with a median time to BMT of 30 days, and all patients achieved neutrophil and platelet engraftment in a median time of 18 days despite a high median blast count of 30%. On the control arm, only 18% of patients (14/77) achieved remission after salvage therapy, and then received a BMT with a median time to BMT of 67 days and median blast count of 20%. Of the 82% of patients failing to achieve a complete remission ("CR") with conventional care (63/77), 40 patients were eligible and elected to cross over to receive Iomab-B followed by transplant. These patients are considered as having failed the primary endpoint of the study. All crossover patients who received the therapeutic dose of Iomab-B (40/40) received a BMT, with a median time to BMT of 24 days and they achieved engraftment in a median time of 19 days despite high median blast count of 35% at time of crossover. It was also reported that 100-day TRM of the study or Iomab-B arm was 09% (6/65) of patients that received a BMT compared to 14% of patients (2/14) who received a BMT after salvage therapy on the control arm. These data support the value proposition of Iomab-B enabling patients access to BMT who would not otherwise be eligible and potentially better outcomes. Actinium intends to submit a Biologics License Application (BLA) in 2023, seeking approval for Iomab-B to address patients age 55+ with r/r AML who cannot access BMT with currently available therapies. Iomab-B has been granted Orphan Drug Designation from the U.S. Food and Drug Administration (FDA) and has patent protection into 2037.

If approved, we expect our initial commercial launch will target the leading 50-100 BMT and medical centers that perform the vast majority of BMTs in the United States. In the European Union ("EU"), we received favorable feedback from the European Medicines Agency ("EMA") via their scientific advice program that the trial design, primary endpoint and planned statistical analysis from the SIERRA trial are acceptable as the basis for a Marketing Authorization Application, or MAA. Additionally, the EMA commented that it does not anticipate the need for further standalone preclinical toxicology or safety studies. Overall, transplant procedures in the EU are approximately fifty percent higher than in the United States with a similar market dynamic, with a majority of BMT volume being conducted in a concentrated number of leading medical centers. In April 2022, we entered into a license and supply agreement with Immedica Pharma AB, or Immedica, pursuant to which Immedica licensed the exclusive product rights for commercialization of Iomab-B in the European Economic Area, Middle East and North Africa. including Algeria, Andorra, Bahrain, Cyprus, Egypt, Iran, Iraq, Israel, Jordan, Kuwait, Lebanon, Libya. Monaco, Morocco, Oman, Palestine, Qatar, San Marino, Saudi Arabia, Switzerland, Syria, Tunisia, Turkey, the United Arab Emirates, the United Kingdom, the Vatican City and Yemen. Upon signing, we were entitled to an upfront payment of $35 million from Immedica, which we received in May 2022. Under the terms of the agreement, we are eligible to receive regulatory and commercial milestone payments and we are entitled to receive royalties in the mid-20 percent range on net sales of the product in certain countries that may result from the License Agreement. We will continue to be responsible for certain clinical development activities and the manufacturing of Iomab-B and will retain commercialization rights in the U.S. and rest of the world.

Iomab-ACT

Our Iomab-ACT program is intended for targeted conditioning prior to ACT or gene therapy and uses the same I-131-apamistamab construct as Iomab-B at varying doses. At lower doses of one-eighth to one-sixth of the myeloablative dose, it is applicable for lymphodepletion prior to CAR-T or certain gene therapy applications where stem cell myeloablation is not necessary. At higher doses it is applicable for gene therapy applications where stem cell myeloablation is necessary. We believe our Iomab-ACT program is highly differentiated when compared to Fludarabine and Cyclophosphamide ("Flu/Cy") or other chemotherapy-based regimens that are used as the standard of practice today for lymphodepletion prior to CAR-T. CD45 is an antigen expressed on certain immune cell types that are relevant to the mechanism of CAR-T therapies including lymphocytes, regulatory T-cells and macrophages that have been associated with clinical responses that may limit the safety, efficacy and durability of response of these CAR-T therapies including cytokine release syndrome ("CRS") and neurotoxicity. Some of these limitations may be attributable to the chemotherapy-based conditioning agents that are being used prior to CAR-T therapies. Unlike chemotherapy, Iomab-ACT is targeted in nature and due to this CD45-directed targeting, we expect we can improve CAR-T cell expansion, potentially resulting in responses that are more durable, but also resulting in reduced CAR-T related toxicities. Importantly, we expect the Iomab-ACT program construct to enable lymphodepletion through a single-dose, outpatient administration versus Flu/Cy or other chemotherapy-based lymphodepletion regimens that can require multiple infusion cycles over several days. Because of this potentially superior profile, the Iomab-ACT construct could result in improved access to CAR-T therapy and better outcomes.

We are studying Iomab-ACT in a clinical collaboration with Memorial Sloan Kettering Cancer Center ("MSKCC") for targeted conditioning prior to administration of MSKCC's 19-28z CD19, targeting CAR-T in patients with relapsed or refractory B-cell acute lymphoblastic leukemia ("ALL") or diffuse large B-cell lymphoma ("DLBCL"). We received grant funding from the National Institute of Health ("NIH") to fund this trial with MSKCC being a co-recipient on this grant. This is a first of its kind study to use an ARC-based conditioning regimen with CAR-T therapy. The hypothesized rationale for this study is that Iomab-ACT will exert an anti-tumor effect on the chemotherapy-refractory B-ALL cells that are sensitive to radiation, resulting in reduced disease burden and simultaneously deplete CD45 expressing immune cells implicated in CAR-T related toxicities, resulting in an optimal homeostatic environment for the CAR-T cells. The study will evaluate the feasibility of using a targeted radiotherapy based conditioning regimen with CAR-T therapy and will evaluate safety measures including incidence of CRS and neurotoxicity and efficacy measures, including responses and survival outcomes. We expect proof of concept data from this study in 2023.

In addition, we are working in collaboration with the University of California Davis to utilize Iomab-ACT conditioning with a novel anti-HIV autologous gene therapy. We continue to identify additional gene therapies for which Iomab-ACT can be used for targeted conditioning with the goal of collaborating with multiple academic or industry developers to establish Iomab-ACT as a non-chemotherapy universal targeted conditioning solution.

Actinium-225 Based Therapeutic Backbone Therapy Program in AML

Our CD33 Alpha program is evaluating the clinical utility of Actimab-A, comprised of the anti-CD33 mAb lintuzumab linked to the potent alpha-emitting radioisotope Actinium-225 ("Ac-225"). CD33 is expressed in the majority of patients with AML and myelodysplastic syndrome ("MDS") as well as approximately one-third of patients with multiple myeloma. Ac-225 emits four alpha particles and can kill a cell with one alpha-particle hit, making it one of the most powerful cell-killing agents with no know resistance mechanism to the double strand DNA breaks it can cause. We source Ac-225 from the Department of Energy's Oak Ridge National Laboratory. Our CD33 development program is driven by data obtained from over 150 treated patients, including results from a Phase 1/2 trial that studied Actimab-A as a single agent at multiple dose levels in 58 patients with newly diagnosed AML, which was completed in 2018, as well as trials studying Actimab-A in combination with other agents.

We believe that radiation delivered internally via a targeting moiety can be synergistic when used in combination with chemotherapy, targeted agents and immunotherapy based on mechanistic rationales supported by our own clinical data, preclinical research and scientific and clinical evidence in the literature. We have prioritized our efforts and resources in favor of combination trials for our CD33 program development strategy, rather than single agent trials at this time as we believe Actimab-A can be a backbone therapy in AML when combined with other therapeutic modalities. Our CD33 development program encompasses the following ongoing trials:

Actimab-A + CLAG-M

Actimab-A combined with CLAG-M has been studied in a Phase 1 combination trial that was conducted in collaboration with the Medical College of Wisconsin in patients age 18 and above with r/r AML. CLAG-M (cladribine, cytarabine, filgrastim and mitoxantrone) is a salvage chemotherapy regimen routinely used to treat patients with r/r AML. Data from the Phase 1 combination trial of Actimab-A + CLAG-M has been accepted for an oral presentation at ASH in December 2022. Patients enrolled on this study were a median of 63 years of age and were heavily pretreated with a median of 2 lines of prior treatment (range: 1-5) with 55% of patients receiving prior Venetoclax therapy and 55% receiving a prior BMT. Patients had high-risk cytogenetics with 67% having adverse features including 52% having a TP53 mutation. In addition, 52% of patients had secondary AML. Patients with r/r AML with a TP53 mutation have an expected median OS of 2 months and r/r AML patients who relapse after Venetoclax therapy have an expected survival of 2.4 months. Patients with these characteristics would not typically be considered for CLAG-M therapy outside of this clinical trial of the novel Actimab-A combination.

In the 21 patients evaluable for a response who received Actimab-A CLAG-M, median 1-year overall survival is 53% and 2-year overall survival is 32%. These survival results are in conjunction with a 72% rate of minimal residual disease ("MRD) negativity. In patients receiving the recommended Phase 2 dose, an 83% overall response rate ("ORR") and 75% MRD negativity rate was achieved. Based on these positive results, we are working to develop a regulatory and development pathway for the Actimab-A CLAG-M combination and will be evaluating potential registration-enabling strategies. In addition, we believe this Actimab-A + CLAG-M combination study has provided proof of principle that the addition of Actimab-A to other AML therapies can lead to well-tolerated regimens with improved responses and survival, which supports our Actimab-A backbone therapy strategy for patients with AML.

Actimab-A + Venetoclax

We are also conducting a Phase 1/2 trial combining Actimab-A with the Bcl-2 inhibitor Venetoclax in both fit and unfit patients age 18 and above with relapsed or refractory AML. This multi-center trial is being led by UCLA Medical Center. This combination is supported by mechanistic evidence in preclinical studies using Venetoclax - resistant AML tumor cell lines. In these models, we have demonstrated that Actimab-A can deplete Mcl-1 and Bcl-XL, two proteins implicated in mediating resistance to Venetoclax, in addition to causing potentially lethal double-stranded DNA breaks in these CD33 expressing cells. Furthermore, in vivo studies in animal models of Venetoclax-resistant AML demonstrated robust tumor regression and improved survival in cohorts receiving the Actimab-A Venetoclax combination compared to Venetoclax alone. The rationale for this clinical study is that the addition of Actimab-A will; 1) have a direct anti-tumor effect via double-stranded DNA breaks and 2) deplete Mcl-1 and Bcl-XL making the AML cells more susceptible to Venetoclax. The Actimab-A Venetoclax combination has been well tolerated with responses, including a CR and a partial response in early dose escalation cohorts. We are continuing dose escalation and evaluating the appropriate dose sequence to determine our strategy for the Phase 2 portion of this study. Additional data from this novel combination is expected by year-end 2022 and proof of concept in early 2023.

Antibody Warhead Enabling Technology Platform

Our proprietary AWE technology platform is supported by intellectual property, know-how and trade secrets that cover the generation, development, methods of use and manufacture of targeted radiotherapies and certain of their components. Our AWE technology patent portfolio presently includes 43 patent families comprised of over 195 issued patents and pending patent applications, of which 10 are issued and 37 are pending in the United States, and 144 are issued or pending internationally. The effective lives of the issued patents in our portfolio, or patents that may issue from the pending applications in our portfolio, ranges from expirations between 2024 and 2042. Our technology enables the direct labeling, or conjugation and labeling, of a biomolecular targeting agent to a radionuclide warhead and its development and use as a therapeutic regimen for the treatment of diseases such as cancer. Our AWE intellectual property covers various methods of use in multiple diseases, including indication, dose and scheduling, radionuclide warhead, and therapeutic combinations. We have particular expertise in utilizing the alpha emitting isotope Ac-225 including clinical experience in treating approximately 150 patients with our alpha-emitter-based therapies, "gold standard" linker technology and 5 issued patents in the United States and 49 patents internationally related to the manufacturing or Ac-225 in a cyclotron, which we believe has the potential to produce higher quantities of Ac-225 than currently utilized methods.

Our research is focused on applying our AWE technology platform to the development of radiation conjugates and to execute on research collaborations. Our R&D efforts employ a multidisciplinary approach leveraging our team's knowledge and experience in cancer cell biology, radiochemistry, radiation sciences, immunology and oncology drug development. We intend to focus on generating targeted radiotherapies using our existing intellectual property, evaluating assets for in-licensing to complement our existing clinical pipeline and securing collaborations and partnerships with biopharmaceutical companies. By adding research and development capabilities to our clinical development and clinical supply chain capabilities, we seek to enable the rapid translation of radiotherapies.

Our AWE technology platform is being utilized in our ongoing research collaboration with Astellas to arm select targeting agents owned by Astellas with the alpha-emitting radioisotope Ac-225 for the development of theranostics for solid tumor indications, which combine the ability of radioisotopes to be used for both diagnostic and therapeutic purposes.

We are also collaborating with AVEO Oncology ("AVEO") to develop a targeted radiotherapy against ErbB3, also known as HER3, with the Ac-225 isotope for solid tumor indications. HER3 is overexpressed in several solid tumor indications with high unmet needs, including colorectal, gastric, head and neck, breast, ovarian, melanoma, prostate and bladder cancers with HER3 agents under development demonstrating activity in preclinical and clinical studies. To our knowledge, this is the first HER3 targeting radiotherapy in development. AVEO is developing high affinity antibodies including HER3 targeting AV-203, which has demonstrated preclinical activity across a number of solid tumor indications and was studied in a Phase 1 open-label trial in patients with advanced solid tumors where it was found to be safe and generally well tolerated. In April 2022, we presented data at the AACR Annual Meeting showing potent tumor cell cytotoxicity, enhanced antitumor effects and significantly improved survival with an Ac-225 radiolabeled HER3 antibody compared to a naked HER3 antibody in a preclinical NSCLC model. We are continuing to explore the feasibility of this approach as part of the partnership.

We are collaborating with EpicentRx to evaluate Actimab-A in combination with EpicentRx's RRx-001in AML. EpicentRx's RRx-001, currently under investigation in a Phase 3 trial for Small Cell Lung Cancer and in other oncology and non-oncology indications, is a versatile next generation small molecule immunotherapeutic that targets the CD47-SIRPα axis and the NLRP3 inflammasome to alter the tumor microenvironment and optimize immune response. This collaboration will explore the mechanistic synergy of RRx-001's CD47–SIRPα downregulation with Actinium's targeted radiotherapy calreticulin upregulation to increase the immune detection and destruction of cancer cells. Preclinical experiments have begun exploring this combination in AML models. We intend to leverage our experience with CD47 targeting agents such as magrolimab in this collaboration. Based on Actimab-A and RRx-001 both being clinical-stage assets, we believe there is a potentially faster pathway to clinical trials with this novel combination, particularly if the preclinical safety and efficacy profile are in line with what was observed with Actimab-A and magrolimab.

We also utilized AWE to create a HER2-targeting radiotherapy using the antibody Trastuzumab with either Ac-225 or Lu-177 radioisotopes to study in combination with magrolimab for solid tumors. Anti-CD47 monotherapies, such as magrolimab, have not shown meaningful responses in clinical studies in solid tumors. We hypothesized that radiation directed at HER2 expressing cells would upregulate cell surface calreticulin, a pro-phagocytic "eat me" signal, that when combined with an anti-CD47 blockade therapy would enhance antitumor activity. The combination of the Ac-225 or Lu-117 Trastuzumab with magrolimab slowed tumor growth in animal models of solid tumors compared to either the radiolabeled Trastuzumab or magrolimab as single agents. We are continuing to evaluate this combination in additional tumor models, and we intend to continue to study this combination with the goal of advancing to human clinical trials.

Recent Developments

Impact of COVID–19 Pandemic

The global health crisis caused by the novel coronavirus COVID-19 pandemic and its resurgences has and may continue to negatively impact global economic activity, which, despite progress in vaccination efforts, remains uncertain and cannot be predicted with confidence. In addition, the Omicron variants of COVID-19, including subvariants BA.4 and BA.5, which appear to be the most transmissible variants to date, have spread globally. The full impact of the Omicron variants, or any subsequent variants, cannot be predicted at this time, and could depend on numerous factors, including vaccination rates among the population, the effectiveness of COVID-19 vaccines and boosters against the Omicron variants and the response by governmental bodies and regulators. Given the ongoing and dynamic nature of the circumstances, it is difficult to predict the impact of the COVID-19 pandemic on our business.

Many countries around the world have continued to impose quarantines and restrictions on travel and mass gatherings to slow the spread of the virus. Accordingly, our ability to continue to operate our business may also be limited. Such events may result in a period of business, supply and drug product manufacturing disruption, and in reduced operations, any of which could materially affect our business, financial condition and results of operations. In response to COVID-19, we implemented hybrid working for our office-based staff, while our research staff has been actively working in our laboratory throughout the pandemic and thus far have not experienced a significant disruption or delay in our operations as it relates to the clinical development, preclinical research or manufacturing of our drug candidates. Although we are adhering to health and safety protocols, an outbreak of COVID-19 at our facilities could nonetheless cause shutdowns of facilities and a reduction in our workforce, which could cause a disruption or delay in such operations. Certain government-imposed precautionary measures may have been relaxed in certain countries or states, but there is no assurance that more strict measures will be put in place again due to a resurgence in COVID-19 cases, including those involving new variants of the coronavirus, which may be more contagious and deadly than prior strains. Therefore, the COVID-19 pandemic, may further divert the attention and efforts of the medical community to coping with COVID-19, and may disrupt the marketplace in which we operate and may have a material adverse effect on our operations.

A continuation or worsening of the levels of market disruption and volatility seen in the recent past could have an adverse effect on our ability to access capital, which could in the future negatively affect our liquidity. In addition, a recession or market correction resulting from the spread of COVID-19 could materially affect our business and the value of our common stock.

We believe our earlier stage CD33 clinical trials will continue to recruit and enroll patients given the acute nature of relapsed or refractory AML. The continuation of the pandemic could adversely affect our planned clinical trial operations, including our ability to conduct the trials on the expected timelines and recruit and retain patients and principal investigators and site staff who, as healthcare providers, may have heightened exposure to COVID-19 if their geography is impacted by the pandemic. Further, the continuation and/or resurgence of the COVID-19 pandemic could result in delays in our clinical trials due to prioritization of hospital resources toward the pandemic, restrictions in travel, potential unwillingness of patients to enroll in trials at this time, or the inability of patients to comply with clinical trial protocols if quarantines or travel restrictions impede patient movement or interrupt healthcare services. In addition, we rely on independent clinical investigators, contract research organizations and other third-party service providers to assist us in managing, monitoring and otherwise carrying out our preclinical studies and clinical trials, and the pandemic may affect their ability to devote sufficient time and resources to our programs or to travel to sites to perform work for us, which may result in delays or hinder our ability to collect data from our clinical trials.

Additionally, COVID-19 may result in delays in receiving approvals from local and foreign regulatory authorities, delays in necessary interactions with IRB's or Institutional Review Boards, local and foreign regulators, ethics committees and other important agencies and contractors due to limitations in employee resources or forced furlough of government employees.

To date, COVID-19 has not had a direct financial impact on our company. We continue to monitor the impacts of COVID-19 on the global economy and on our business operations. However, the ultimate impact of COVID-19 on our business operations and financial results during 2022 will depend on, among other things, the ultimate severity and scope of the pandemic, including the new variants of the virus, the possible imposition of governmental and private travel restrictions and public concerns about public gatherings will ease, the rate at which historically large increases in unemployment rates will decrease, if at all, and whether, and the speed with which the economy recovers. We are not able to fully quantify the impact that these factors will have on our financial results during 2022 and beyond.

Results of Operations – Three Months Ended September 30, 2022 Compared to Three Months Ended September 30, 2021

The following table sets forth, for the periods indicated, data derived from our statements of operations:

	For the Three Months Ended September 30,	
(amounts in thousands)	**2022**	**2021**
Revenue:		
Revenue	$ -	$ -
Other revenue	45	233
Total revenue	45	233
Operating expenses:		
Research and development, net of reimbursements	6,771	4,708
General and administrative	3,073	1,994
Total operating expenses	9,844	6,702
Other income:		
Interest income – net	325	46
Total other income	325	46
Net loss	$ (9,474)	$ (6,423)

Revenue

We recorded no commercial revenue for the three months ended September 30, 2022 and September 30, 2021.

Other revenue

We determined that certain collaborations with a third-party are within the scope of Topic ASC 606, *Revenue Recognition from Contracts with Customers,* or ASC 606. The collaboration agreement is made up of multiple modules related to various research activities. While the third party has the option to terminate the agreement at the conclusion of any module, we identified a single performance obligation to provide research services within each module for which we receive monetary consideration. Other revenue recognized during the three months ended September 30, 2022 was $45 thousand. No revenue associated with this collaboration was recognized during the three months ended September 30, 2021.

The National Institutes of Health, or NIH, awarded us a Small Business Technology Transfer cost reimbursable grant to support a clinical collaboration with Memorial Sloan Kettering Cancer Center, or MSK, to study Iomab-ACT for targeted conditioning to achieve lymphodepletion prior to administration of a CD19-targeted CAR T-cell therapy developed at MSK. No revenue associated with this grant was recognized during the three months ended September 30, 2022. We recognized other revenue during the three months ended September 30, 2021 of $0.2 million.

Research and development, net of reimbursements

Research and development expenses of $6.8 million for the three months ended September 30, 2022 increased $2.1 million from $4.7 million for the three months ended September 30, 2021. The increase was primarily due to increased CMC activity, higher expenses related to our research activities at our laboratory space, as well as higher expenses due to an increase in the number of employees.

General and administrative

General and administrative expenses of $3.1 million for the three months ended September 30, 2022 increased $1.1 million from $2.0 million for the three months ended September 30, 2021. The increase was primarily attributable to increased non-cash equity compensation of $0.5 million, and increased compensation due to an increase in the number of employees.

Other income

Other income is comprised of net interest income in both reporting periods. The amount for the three months ended September 30, 2022 of $325 thousand increased from $46 thousand for the three months ended September 30, 2021 due to a higher average balance and higher interest rates.

Net loss

Net loss of $9.5 million for the three months ended September 30, 2022 increased by $3.1 million from $6.4 million for the three months ended September 30, 2021, primarily due to the increases in research and development expenses and general and administrative expenses.

Results of Operations – Nine Months Ended September 30, 2022 Compared to Nine Months Ended September 30, 2021

The following table sets forth, for the periods indicated, data derived from our statements of operations:

(amounts in thousands)	For the Nine Months Ended September 30, 2022	2021
Revenue:		
Revenue	$ -	$ -
Other revenue	1,030	1,121
Total revenue	1,030	1,121
Operating expenses:		
Research and development, net of reimbursements	15,802	12,615
General and administrative	8,041	5,422
Total operating expenses	23,843	18,037
Other income:		
Interest income – net	443	152
Total other income	443	152
Net loss	$ (22,370)	$ (16,764)

Revenue

We recorded no commercial revenue for the nine months ended September 30, 2022 and September 30, 2021.

Other revenue

We determined that certain collaborations with a third-party are within the scope of ASC 606. Other revenue related to these collaborations recognized during the nine months ended September 30, 2022 and September 30, 2021 was $0.9 million in each reporting period.

We recognized other revenue related to our NIH Small Business Technology Transfer grant during the nine months ended September 30, 2022 and September 30, 2021 of $0.1 million and $0.2 million, respectively.

Our contract liabilities are recorded within Other revenue deferred – current liability or Long-term license revenue deferred in our condensed consolidated balance sheets depending on the short-term or long-term nature of the payments to be recognized. Our contract liabilities primarily consist of advanced payments from licensees. Other revenue deferred – current liability was $0.1 million at September 30, 2022 and $0.9 million at December 31, 2021. Long-term license revenue deferred was $35.0 million at September 30, 2022; there was no long-term license revenue deferred at December 31, 2021. This deferred revenue will be recognized upon European Union regulatory approval of Iomab B.

Research and development, net of reimbursements

Research and development expenses of $15.8 million for the nine months ended September 30, 2022 increased $3.2 million from $12.6 million for the nine months ended September 30, 2021. The increase was due to increased CMC activity, higher expenses related to our research activities at our laboratory space and government grant program and increased compensation of $0.5 million resulting from an increased number of employees.

General and administrative

General and administrative expenses of $8.0 million for the nine months ended September 30, 2022 increased $2.6 million from $5.4 million for the nine months ended September 30, 2021. The increase was primarily attributable to increased compensation of $1.1 million, increased non-cash equity compensation of $0.5 million, higher professional fees and consulting fees including recruitment costs, and higher legal fees.

Other income

Other income is comprised of net interest income in both reporting periods. The amount for the nine months ended September 30, 2022 of $443 thousand increased from $152 thousand for the nine months ended September 30, 2021 due to a higher average balance and higher interest rates.

Net loss

Net loss of $22.4 million for the nine months ended September 30, 2022 increased by $5.6 million from $16.8 million for the nine months ended September 30, 2021, due to the increases in research and development expenses and general and administrative expenses.

Liquidity and Capital Resources

Historically, we have financed our operations primarily through sales of shares of our stock. The following tables sets forth selected cash flow information for the periods indicated:

	For the Nine Months Ended September 30,	
(amounts in thousands)	**2022**	**2021**
Cash provided by/used in operating activities	$ 16,422	$ (15,814)
Cash used in investing activities	(350)	(133)
Cash provided by financing activities	18,216	34,420
Net change in cash, cash equivalents and restricted cash	$ 34,288	$ 18,473

Net cash provided by operating activities for the nine months ended September 30, 2022 of $16.4 million increased by $32.2 million from a use of funds of $15.8 million in the prior-year period. This increase was due to the receipt of the $35.0 million up-front payment from Immedica.

Net cash used in investing activities of $0.4 million for the nine months ended September 30, 2022 and $0.1 million for the prior-year period are primarily due to the acquisition of equipment for our laboratory.

Net cash provided by financing activities for the nine months ended September 30, 2022 of $18.2 million and for the nine months ended September 30, 2021 of $34.4 million was primarily from the sale of shares of our common stock.

We entered into a lease for corporate office space effective June 1, 2022 and paid a security deposit to the landlord. The lease has a term of 5 years 2 months, with an expiration date of July 30, 2027, and a current annual rate of $0.6 million. We are also responsible for certain other costs, such as insurance, utilities and maintenance. In July, 2022 a certificate of deposit was provided as collateral for a letter of credit and the security deposit was returned.

In August 2020 we entered into a Capital on Demand™ Sales Agreement with JonesTrading Institutional Services LLC, or JonesTrading, pursuant to which we may sell, from time to time, through or to JonesTrading, up to an aggregate of $200 million of our common stock. Shares of common stock are offered pursuant to our shelf registration statement on Form S-3 filed with the SEC on August 7, 2020. On June 28, 2022, we entered into an Amendment and Restated Capital on Demand™ Sales Agreement, or the A&R Sales Agreement, with JonesTrading and B. Riley Securities, Inc., or B. Riley Securities. The A&R Sales Agreement modifies the original Capital on Demand™ Sales Agreement to include B. Riley Securities as an additional sales agent thereunder.

As of December 31, 2021, we had sold 6.7 million shares of common stock, resulting in gross proceeds of $59.1 million and net proceeds of $57.0 million. For the nine months ended September 30, 2022, we sold 3.0 million shares of common stock, resulting in gross proceeds of $18.9 million and net proceeds of $18.3 million. For the nine months ended September 30, 2021, we sold 4.5 million shares of common stock, resulting in gross proceeds of $35.6 million and net proceeds of $34.5 million.

As of the date of filing this report, we expect that our existing resources will be more than sufficient to fund our planned operations for more than 12 months following the date of this report.

Critical Accounting Policies and Use of Estimates

Our management's discussion and analysis of financial condition and results of operations is based on our consolidated financial statements, which have been prepared in accordance with accounting principles generally accepted in the United States, ("GAAP"). The preparation of these financial statements requires us to make estimates and judgments that affect the reported amounts of assets, liabilities and expenses and the disclosure of contingent assets and liabilities in our consolidated financial statements during the reporting periods. These items are monitored and analyzed by us for changes in facts and circumstances, and material changes in these estimates could occur in the future. We base our estimates on historical experience, known trends and events, and on various other factors that we believe are reasonable under the circumstances, the results of which form the basis for making judgments about the carrying value of assets and liabilities that are not readily apparent from other sources. Changes in estimates are reflected in reported results for the period in which they become known. Actual results may differ materially from these estimates under different assumptions or conditions.

Our significant accounting policies are described in detail in the notes to our consolidated financial statements appearing in our Annual Report filed on Form 10-K for the year ended December 31, 2021.

Revenue Recognition

We recognize revenue in accordance with ASC 606. Under ASC 606, we recognize revenue when our customer obtains control of promised goods or services, in an amount that reflects the consideration that we expect to receive in exchange for those goods or services. To determine revenue recognition for arrangements within the scope of ASC 606, we perform the following five steps: (i) identify the contract(s) with a customer; (ii) identify the performance obligations in the contract; (iii) determine the transaction price, including variable consideration, if any; (iv) allocate the transaction price to the performance obligations in the contract; and (v) recognize revenue as we satisfy a performance obligation. We only apply the five-step model to contracts when it is probable that we will collect the consideration to which we are entitled in exchange for the goods or services we transfer to the customer.

At contract inception, once the contract is determined to be within the scope of ASC 606, we assess whether the promised goods or services promised within each contract are distinct and, therefore, represent a separate performance obligation. Goods and services that are determined not to be distinct are combined with other promised goods and services until a distinct bundle is identified. In determining whether goods or services are distinct, we evaluate certain criteria, including whether (i) the customer can benefit from the good or service either on its own or together with other resources that are readily available to the customer (capable of being distinct) and (ii) the good or service is separately identifiable from other goods or services in the contract (distinct in the context of the contract).

ASC 606 requires us to allocate the arrangement consideration on a relative standalone selling price basis for each performance obligation after determining the transaction price of the contract and identifying the performance obligations to which that amount should be allocated. The relative standalone selling price is defined in the new revenue standard as the price at which an entity would sell a promised good or service separately to a customer. We then recognize as revenue the amount of the transaction price that is allocated to the respective performance obligation as each performance obligation is satisfied, either at a point in time or over time, and if over time, recognition is based on the use of an output or input method.

Collaborative Arrangements

We follow the accounting guidance for collaboration agreements, which requires that certain transactions between us and collaborators be recorded in our consolidated statements of operations and comprehensive loss on either a gross basis or net basis, depending on the characteristics of the collaborative relationship, and requires enhanced disclosure of collaborative relationships. We evaluate our collaboration agreements for proper classification in our consolidated statements of operations and comprehensive loss based on the nature of the underlying activity. When we conclude that we have a customer relationship with one of our collaborators, we follow the guidance of ASC 606.

License Revenue

We entered into a product licensing agreement whereby we allowed a third party to commercialize a certain product in specified territories using our trademarks. The terms of this arrangement includes payment to us for a combination of one or more of the following: upfront license fees; development, regulatory and sales-based milestone payments; and royalties on net sales of licensed products. We use judgment to determine whether milestones or other variable consideration should be included in the transaction price.

Upfront license fees: If the license to our intellectual property is determined to be distinct from the other performance obligations identified in the arrangement, we will recognize revenue from upfront license fees allocated to the license when the license is transferred to the licensee and the licensee is able to use and benefit from the license. For licenses that are bundled with other promises, we determine whether the combined performance obligation is satisfied over time or at a point in time.

Development, regulatory or commercial milestone payments: At the inception of each arrangement that includes payments based on the achievement of certain development, regulatory and sales-based or commercial events, we evaluate whether the milestones are considered probable of being achieved and estimate the amount to be included in the transaction price using the most likely amount method. If it is probable that a significant revenue reversal would not occur, the associated milestone value is included in the transaction price. Milestone payments that are not within our or the licensee's control, such as regulatory approvals, are not considered probable of being achieved until regulatory approval is received. At the end of each subsequent reporting period, we will re-evaluate the probability of achieving such development and regulatory milestones and any related constraint, and if necessary, adjust our estimate of the overall transaction price. Any such adjustments are recorded on a cumulative catch-up basis and recorded as part of license revenues during the period of adjustment.

Sales-based milestone payments and royalties: For arrangements that include sales-based royalties, including milestone payments based on the volume of sales, we will determine whether the license is deemed to be the predominant item to which the royalties or sales-based milestones relate and if such is the case, we will recognize revenue at the later of (i) when the related sales occur, or (ii) when the performance obligation to which some or all of the royalty has been allocated has been satisfied (or partially satisfied).

Upfront payments and fees may require deferral of revenue recognition to a future period until we perform our obligations under these arrangements or when it is probable that a significant reversal in the amount of cumulative revenue recognized will not occur when the uncertainty associated with any variable consideration is subsequently resolved. Amounts payable to us are recorded as accounts receivable when our right to consideration is unconditional.

Research and Development Costs

Research and development costs are expensed as incurred. These costs include the costs of manufacturing drug product, the costs of clinical trials, costs of employees and associated overhead, and depreciation and amortization costs related to facilities and equipment. Research and development reimbursements are recorded by us as a reduction of research and development costs.

Share-Based Payments

We estimate the fair value of each stock option award at the grant date by using the Black-Scholes option pricing model. The fair value determined represents the cost for the award and is recognized over the vesting period during which an employee is required to provide service in exchange for the award. We account for forfeitures of stock options as they occur.

Accounting Standards Recently Adopted

In May 2021, FASB issued ASU 2021-04, *Earnings Per Share (topic 260), Debt — Modifications and Extinguishments (Subtopic 470-50), Compensation – Stock Compensation (Topic 718) and Derivatives and Hedging – Contracts in an Entity's Own Equity (Subtopic 815-40) – Issuer's Accounting for Certain Modifications or Exchanges of Freestanding Equity-Classified Written Call Options*, which provides guidance of a modification or an exchange of a freestanding equity-classified written call option that remains equity classified after modification or exchange as (1) an adjustment to equity and, if so, the related earnings per share (EPS) effects, if any, or (2) an expense and, if so, the manner and pattern of recognition. The amendments in this ASU are effective January 1, 2022, including interim periods. We adopted this standard effective January 1, 2022 and the standard did not have a material effect on our financial statements.

In November 2021, the FASB issued ASU 2021-10, *Government Assistance (Topic 832), Disclosures by Business Entities about Government Assistance*, which provides guidance on disclosure requirements to entities other than not-for-profit entities about transaction with a government that are accounted for by applying a grant or contribution accounting model by analogy. ASU 2021-10 requires an entity to make annual disclosures related to (1) the nature of the transactions and the related accounting policy used to account for the government transactions, (2) quantification and disclosure of amounts related to the government transactions included in balance sheet and income statement financial statement line items, and (3) significant terms and conditions of the government transactions, including commitments and contingencies. The amendments of ASU 2021-10 are effective January 1, 2022, including interim periods. We adopted this standard effective January 1, 2022 and the standard did not have a material impact on our financial statements.

Accounting Standards Recently Issued

In October 2021, FASB issued ASU 2021-08, *Business Combinations (Topic 805), Account for Contract Assets and Contract Liabilities from Contracts with Customers*, which provides guidance on accounting for contract assets and contract liabilities acquired in a business combination in accordance ASC 606. To achieve this, an acquirer may assess how the acquiree applied ASC 606 to determine what to record for the acquired revenue contracts. Generally, this should result in an acquirer recognizing and measuring the acquired contract assets and contract liabilities consistent with how they were recognized and measured in the acquiree's financial statements. The amendments of ASU 2021-08 are effective January 1, 2023, including interim periods. Early adoption is permitted, including adoption in an interim period. We will evaluate the impact of ASU 2021-08 on any future business combinations that we may enter in the future.

Recent Developments

On August 10, 2022, our Board of Directors adopted the Third Amendment to Actinium Pharmaceuticals, Inc. 2019 Stock Plan, which provided for the future issuance of restricted stock units under the Company's 2019 Stock Plan.

Subsequent Event

Since September 30, 2022, we have sold 0.3 million shares of common stock under our A&R Sales Agreement, resulting in net proceeds of $2.7 million.

ITEM 3. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK.

We are not currently exposed to significant market risk related to changes in interest rates. As of September 30, 2022, our cash equivalents consisted primarily of short-term money market funds. Our primary exposure to market risk is interest rate sensitivity, which is affected by changes in the general level of U.S. interest rates. Due to the short-term nature of the cash equivalents in our portfolio and the low risk profile of our cash equivalents, an immediate 10% change in interest rates would not have a material effect on the fair market value of our financial position or results of operations.

We are not currently exposed to significant market risk related to changes in foreign currency exchange rates. Our operations may be subject to fluctuations in foreign currency exchange rates in the future.

Inflation generally affects us by increasing our cost of labor and clinical trial costs. We do not believe that inflation had a material effect on our business, financial condition or results of operations during the nine months ended September 30, 2022 and 2021.

ITEM 4. CONTROLS AND PROCEDURES.

Evaluation of Disclosure Controls and Procedures. Under the supervision and with the participation of our management, including our principal executive officer and principal financial and accounting officer, we conducted an evaluation of the effectiveness, as of September 30, 2022, of our disclosure controls and procedures, as defined in Rules 13a-15(e) and 15d-15(e) under the Securities Exchange Act of 1934, as amended, or the Exchange Act. Based upon such evaluation, our principal executive officer and principal financial and accounting officer have concluded that, as of September 30, 2022, our disclosure controls and procedures were effective to provide reasonable assurance that the information we are required to disclose in our filings with the Securities and Exchange Commission, or SEC, under the Exchange Act (i) is recorded, processed, summarized and reported within the time periods specified in the SEC's rules and forms and (ii) accumulated and communicated to our management, including our principal executive officer and principal financial and accounting officer, as appropriate to allow timely decisions regarding required disclosure.

Changes in Internal Control over Financial Reporting. There were no changes in our system of internal controls over financial reporting during the period covered by this report that has materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

PART II – OTHER INFORMATION

ITEM 1. LEGAL PROCEEDINGS

None.

ITEM 1A. RISK FACTORS

In analyzing our company, you should consider carefully the following risk factors, together with all of the other information included in this Quarterly Report on Form 10-Q. Factors that could cause or contribute to differences in our actual results include those discussed in the following subsection, as well as those discussed above in "Management's Discussion and Analysis of Financial Condition and Results of Operations" and in our Annual Report filed on Form 10-K for the year ended December 31, 2021. Each of the following risk factors, either alone or taken together, could adversely affect our business, operating results and financial condition, as well as adversely affect the value of an investment in our company. The risks and uncertainties described below are not the only ones we face. Additional risks not currently known to us or other factors not perceived by us to present significant risks to our business at this time also may impair our business operations.

Summary of Risk Factors

We are providing the following summary of the risk factors contained in this Annual Report on Form 10-K to enhance the readability and accessibility of our risk factor disclosures. We encourage you to carefully review the full risk factors contained in this Annual Report on Form 10-K in their entirety for additional information regarding the material factors that make an investment in our securities speculative or risky. These risks and uncertainties include, but are not limited to, the following:

- We are a clinical-stage company and have generated no revenue from commercial sales to date;
- We have incurred net losses in every year since our inception and anticipate that we will continue to incur net losses in the future;
- If we fail to obtain additional financing, we will be unable to continue or complete our product development and you will likely lose your entire investment;
- We are highly dependent on the success of Iomab-B and the SIERRA trial and we may not be able to complete the necessary clinical development or our development efforts may not result in the data necessary to receive regulatory approval;
- Our business could be adversely affected by the effects of health epidemics, including the global COVID-19 pandemic;
- We have not demonstrated that any of our products are safe and effective for any indication and will continue to expend substantial time and resources on clinical development before any of our current or future product candidates will be eligible for FDA approval, if ever;
- Our clinical trials may fail to demonstrate adequately the efficacy and safety of our product candidates, which would prevent or delay regulatory approval and commercialization;
- Preliminary, Interim, and "top-line" data from our clinical trials that we announce or publish from time to time may change as more patient data become available and are subject to audit and verification procedures that could result in material changes in the final data.;

- Healthcare legislative reform measures intended to increase pressure to reduce prices of pharmaceutical products paid for by Medicare or, otherwise, affect the federal regulation of the U.S. healthcare system could have a material adverse effect our business, future revenue, if any, and results of operations;

- We rely on third parties to conduct our clinical trials. If these third parties do not successfully carry out their contractual duties or meet expected deadlines or comply with regulatory requirements, we may not be able to obtain regulatory approval for or commercialize our product candidates;

- We currently depend on a single third-party manufacturer to produce our pre-clinical and clinical trial drug supplies. Any disruption in the operations of our current third-party manufacturer, or other third-party manufacturers we may engage in the future, could adversely affect our business and results of operations;

- Our product candidates may cause undesirable side effects or have other properties that could halt their clinical development, prevent their regulatory approval, limit their commercial potential, or result in significant negative consequences;

- Our patent position is highly uncertain and involves complex legal and factual questions.

- The use of hazardous materials, including radioactive and biological materials, in our research and development efforts imposes certain compliance costs on us and may subject us to liability for claims arising from the use or misuse of these materials;

- We are highly dependent on our key personnel, and the demand for talent in the biotechnology industry is highly competitive; if we are not successful in attracting and retaining highly qualified personnel, we may not be able to successfully implement or execute our business strategy;

- Certain provisions of our Certificate of Incorporation and Bylaws and Delaware law make it more difficult for a third party to acquire us and make a takeover more difficult to complete, even if such a transaction were in our stockholders' interest; and

- Our ability to utilize our net operating loss carryforwards and certain other tax attributes may be limited.

Risks Related to Our Business

We are a clinical-stage company and have generated no revenue from commercial sales to date.

We are a clinical-stage biopharmaceutical company with a limited operating history. We have no products approved for commercial sale and have not generated any revenue from product sales to date. We will encounter risks and difficulties frequently experienced by early-stage companies in rapidly evolving fields. If we do not address these risks successfully, our business will suffer.

We have incurred net losses in every year since our inception and anticipate that we will continue to incur net losses in the future.

We are not profitable and have incurred losses in each period since our inception. As of September 30, 2022, and December 31, 2021, we had an accumulated deficit of $278.1 million and $255.7 million, respectively. We reported a net loss of $22.3 million and $16.8 million for the nine months ended September 30, 2022, and 2021, respectively. We expect to continue to operate at a net loss as we continue our research and development efforts, continue to conduct clinical trials and develop manufacturing, sales, marketing and distribution capabilities. There can be no assurance that the products under development by us will be approved for sale in the United States or elsewhere. Furthermore, there can be no assurance that if such products are approved, they will be successfully commercialized, which would have an adverse effect on our business prospects, financial condition and results of operation.

If we fail to obtain additional financing, we will be unable to continue or complete our product development and you will likely lose your entire investment.

As of the date of filing this report, we expect that our existing resources will be more than sufficient to fund our planned operations for more than 12 months following the date of this report.

Our business or operations may change in a manner that would consume available funds more rapidly than anticipated and substantial additional funding may be required to maintain operations, fund expansion, develop new or enhanced products, acquire complementary products, business or technologies or otherwise respond to competitive pressures and opportunities, such as a change in the regulatory environment or a change in preferred cancer treatment modalities. However, we may not be able to secure funding when we need it or on favorable terms or indeed on any terms. In addition, from time to time, we may not be able to secure enough capital in a timely enough manner which may cause the generation of a going-concern opinion from our auditors which can and may impair our stock market valuation and also our ability to finance on favorable terms or indeed on any terms.

To raise additional capital, we may in the future offer additional shares of our common stock or other securities convertible into or exchangeable for our common stock. We cannot assure you that we will be able to sell shares or other securities in any other offering at a price per share that is equal to or greater than the price per share paid by investors, and investors purchasing shares or other securities in the future could have rights superior to existing stockholders.

If we cannot raise adequate funds to satisfy our capital requirements, we will have to delay, scale back or eliminate our research and development activities, clinical studies or future operations. We may also be required to obtain funds through arrangements with collaborators, which arrangements may require us to relinquish rights to certain technologies or products that we otherwise would not consider relinquishing, including rights to future product candidates or certain major geographic markets. We may further have to license our technology to others. This could result in sharing revenues which we might otherwise have retained for ourselves. Any of these actions may harm our business, financial condition and results of operations.

The amount of funding we will need depends on many factors, including the progress, timing and scope of our product development programs; the progress, timing and scope of our preclinical studies and clinical trials; the time and cost necessary to obtain regulatory approvals; the time and cost necessary to further develop manufacturing processes and arrange for contract manufacturing; our ability to enter into and maintain collaborative, licensing and other commercial relationships; and our partners' commitment of time and resources to the development and commercialization of our products.

We have limited access to the capital markets and even if we can raise additional funding, we may be required to do so on terms that are dilutive to you.

We have limited access to the capital markets to raise funds. The capital markets have been unpredictable in the recent past for radioisotope and other oncology companies and unprofitable companies such as ours. In addition, it is generally difficult for development-stage companies to raise capital under current market conditions. The amount of capital that a company such as ours is able to raise often depends on variables that are beyond our control. As a result, we may not be able to secure financing on terms attractive to us, or at all. If we are able to consummate a financing arrangement, the amount raised may not be sufficient to meet our future needs. If adequate funds are not available on acceptable terms, or at all, our business, including our technology licenses, results of operations, financial condition and our continued viability will be materially adversely affected.

We are highly dependent on the success of Iomab-B and the SIERRA trial and we may not be able to complete the necessary clinical development or our development efforts may not result in the data necessary to receive regulatory approval.

We have completed patient enrollment in the pivotal Phase 3 SIERRA trial (Study of Iomab-B in Elderly Relapsed or Refractory AML), a 153-patient multi-center randomized trial that will compare outcomes of patients who receive Iomab-B and a BMT to those patients receiving physician's choice of salvage chemotherapy, defined as conventional care, as no standard of care exists for this patient population. We have announced that Iomab-B met the primary endpoint of dCR in the SIERRA trial with statistical significance ($p<0.0001$). The SIERRA trial may be unsuccessful and fail to demonstrate a safety and efficacy profile that is necessary to receive favorable regulatory approval. Even if Iomab-B receives favorable regulatory approval, we may not be successful in securing adequate reimbursement or establishing successful commercial operations. Any or all of these factors could have a material adverse impact on our business and ability to continue operations.

We may be unable to establish sales, marketing and commercial supply capabilities.

We do not currently have, nor have we ever had, commercial sales and marketing capabilities. If any of our product candidates become approved, we would have to build and establish these capabilities in order to commercialize our approved product candidates. The process of establishing commercial capabilities will be expensive and time consuming. Even if we are successful in building sales and marketing capabilities, we may not be successful in commercializing any of our product candidates. Any delays in commercialization or failure to successfully commercialize any product candidate may have material adverse impacts on our business and ability to continue operations.

Our business could be adversely affected by the effects of health epidemics, including the global COVID-19 pandemic.

The global health crisis caused by the novel coronavirus COVID-19 pandemic and its resurgences has and may continue to negatively impact global economic activity, which, despite progress in vaccination efforts, remains uncertain and cannot be predicted with confidence. In addition, the Omicron variants of COVID-19, including subvariants BA.4 and BA.5, which appear to be the most transmissible variants to date, have spread globally. The full impact of the Omicron variant, or any subsequent variant, cannot be predicted at this time, and could depend on numerous factors, including vaccination rates among the population, the effectiveness of COVID-19 vaccines and boosters against the Omicron variant and the response by governmental bodies and regulators. Given the ongoing and dynamic nature of the circumstances, it is difficult to predict the impact of the COVID-19 pandemic on our business.

Many countries around the world have continued to impose quarantines and restrictions on travel and mass gatherings to slow the spread of the virus. Accordingly, our ability to continue to operate our business may also be limited. Such events may result in a period of business, supply and drug product manufacturing disruption, and in reduced operations, any of which could materially affect our business, financial condition and results of operations. In response to COVID-19, we implemented hybrid working for our office-based staff, while our research staff has been actively working in our laboratory throughout the pandemic and thus far have not experienced a significant disruption or delay in our operations as it relates to the clinical development, preclinical development of manufacturing of our drug candidates. Although we are adhering to health and safety protocols, an outbreak of COVID-19 at our facilities could nonetheless cause shutdowns of facilities and a reduction in our workforce, which could cause a disruption or delay in such operations. Certain government-imposed precautionary measures may have been relaxed in certain countries or states, but there is no assurance that more strict measures will be put in place again due to a resurgence in COVID-19 cases, including those involving new variants of the coronavirus, which may be more contagious and deadly than prior strains. Therefore, the COVID-19 pandemic may further divert the attention and efforts of the medical community to coping with COVID-19, and may disrupt the marketplace in which we operate and may have a material adverse effect on our operations.

A continuation or worsening of the levels of market disruption and volatility seen in the recent past could have an adverse effect on our ability to access capital, which could in the future negatively affect our liquidity. In addition, a recession or market correction resulting from the spread of COVID-19 could materially affect our business and the value of our common stock.

We believe our earlier stage CD33 clinical trials will continue to recruit and enroll patients given the acute nature of relapsed or refractory AML. The continuation of the pandemic could adversely affect our planned clinical trial operations, including our ability to conduct the trials on the expected timelines and recruit and retain patients and principal investigators and site staff who, as healthcare providers, may have heightened exposure to COVID-19 if their geography is impacted by the pandemic. Further, the continuation and/or resurgence of the COVID-19 pandemic could result in delays in our clinical trials due to prioritization of hospital resources toward the pandemic, restrictions in travel, potential unwillingness of patients to enroll in trials at this time, or the inability of patients to comply with clinical trial protocols if quarantines or travel restrictions impede patient movement or interrupt healthcare services. In addition, we rely on independent clinical investigators, contract research organizations and other third-party service providers to assist us in managing, monitoring and otherwise carrying out our preclinical studies and clinical trials, and the pandemic may affect their ability to devote sufficient time and resources to our programs or to travel to sites to perform work for us, which may result in delays or hinder our ability to collect data from our clinical trials.

Additionally, COVID-19 may result in delays in receiving approvals from local and foreign regulatory authorities, delays in necessary interactions with IRB's or Institutional Review Boards, local and foreign regulators, ethics committees and other important agencies and contractors due to limitations in employee resources or forced furlough of government employees.

We continue to monitor the impacts of COVID-19 on the global economy and on our business operations. However, the ultimate impact from COVID-19 on our business operations and financial results during 2022 will depend on, among other things, the ultimate severity and scope of the pandemic, including the new variants of the virus, the possible imposition of governmental and private travel restrictions and public concerns about public gatherings will ease, the rate at which historically large increases in unemployment rates will decrease, if at all, and whether, and the speed with which the economy recovers. We are not able to fully quantify the impact that these factors will have on our financial results during 2022 and beyond.

Our business is subject to cybersecurity risks.

Our operations are increasingly dependent on information technologies and services. Threats to information technology systems associated with cybersecurity risks and cyber incidents or attacks continue to grow, and include, among other things, storms and natural disasters, terrorist attacks, utility outages, theft, viruses, phishing, malware, design defects, human error, and complications encountered as existing systems are maintained, repaired, replaced, or upgraded. Risks associated with these threats include, among other things:

- theft or misappropriation of funds;
- loss, corruption, or misappropriation of intellectual property, or other proprietary, confidential or personally identifiable information (including supplier, clinical data or employee data);
- disruption or impairment of our and our business operations and safety procedures;
- damage to our reputation with our potential partners, patients and the market;
- exposure to litigation; and
- increased costs to prevent, respond to or mitigate cybersecurity events.

Although we utilize various procedures and controls to mitigate our exposure to such risk, cybersecurity attacks and other cyber events are evolving and unpredictable. Moreover, we have no control over the information technology systems of third parties conducting our clinical trials, our suppliers, and others with which our systems may connect and communicate. As a result, the occurrence of a cyber incident could go unnoticed for a period time.

We have cybersecurity insurance coverage in the event we become subject to various cybersecurity attacks, however, we cannot ensure that it will be sufficient to cover any particular losses we may experience as a result of such cyberattacks. Any cyber incident could have a material adverse effect on our business, financial condition and results of operations.

Risks Related to Regulation

The FDA or comparable foreign regulatory authorities may disagree with our regulatory plans and we may fail to obtain regulatory approval of our product candidates.

Our products are subject to rigorous regulation by the FDA and numerous other federal, state and foreign governmental authorities. The process of seeking regulatory approval to market an antibody radiation-conjugate product is expensive and time-consuming, and, notwithstanding the effort and expense incurred, approval is never guaranteed. If we are not successful in obtaining timely approval of our products from the FDA, we may never be able to generate significant revenue and may be forced to cease operations. In particular, the FDA permits commercial distribution of a new antibody radiation-conjugate product only after a BLA for the product has received FDA approval. The BLA process is costly, lengthy and inherently uncertain. Any BLA filed by us will have to be supported by extensive data, including, but not limited to, technical, preclinical, clinical trial, chemistry, manufacturing and controls ("CMC") and labeling data, to demonstrate to the FDA's satisfaction the safety and efficacy of the product for its intended use. The lengthy approval process as well as the unpredictability of future clinical trial results may result in our failing to obtain regulatory approval to market our product candidates, which would significantly harm our business, results of operations and prospects. In addition, even if we were to obtain approval, 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 approval contingent on the performance of costly post-marketing clinical trials, or may approve 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.

In June 2012, we acquired rights to apamistamab, a clinical stage anti-CD45 monoclonal antibody with safety and efficacy data in more than 300 patients in need of a BMT. Iomab-B is our product candidate that links I-131 to apamistamab that is being studied in the pivotal Phase 3 SIERRA trial. Product candidates utilizing apamistamab would require BLA approval before they can be marketed in the United States. We are also evaluating Iomab-ACT, which uses a lower dose I-131 for lymphodepletion prior to CAR-T or adoptive cell therapy. We are currently evaluating clinical trials that would use our construct for lymphodepletion. Our CD33 Alpha program studying Actimab-A (lintuzumab-Ac-225) product candidate is also being studied in several Phase 1 trials under our sponsorship and investigator-initiated trials in patients with r/r AML. Product candidates utilizing the lintuzumab antibody would require BLA approval before they can be marketed in the United States. We are in the early stages of evaluating other product candidates consisting of conjugates of Ac-225 with human or humanized antibodies for pre-clinical and clinical development in other types of cancer. The FDA may not approve these products for the indications that are necessary or desirable for successful commercialization. The FDA may fail to approve any BLA we submit for new product candidates or for new intended uses or indications for approved products or future product candidates. Failure to obtain FDA approval for our products in the proposed indications would have a material adverse effect on our business prospects, financial condition and results of operations.

The approval process in the United States and in other countries could result in unexpected and significant costs for us and consume management's time and other resources. The FDA and other foreign regulatory agencies could ask us to supplement our submissions, collect non-clinical data, conduct additional clinical trials or engage in other time-consuming actions, or it could simply deny our applications. In addition, even if we obtain approval to market our products in the United States or in other countries, the approval could be revoked, or other restrictions imposed if post-market data demonstrates safety issues or lack of effectiveness. We cannot predict with certainty how, or when, the FDA or other regulatory authorities will act. If we are unable to obtain the necessary regulatory approvals, our financial condition and cash flow may be materially adversely affected, and our ability to grow domestically and internationally may be limited. Additionally, even if we obtain approval, regulatory authorities may approve any of our product candidates for fewer or more limited indications that we request. The Company's products may not be approved for the specific indications that are most necessary or desirable for successful commercialization or profitability.

We have not demonstrated that any of our products are safe and effective for any indication and will continue to expend substantial time and resources on clinical development before any of our current or future product candidates will be eligible for FDA approval, if ever.

We expect that a substantial portion of our efforts and expenditures over the next few years will be devoted to development of our existing and contemplated biological product candidates. Accordingly, our business currently depends heavily on the successful development, FDA approval, and commercialization of such candidates, which may never receive FDA approval or be successfully commercialized even if FDA approval is received. The research, testing, manufacturing, labeling, approval, sale, marketing, and distribution of our biological product candidates are, and will remain, subject to extensive regulation by the FDA and other regulatory authorities in the United States and other countries, as applicable. We are currently not permitted to market any of our current or future product candidates in the United States until we receive FDA approval (of each) via the BLA process. To date, we have two product candidates in clinical development and have not-yet submitted a BLA for any of our candidates and, for many such candidates, do not expect to be in a position to do so for the foreseeable future, as there are numerous developmental steps that must be completed before we can prepare and submit a BLA.

In the United States, the FDA regulates pharmaceutical and biological product candidates under the FDCA and the Public Health Service Act ("PHSA"), as well as their respective implementing regulations. Such products and product candidates are also subject to other federal, state, and local statutes and regulations. The process of obtaining regulatory approvals and the subsequent compliance with appropriate federal, state, local, and foreign statutes and regulations requires the expenditure of substantial time and financial resources. The process required by the FDA before a drug or biological product may be marketed in the United States generally involves the following:

- completion of preclinical laboratory tests and animal studies in accordance with FDA's good laboratory practices ("GLPs") and applicable requirements for the humane use of laboratory animals or other applicable regulations;

- submission to the FDA of an Investigational New Drug ("IND"), which must become effective before human clinical trials in the United States may begin;

- performance of adequate and well-controlled human clinical trials in accordance with FDA's IND regulations, GCPs, and any additional requirements for the protection of human research subjects and their health information, to establish the safety and efficacy of the proposed biological product for its intended use;

- submission to the FDA of a BLA for marketing approval that meets applicable requirements to ensure the continued safety, purity, and potency of the product that is the subject of the BLA based on results of preclinical testing and clinical trials;

- satisfactory completion of an FDA inspection of the manufacturing facility or facilities where the biological product is produced, to assess compliance with cGMPs and assure that the facilities, methods and controls are adequate to preserve the biological product's identity, strength, quality and purity;

- potential FDA audit of the nonclinical study and clinical trial sites that generated the data in support of the BLA; and

- FDA review and approval, or denial, of the BLA.

Before testing any biological product candidate in humans, the product candidate enters the preclinical testing stage. Preclinical tests include laboratory evaluations of product chemistry, toxicity and formulation, as well as animal studies to assess the potential safety and activity of the product candidate. The conduct of the preclinical tests must comply with federal regulations and requirements including GLPs. The clinical trial sponsor must submit the results of the preclinical tests, together with manufacturing information, analytical data, any available clinical data or literature and a proposed clinical protocol, to the FDA as part of the IND. Some preclinical testing may continue even after the IND is submitted. The IND automatically becomes effective 30 days after receipt by the FDA, unless the FDA raises concerns or questions regarding the proposed clinical trials and places the trial on a clinical hold within that 30-day time period. In such a case, the IND sponsor and the FDA must resolve any outstanding concerns before the clinical trial can begin. The FDA may also impose clinical holds on a biological product candidate at any time before or during clinical trials due to safety concerns or non-compliance. If the FDA imposes a clinical hold, trials may not recommence without FDA authorization and then only under terms authorized by the FDA. Accordingly, we cannot be sure that submission of an IND will result in the FDA allowing clinical trials to begin or that, for those that have already commenced under an active IND, that issues will not arise that suspend or terminate such trials.

Clinical trials involve the administration of the biological product candidate to healthy volunteers or patients under the supervision of qualified investigators, generally physicians not employed by or under the trial sponsor's control. Clinical trials are conducted under protocols detailing, among other things, the objectives of the clinical trial, dosing procedures, subject selection and exclusion criteria, and the parameters to be used to monitor subject safety, including stopping rules that assure a clinical trial will be stopped if certain adverse events should occur. Each protocol and any amendments to the protocol must be submitted to the FDA as part of the IND. Clinical trials must be conducted and monitored in accordance with the FDA's regulations composing the GCP requirements, including the requirement that all research subjects provide informed consent. Further, each clinical trial must be reviewed and approved by an independent institutional review board, or IRB, at or servicing each institution at which the clinical trial will be conducted. An IRB is charged with protecting the welfare and rights of trial participants and considers such items as whether the risks to individuals participating in the clinical trials are minimized and are reasonable in relation to anticipated benefits. The IRB also approves the form and content of the informed consent that must be signed by each clinical trial subject or his or her legal representative and must monitor the clinical trial until completed. Human clinical trials are typically conducted in three sequential phases that may overlap or be combined:

- Phase 1. The biological product is initially introduced into healthy human subjects and tested for safety. In the case of some products for severe or life-threatening diseases, especially when the product may be too inherently toxic to ethically administer to healthy volunteers, the initial human testing is often conducted in subjects.

- Phase 2. The biological product is evaluated in a limited patient population to identify possible adverse effects and safety risks, to preliminarily evaluate the efficacy of the product for specific targeted diseases and to determine dosage tolerance, optimal dosage and dosing schedule.

- Phase 3. Clinical trials are undertaken to further evaluate dosage, clinical efficacy, potency, and safety in an expanded patient population at geographically dispersed clinical trial sites. These clinical trials are intended to establish the overall risk to benefit ratio of the product and provide an adequate basis for product labeling.

Post-approval clinical trials, sometimes referred to as Phase 4 clinical trials, may be conducted after initial marketing approval. These clinical trials are used to gain additional experience from the treatment of patients in the intended therapeutic indication, particularly for long-term safety follow-up.

After the completion of clinical trials of a biological product, FDA approval of a BLA must be obtained before commercial marketing of the biological product. The BLA must include results of product development, laboratory and animal studies, human trials, information on the manufacture and composition of the product, proposed labeling and other relevant information. The FDA may grant deferrals for submission of data, or full or partial waivers. The testing and approval processes require substantial time and effort and there can be no assurance that the FDA will accept the BLA for filing and, even if filed, that any approval will be granted on a timely basis, if at all. Before approving a BLA, the FDA will inspect the facilities at which the product is manufactured. The FDA will not approve the product unless it determines that the manufacturing processes and facilities are in compliance with cGMP requirements and adequate to assure consistent production of the product within required specifications. Additionally, before approving a BLA, the FDA will typically inspect one or more clinical sites to assure that the clinical trials were conducted in compliance with IND trial requirements and GCP requirements. To assure cGMP and GCP compliance, an applicant must incur significant expenditure of time, money and effort in the areas of training, record keeping, production, and quality control.

Notwithstanding the submission of relevant data and information, the FDA may ultimately decide that the BLA does not satisfy its regulatory criteria for approval and deny approval. Data obtained from clinical trials are not always conclusive and the FDA may interpret data differently than we interpret the same data. Our product candidates are in the earliest stages of clinical development and, therefore, a long way from BLA submission. We cannot predict with any certainty if or when we might submit a BLA for regulatory approval for our product candidates or whether any such BLA will be approved by the FDA. Human clinical trials are very expensive and difficult to design and implement, in part because they are subject to rigorous regulatory requirements. For example, the FDA may not agree with our proposed endpoints for any clinical trial we propose, which may delay the commencement of our clinical trials. The clinical trial process is also lengthy and requires substantial time and effort.

In December 2015, the FDA cleared our IND filing for Iomab-B and we have completed patient enrollment of a randomized, controlled, pivotal Phase 3 clinical trial under such IND to study Iomab-B in patients 55 years of age or older with relapsed or refractory AML. The Phase 3 trial SIERRA trial has met its primary endpoint assuming there are no unexpected issues or delays, including with secondary endpoints, it is expected to form the basis for a BLA for Iomab-B for use in preparing and conditioning AML patients for a BMT. Additionally, there are physician IND trials at the FHCRC that have been conducted or are currently ongoing at FHCRC with Iomab-B (for other target indications) and the apamistamab antibody (formerly known as BC8) we licensed. And, we have multiple Phase 1 and Phase 2 clinical trials ongoing and others that we have planned but not-yet commenced, for our other drug candidates under our own sponsorship and multiple investigator-initiated trials ongoing. Except for Iomab-B (for patients with AML), we expect that the clinical trials we need to conduct to be in a position to submit BLAs for our product candidates currently in-development will take, at least, several years to complete. Moreover, failure can occur at any stage of the trials, and we could encounter problems that cause us to abandon or repeat clinical trials. Also, the results of early preclinical and clinical testing may not be predictive of the results of subsequent clinical trials. A number of companies in the biopharmaceutical industry have suffered significant setbacks in advanced clinical trials due to lack of efficacy or adverse safety profiles, notwithstanding promising results in earlier studies. And, preclinical and clinical data are often susceptible to multiple interpretations and analyses. Many companies that have believed their product candidates performed satisfactorily in preclinical studies and clinical trials have, nonetheless, failed to obtain marketing approval of their products. Success in preclinical testing and early clinical trials does not ensure that later clinical trials, which involve many more subjects, and the results of later clinical trials may not replicate the results of prior clinical trials and preclinical testing. Any failure or substantial delay in our product development plans may have a material adverse effect on our business.

We may encounter substantial delays in our clinical trials or may not be able to conduct our trials on the timelines we expect.

We cannot predict whether we will encounter problems with any of our ongoing or planned clinical trials that will cause us or regulatory authorities to delay, suspend, or discontinue clinical trials or to delay the collection or analysis of data from ongoing clinical trials. Any of the following could delay or disrupt the clinical development of our product candidates and potentially cause our product candidates to fail to receive regulatory approval:

- conditions imposed on us by the FDA or comparable foreign authorities regarding the scope or design of our clinical trials;
- delays in receiving, or the inability to obtain, required approvals from IRBs or other reviewing entities at clinical sites selected for participation in our clinical trials;
- delays in enrolling patients into clinical trials;
- a lower than anticipated retention rate of patients in clinical trials;
- the need to repeat or discontinue clinical trials as a result of inconclusive or negative results or unforeseen complications in testing or because the results of later trials may not confirm positive results from earlier preclinical studies or clinical trials;
- inadequate supply, delays in distribution, deficient quality of, or inability to purchase or manufacture drug product, comparator drugs or other materials necessary to conduct our clinical trials;
- unfavorable FDA or other foreign regulatory inspection and review of a clinical trial site or records of any clinical or preclinical investigation;
- serious and unexpected drug-related side effects experienced by participants in our clinical trials, which may occur even if they were not observed in earlier trials or only observed in a limited number of participants;
- a finding that the trial participants are being exposed to unacceptable health risks;
- the placement by the FDA or a foreign regulatory authority of a clinical hold on a trial;
- delays in obtaining regulatory agency authorization for the conduct of our clinical trials;
- delays by us or third parties in the collection or analysis of data from our clinical trials; or
- delays due to COVID-19 or a similar global health pandemic.

We may suspend, or the FDA or other applicable regulatory authorities may require us to suspend, clinical trials of a product candidate at any time if we or they believe the patients participating in such clinical trials, or in independent third-party clinical trials for drugs based on similar technologies, are being exposed to unacceptable health risks including but not limited to unacceptable or suboptimal factors related to toxicity, clinical efficacy, imbalances in safety and efficacy profiles or for other reasons.

Further, individuals involved with our clinical trials may serve as consultants to us from time to time and receive stock options or cash compensation in connection with such services. If these relationships and any related compensation to the clinical investigator carrying out the study result in perceived or actual conflicts of interest, or the FDA concludes that the financial relationship may have affected interpretation of the study, the integrity of the data generated at the applicable clinical trial site may be questioned and the utility of the clinical trial itself may be jeopardized. The delay, suspension or discontinuation of any of our clinical trials, or a delay in the analysis of clinical data for our product candidates, for any of the foregoing reasons, could adversely affect our efforts to obtain regulatory approval for and to commercialize our product candidates, increase our operating expenses and have a material adverse effect on our financial results.

Clinical trials may also be delayed or terminated as a result of ambiguous or negative interim results. In addition, a clinical trial may be suspended or terminated by us, the FDA, the IRBs at the sites where the IRBs are overseeing a trial, or a data safety monitoring board, or DSMB (Data Safety Monitoring Board)/DMC (Data Monitoring Committee), overseeing the clinical trial at issue, or other regulatory authorities due to a number of factors, including:

- failure to conduct the clinical trial in accordance with regulatory requirements or our clinical protocols;
- inspection of the clinical trial operations or trial sites by the FDA or other regulatory authorities resulting in the imposition of a clinical hold;
- varying interpretation of data by the FDA or similar foreign regulatory authorities;
- failure to achieve primary or secondary endpoints or other failure to demonstrate efficacy;
- unforeseen safety issues; or
- lack of adequate funding to continue the clinical trial.

Modifications to our product candidates may require federal approvals.

The BLA application is the vehicle through which the company may formally propose that the FDA approve a new pharmaceutical for sale and marketing in the United States. Once a particular product candidate receives FDA approval, expanded uses or uses in new indications of our products may require additional human clinical trials and new regulatory approvals, including additional IND and BLA submissions and premarket approvals before we can begin clinical development, and/or prior to marketing and sales. If the FDA requires new approvals for a particular use or indication, we may be required to conduct additional clinical studies, which would require additional expenditures and harm our operating results. If the products are already being used for these new indications, we may also be subject to significant enforcement actions.

Conducting clinical trials and obtaining approvals is a time-consuming process, and delays in obtaining required future approvals could adversely affect our ability to introduce new or enhanced products in a timely manner, which in turn would have an adverse effect on our business prospects, financial condition and results of operation.

Clinical trials necessary to support approval of our product candidates are time-consuming and expensive.

Initiating and completing clinical trials necessary to support FDA approval of a BLA for Iomab-B, CD33 program candidates, and other product candidates, is a time-consuming and expensive process, and the outcome is inherently uncertain. Moreover, the results of early clinical trials are not necessarily predictive of future results, and any product candidate we advance into clinical trials may not have favorable results in later clinical trials. We worked with the FDA to develop the SIERRA clinical trial to test the safety and efficacy of Iomab-B in patients with relapsed or refractory AML who are age 55 and above prior to a BMT. This trial is designed to support a BLA filing for marketing approval by the FDA, pending results from the trial. In addition to clinical data, a BLA filing encompasses preclinical, CMC, labeling and other information. Even if the clinical data from the SIERRA trial is positive, there can be no assurances that the BLA filing we produce will meet all of the FDA's requirements or that they will not request additional information or studies, which may delay the FDA's review or we may not be able to produce. We have also worked with the FDA to develop a regulatory pathway for lintuzumab-Ac-225 in patients with high-risk MDS that consists of a dose-confirming Phase 1 trial that can be followed by a randomized, controlled pivotal trial that could support a BLA filing. To date, we have not initiated this clinical trial and we may never elect or be able to do so. There can be no assurance that the data generated during the trial will meet our chosen safety and effectiveness endpoints or otherwise produce results that will eventually support the filing or approval of a BLA. Even if the data from this trial are favorable, the data may not be predictive of the results of any future clinical trials.

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

From time to time, we may publicly disclose preliminary, interim, and top-line data from our clinical trials, which is based on a preliminary analysis of then-available data, and the results and related findings and conclusions are subject to change as more patient data become available or following a more comprehensive review of the data related to the particular study or trial. For example, in October 2022 we announced that Iomab-B met the primary endpoint of dCR in the SIERRA trial with statistical significance ($p<0.0001$). We also make assumptions, estimations, calculations and conclusions as part of our analyses of data, and we may not have received or had the opportunity to fully and carefully evaluate all data. Our clinical trials may be open label studies and certain of our clinical development and or operations staff may review interim or preliminary safety or efficacy data during routine data collection, cleaning and analysis from time to time. Interim or preliminary results that we report may differ from future results of the same studies, or different conclusions or considerations may qualify such results once additional data have been received and fully evaluated. Preliminary, interim or top-line data also remain subject to audit and verification procedures that may result in the final data being materially different from the top-line, interim or preliminary data we previously published. As a result, top-line, interim and preliminary data should be viewed with caution until the final data are available.

From time to time, we may also disclose interim data from our preclinical studies and 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. Adverse differences between interim data and final data could significantly harm our business prospects. Further, disclosure of interim data by us or by our competitors could result in volatility in the price of our common stock.

Further, others, including regulatory agencies, may not accept or agree with our assumptions, estimates, calculations, conclusions or analyses or may interpret or weigh the importance of data differently, which could impact the value of the particular program, the approvability or commercialization of the particular product candidate or product and our company in general. In addition, the information we choose to publicly disclose regarding a particular study or clinical trial is based on what is typically extensive information, and you or others may not agree with what we determine is material or otherwise appropriate information to include in our disclosure.

If the interim, top-line or preliminary data that we report differ from final results, or if others, including regulatory authorities, disagree with the conclusions reached, our ability to obtain approval for, and commercialize, our product candidates may be harmed, which could harm our business, operating results, prospects or financial condition.

Our clinical trials may fail to demonstrate adequately the efficacy and safety of our product candidates, which would prevent or delay regulatory approval and commercialization.

Even if our clinical trials are completed as planned, we cannot be certain that their results will support our product candidate claims or that the FDA or foreign authorities will agree with our conclusions regarding them. Success in pre-clinical studies and early clinical trials does not ensure that later clinical trials will be successful, and we cannot be sure that the later trials will replicate the results of prior trials and pre-clinical studies. The clinical trial process may fail to demonstrate that our product candidates are safe and effective for the proposed indicated uses. If FDA concludes that the clinical trials for Iomab-B, Actimab-A, or any other product candidate for which we might seek approval, have failed to demonstrate safety and effectiveness, we would not receive FDA approval to market that product candidate in the United States for the indications sought. In addition, such an outcome could cause us to abandon the product candidate and might delay development of others. Any delay or termination of our clinical trials will delay or preclude the filing of any submissions with the FDA and, ultimately, our ability to commercialize our product candidates and generate revenues. It is also possible that patients enrolled in clinical trials will experience adverse side effects that are not currently part of a product candidate's profile.

The intellectual property related to antibodies we have licensed has expired or likely expired.

The key patents related to the humanized antibody, lintuzumab, which we use in our CD33 program product candidates have expired. It is generally possible that others may be eventually able to use an antibody with the same sequence, and we will then need to rely on additional patent protection covering alpha particle drug products comprising Ac-225. Our final drug construct, Actimab-A, consists of the lintuzumab antibody labeled with the isotope Ac-225. We currently own issued and pending patents relating to methods of manufacturing Actimab-A, methods of treatment using Actimab-A and production of the Ac-225 isotope. In addition, we possess trade secrets and know how related to the manufacturing and use of isotopes. Any competing product based on the lintuzumab antibody is likely to require several years of development before achieving our product candidate's current status and may be subject to significant regulatory hurdles but such development by others is nevertheless a possibility that could negatively impact our business in the future. We own 3 issued U.S. patents, 1 issued European patent (validated as a national patent in several countries) and 1 issued Japanese patent that relate to the composition of our Iomab-B product candidate. Several patent applications relating to Iomab-B are also pending in the U.S. and internationally. We have and may continue to file patents related to Iomab-B that can provide barriers to entry but there is no certainty that these patents will be granted or such granting thereof will adequately prevent others from seeking to replicate and use the apamistamab antibody or the construct. We have pending patents related to radioimmunoconjugate composition, formulation administration, and methods of use in solid or liquid cancers. This subject matter includes composition, administration, and methods of treatment for our product candidates Actimab-A and Iomab-B. Any competing product based on the antibody used in Iomab-B is likely to require several years of development before achieving our product candidate's current status and may be subject to significant regulatory hurdles but such development by others is nevertheless a possibility that could negatively impact our business in the future.

Our CD33 program clinical trials are testing the same drug construct.

Our CD33 program is comprised of several clinical trials including investigator-initiated trials in r/r AML that are studying the same drug construct consisting of lintuzumab-Ac-225. Negative results from any of these trials could negatively impact our ability to enroll or complete our other trials studying lintzumab-Ac-225. Additionally, negative outcomes including safety concerns, may result in the FDA discontinuing other trials utilizing lintuzumab-Ac-225.

We may be unable to obtain a sufficient supply of isotopes to support clinical development or at commercial scale.

Iodine-131 is a key component of our Iomab-B drug candidate. We currently source medical grade I-131 from three suppliers including two leading global manufacturers. Currently, there is sufficient supply of I-131 to support additional trials we may undertake utilizing I-131 and for commercialization of Iomab-B. We continually evaluate I-131 manufacturers and suppliers and intend to have multiple qualified suppliers prior to the commercial launch of Iomab-B. While we consider I-131 to be commoditized and obtainable through several suppliers, there can be no guarantee that we will be able to secure I-131 or obtain I-131 on terms that are acceptable to us.

Actinium-225 is a key component of our CD33 Alpha program, AWE platform and other drug candidates that we might consider for development with the Ac-225 payload. There are adequate quantities of Ac-225 available today to meet our current needs via our present supplier, the Department of Energy ("DOE"). The Ac-225 currently supplied to Actinium's clinical trials from the DOE is derived from the natural decay of thorium-229 from so-called 'thorium-cows' and is able to produce sufficient quantities that are several multiples of the amount of Ac-225 we require to supply our clinical programs through to early commercialization phase. The DOE is also producing Ac-225 from a recently developed alternative route for Ac-225 production via a linear accelerator that is currently being evaluated by Actinium. Initial preclinical and modelling results have indicated that the linear accelerator sourced Ac-225 does not impact labelling efficiency and expected distribution. In accordance with representations made by the DOE, the capacity of Ac-225 from this route is expected to be sufficient to supply all of Actinium's pipeline and commercial Ac-225 needs and support new program expansion by not just Actinium but also other companies that are developing Ac-225 based products. Additional routes of Ac-225 production are being pursued by the DOE including the generation of new thorium cows and production via a cyclotron. The cyclotron production method for Ac-225 production leverages Actinium's proprietary technology and know-how and presents an additional path towards production of high-quality Ac-225 that would be able to satisfy commercial needs. In addition, we are aware of at least six other government and non-government entities globally including the U.S., Canada, Russia, Belgium, France and Japan that have, or expect to have ability to supply Ac-225 or equipment for its production within the timeframes relevant to the potential first commercial approval of our Ac-225 ARC.

Our contract for supply of Ac-225 from the DOE must be renewed annually and our current contract extends through the end of 2022. While we expect this contract will continue to be renewed at the end of its term as it has since 2009, there can be no assurance that the DOE will renew the contract or change its policies that allow for the sale of isotope to us. Failure to acquire sufficient quantities of medical grade Ac-225 at a cost effective price would make it impossible to effectively complete clinical trials and to commercialize any Ac-225 based drug candidates that we may develop and would materially harm our business.

Our ability to conduct clinical trials to advance our drug candidates is dependent on our ability to obtain the radioisotopes I-131, Ac-225 and other isotopes we may choose to utilize in the future. Currently, we are dependent on third party manufacturers and suppliers for our isotopes. These suppliers may not perform their contracted services or may breach or terminate their agreements with us. Our suppliers are subject to regulations and standards that are overseen by regulatory and government agencies and we have no control over our suppliers' compliance to these standards. Failure to comply with regulations and standards may result in their inability to supply isotopes and could result in delays in our clinical trials, which could have a negative impact on our business. We have developed intellectual property, know-how and trade secrets related to the manufacturing process of Ac-225. While we have manufactured medical grade Ac-225 of a purity compared to the cyclotron sourced material in the past, this activity was terminated due to operating cost reasons and we currently do not have experience in manufacturing medical grade Ac-225 and may not obtain the resources necessary to establish our own manufacturing capabilities in future. Our inability to build out and establish our own manufacturing facilities would require us to continue to rely on third party suppliers as we currently do. However, based on our current third-party suppliers and potential future suppliers of Ac-225 we expect to have adequate isotope supply to support our current ongoing clinical trials, current AWE program activities and commercialization should our drug candidates receive approval.

If we encounter difficulties enrolling patients in our clinical trials, our clinical development activities could be delayed or otherwise adversely affected.

The timely completion of clinical trials in accordance with their protocols depends on our ability to enroll a sufficient number of patients who remain in the trial until its conclusion. We may experience difficulties in patient enrollment in our clinical trials for a variety of reasons, including:

- the size and nature of the patient population;
- the patient eligibility criteria defined in the protocol;
- the size of the study population required for analysis of the trial's primary and secondary endpoints;
- the proximity of patients to trial sites;
- the design of the trial;
- our ability to recruit clinical trial investigators with the appropriate competencies and expertise;
- competing clinical trials for similar or alternate therapeutic treatments;
- clinician's and patients' perceptions as to the potential advantages and side effects of the product candidate being studied in relation to other available therapies;
- our ability to obtain and maintain patient consents; and
- the risk that patients enrolled in clinical trials will not complete a clinical trial.

In addition, refractory patients, which several of our trials are enrolling, participating in clinical trials are seriously and often terminally ill and therefore may not complete the clinical trial due to reasons including comorbid conditions or occurrence of adverse medical events related or unrelated to the investigational products, or death. Even if we are able to enroll a sufficient number of patients in our clinical trials, delays in patient enrollment will result in increased costs or affect the timing of our planned trials, which could adversely affect our ability to advance the development of our product candidates.

FDA may take actions that would prolong, delay, suspend, or terminate clinical trials of our product candidates, which may delay or prevent us from commercializing our product candidates on a timely basis.

There can be no assurance that the data generated in our clinical trials will be acceptable to FDA or that if future modifications during the trial are necessary, that any such modifications will be acceptable to FDA. Certain modifications to a clinical trial protocol made during the course of the clinical trial have to be submitted to the FDA. This could result in the delay or halt of a clinical trial while the modification is evaluated. In addition, depending on the quantity and nature of the changes made, FDA could take the position that some or all of the data generated by the clinical trial is not usable because the same protocol was not used throughout the trial. This might require the enrollment of additional subjects, which could result in the extension of the clinical trial and the FDA delaying approval of a product candidate. If the FDA believes that its prior approval is required for a particular modification, it can delay or halt a clinical trial while it evaluates additional information regarding the change.

Any delay or termination of our current or future clinical trials as a result of the risks summarized above, including delays in obtaining or maintaining required approvals from IRBs, delays in patient enrollment, the failure of patients to continue to participate in a clinical trial, and delays or termination of clinical trials as a result of protocol modifications or adverse events during the trials, may cause an increase in costs and delays in the filing of any submissions with the FDA, delay the approval and commercialization of our product candidates or result in the failure of the clinical trial, which could adversely affect our business, operating results and prospects. Lengthy delays in the completion of our Iomab-B clinical trials would adversely affect our business and prospects and could cause us to cease operations.

We have obtained orphan drug designation from FDA for two of our current product candidates and intend to pursue such designation for other candidates and indications in the future, but we may be unable to obtain such designations or to maintain the benefits associated with any orphan drug designations we have received or may receive in the future.

We have received orphan drug designation for Iomab-B and lintuzumab-CD33 ARC for treatment of AML in both the United States and the EU. Under the Orphan Drug Act, the FDA may grant orphan designation to a drug or biologic intended to treat a rare disease or condition, which is a disease or condition that affects fewer than 200,000 individuals in the United States, or if it affects more than 200,000 individuals in the United States, there is no reasonable expectation that the cost of developing and making available a drug or biologic for this type of disease or condition will be recovered from sales in the United States for that drug or biologic. Similarly, the EMA grants orphan drug designation to promote the development of products that are intended for the diagnosis, prevention, or treatment of a life-threatening or chronically debilitating condition affecting not more than five in 10,000 persons in the EU.

Orphan drug designation neither shortens the development time or regulatory review time of a drug or biologic nor gives the drug or biologic any advantage in the regulatory review or approval process. 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 application fee waivers. In addition, if a product candidate receives the first FDA approval for the indication for which it has orphan designation, such product is entitled, upon approval, to seven years of orphan-drug exclusivity, during which the FDA may not approve any other application to market the same drug for the same indication, unless a subsequently approved product is clinically superior to orphan drug or where the manufacturer is unable to assure sufficient product quantity in the applicable patient population. In the EU, orphan drug designation entitles a party to financial incentives such as reduction of fees or fee waivers and ten years of market exclusivity following drug or biological product approval. This period may be reduced to six years if the orphan drug designation criteria are no longer met, including where it is shown that the product is sufficiently profitable not to justify maintenance of market exclusivity.

Even if we obtain (or have obtained) orphan drug designation for certain product candidates, we may not be the first to obtain marketing approval for such candidates for the applicable indications due to the uncertainties inherent in the development of novel biologic products. And, an orphan drug candidate may not receive orphan-drug exclusivity upon approval if such candidate is approved for a use that is broader than the indication for which it received orphan designation. In addition, exclusive marketing rights in the United States may be lost if the FDA later determines that the request for designation was materially defective or if the manufacturer is unable to assure sufficient quantities of the product to meet the needs of patients with the rare disease or condition.

Finally, even if we successfully obtain orphan-drug exclusivity for an orphan drug candidate upon approval, such exclusivity may not effectively protect the product from competition because (i) different drugs with different active moieties can be approved for the same condition; and (ii) the FDA or EMA can also subsequently approve a subsequent product with the same active moiety and for the same indication as the orphan drug if the later-approved drug if deemed clinically superior to the orphan drug.

Even if we receive regulatory approval of our product candidates, we will be subject to ongoing regulatory obligations and continued regulatory review.

Any regulatory approvals that we receive for our product candidates will require surveillance to monitor the safety and efficacy of the product candidate. The FDA may also require a REMS in order to approve our product candidates, which could entail requirements for 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. In addition, if the FDA or a comparable foreign regulatory authority approves our product candidates, the manufacturing processes, labeling, packaging, distribution, adverse event reporting, storage, advertising, promotion, import, export and recordkeeping for our product candidates will be subject to extensive and ongoing regulatory requirements. These requirements include submissions of safety and other post-marketing information and reports, registration, as well as continued compliance with cGMPs and GCPs for any clinical trials that we conduct post-approval. In addition, the FDA could require us to conduct another study to obtain additional safety or biomarker information. Later discovery of previously unknown problems with our product candidates, including adverse events of unanticipated severity or frequency, or with our third-party suppliers or manufacturing processes, or failure to comply with regulatory requirements, may result in, among other things:

- restrictions on the marketing or manufacturing of our product candidates, 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 to approve pending applications or supplements to approved applications filed by us or suspension or revocation of license approvals;
- 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.

The FDA's and other regulatory authorities' policies may change, and additional government regulations may be enacted that could prevent, limit or delay regulatory approval 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 approval that we may have obtained, and we may not achieve or sustain profitability.

Coverage and reimbursement may be limited or unavailable in certain market segments for our product candidates which could limit our sales of our product candidates, if approved.

The commercial success of our product candidates in both domestic and international markets will be substantially dependent on whether third-party coverage and reimbursement is available for patients that use our products. However, the availability of insurance coverage and reimbursement for newly approved cancer therapies is uncertain, and therefore, third-party coverage may be particularly difficult to obtain even if our products are approved by the FDA as safe and efficacious. Patients using existing approved therapies are generally reimbursed all or part of the product cost by Medicare or other third-party payors. Medicare, Medicaid, health maintenance organizations and other third-party payors are increasingly attempting to contain healthcare costs by limiting both coverage and the level of reimbursement of new drugs, and, as a result, they may not cover or provide adequate payment for these products. Submission of applications for reimbursement approval generally does not occur prior to the filing of a BLA for that product and may not be granted until many months after BLA approval. In order to obtain coverage and reimbursement for these products, we or our commercialization partners may have to agree to a net sales price lower than the net sales price we might charge in other sales channels. The continuing efforts of government and third-party payors to contain or reduce the costs of healthcare may limit our revenue. Initial dependence on the commercial success of our products may make our revenues particularly susceptible to any cost containment or reduction efforts.

Healthcare legislative reform measures intended to increase pressure to reduce prices of pharmaceutical products paid for by Medicare or, otherwise, affect the federal regulation of the U.S. healthcare system could have a material adverse effect our business, future revenue, if any, and results of operations.

In the United States, there have been a number of legislative and regulatory initiatives focused on containing the cost of healthcare. The Affordable Care Act, for example, substantially changed the way healthcare is financed by both governmental and private insurers. The Affordable Care Act contains a number of provisions that could impact our business and operations, primarily, once we obtain FDA approval to commercialize one of our product candidates in the United States, if ever, and may also affect our operations in ways we cannot currently predict. Affordable Care Act provisions that may affect our business include, among others, those governing enrollment in federal healthcare programs, reimbursement changes, rules regarding prescription drug benefits under health insurance exchanges, expansion of the 340B program, expansion of state Medicaid programs, fees and increased discount and rebate obligations, transparency and reporting requirements, and fraud and abuse enforcement. Such changes may impact existing government healthcare programs, industry competition, formulary composition, and may result in the development of new programs, including Medicare payment for performance initiatives, health technology assessments, and improvements to the physician quality reporting system and feedback program.

There have been significant ongoing judicial, administrative, executive, and legislative initiatives to modify, limit, replace, or repeal the Affordable Care Act. For example, former President Trump issued several Executive Orders and other directives designed to delay the implementation of certain provisions of the Affordable Care Act or otherwise circumvent some of the requirements for health insurance mandated by the Affordable Care Act. Concurrently, Congress considered legislation that would repeal or replace all or part of the Affordable Care Act. While Congress has not passed comprehensive repeal legislation, several bills affecting the implementation the Affordable Care Act have been passed. For example, the Tax Cuts and Jobs Act of 2017 eliminated the Affordable Care Act provision requiring individuals to purchase and maintain health coverage, or the "individual mandate," by reducing the associated penalty to zero, beginning in 2019. In December 2018, a district court in Texas held that the individual mandate is unconstitutional and that the rest of the Affordable Care Act is, therefore, invalid. On appeal, the Fifth Circuit Court of Appeals affirmed the holding on the individual mandate but remanded the case back to the lower court to reassess whether and how such holding affects the validity of the rest of the Affordable Care Act. The Fifth Circuit's decision on the individual mandate was appealed to the U.S. Supreme Court. On June 17, 2021, the Supreme Court held that the plaintiffs (comprised of the state of Texas, as well as numerous other states and certain individuals) did not have standing to challenge the constitutionality of the Affordable Care Act's individual mandate and, accordingly, vacated the Fifth Circuit's decision and instructed the district court to dismiss the case. As a result, the Affordable Care Act will remain in-effect in its current form for the foreseeable future; however, we cannot predict what additional challenges may arise in the future, the outcome thereof, or the impact any such actions may have on our business.

The adoption or implementation of new or amended legislation at the federal or state level could affect our ability to obtain regulatory approval for any of our vaccine candidates and the commercial viability of our future approved products, if any. We cannot predict the ultimate nature, timing, or effect of any changes to the Affordable Care Act or other federal and state reform efforts, and there is no assurance that such efforts will not adversely affect our future business and financial results.

In addition to the Affordable Care Act, there have been several recent Congressional inquiries and proposed and enacted federal and state legislation designed to, among other things, bring more transparency to drug pricing, review the relationship between pricing and manufacturer patient programs, and reform government program reimbursement methodologies for drug products. Pharmaceutical product prices have been the focus of increased scrutiny by the government, including certain state attorneys general, members of Congress and the United States Department of Justice. State or federal healthcare reform measures or other social or political pressure to lower the cost of pharmaceutical products could have a material adverse impact on our business, results of operations and financial condition.

The Biden administration also introduced various measures in 2021 focusing on healthcare and drug pricing, in particular. For example, on January 28, 2021, President Biden issued an executive order that initiated a special enrollment period for purposes of obtaining health insurance coverage through the Affordable Care Act marketplace, which began on February 15, 2021, and remained open through August 15, 2021. 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, reexamining Medicaid demonstration projects and waiver programs that include work requirements and policies that create unnecessary barriers to obtaining access to health insurance coverage through Medicaid or the Affordable Care Act. On the legislative front, the American Rescue Plan Act of 2021 was signed into law on March 11, 2021, which, in relevant part, eliminates the statutory Medicaid drug rebate cap, currently set at 100% of a drug's average manufacturer price, for single source drugs and innovator multiple source drugs, beginning January 1, 2024. And, in July 2021, the Biden administration released an executive order entitled, "Promoting Competition in the American Economy," with multiple provisions aimed at prescription drugs. In response, on September 9, 2021, HHS released a "Comprehensive Plan for Addressing High Drug Prices" that outlines principles for drug pricing reform and sets out a variety of potential legislative policies that Congress could pursue as well as potential administrative actions HHS can take to advance these principles. And, in November 2021, President Biden announced the "Prescription Drug Pricing Plan" as part of the Build Back Better Act (H.R. 5376) passed by the House of Representatives on November 19, 2021, which aims to lower prescription drug pricing by, among other things, allowing Medicare to negotiate prices for certain high-cost prescription drugs covered under Medicare Part D and Part B after the drugs have been on the market for a certain number of years and imposing tax penalties on drug manufacturers that refuse to negotiate pricing with Medicare or increase drug prices "faster than inflation." If enacted, this bill could have a substantial impact on our business, particularly once we have commercially available products on the U.S. market, if ever. In the coming years, additional legislative and regulatory changes could be made to governmental health programs that could significantly impact pharmaceutical companies and the potential success of our vaccine candidates.

Most recently, on August 16, 2022, President Biden signed into law the Inflation Reduction Act of 2022 (the "IRA Act"), which, among other provisions, included several measures intended to lower the cost of prescription drugs and related healthcare reforms. Specifically, the IRA Act authorizes and directs the Department of Health and Human Services (the "DHHS") to set drug price caps for certain high-cost Medicare Part B and Part D qualified drugs, with the initial list of drugs to be selected by September 1, 2023, and the first year of maximum price applicability to begin in 2026. The IRA Act further authorizes the DHHS to penalize pharmaceutical manufacturers that increase the price of certain Medicare Part B and Part D drugs faster than the rate of inflation. Finally, the IRA Act creates significant changes to the Medicare Part D benefit design by capping Part D beneficiaries' annual out-of-pocket spending at $2,000 beginning in 2025. We cannot be sure whether additional or related legislation or rulemaking will be issued or enacted, or what impact, if any, such changes will have on the profitability of any of our drug candidates, if approved for commercial use, in the future.

Our relationships with customers, health care professionals and third-party payors may be subject to applicable healthcare laws, which could expose us to penalties, including administrative, civil or criminal penalties, damages, fines, imprisonment, exclusion from participation in federal healthcare programs such as Medicare and Medicaid, reputational harm, the curtailment or restructuring of our operations and diminished future profits and earnings.

Healthcare professionals and third-party payors will play a primary role in the recommendation and prescription of any product candidates for which we obtain marketing approval. Our current and future arrangements with customers, healthcare professionals and third-party payors may expose us to broadly applicable fraud and abuse and other healthcare laws and regulations that may constrain the business or financial arrangements and relationships through which we conduct research, market, sell and distribute any products for which we obtain marketing approval. Federal and state healthcare laws and regulations that may affect our operations, directly or indirectly, include the following, among others:

- the federal Anti-Kickback Statute, which prohibits persons and entities from, among other things, knowingly and willfully soliciting, offering, receiving or providing remuneration, directly or indirectly, in cash or in kind, to induce or reward either the referral of an individual for, or the purchase, lease, order or recommendation of, any good, facility, item or service, for which payment may be made under federal and state healthcare programs such as Medicare and Medicaid;

- the federal false claims laws, including civil whistleblower or qui tam actions under the federal False Claims Act, which impose criminal and civil penalties against individuals or entities for, among other things, knowingly presenting, or causing to be presented, to the federal government, claims for payment that are false or fraudulent or making a false statement to avoid, decrease or conceal an obligation to pay money to the federal government;

- the federal Health Insurance Portability and Accountability Act of 1996, or HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act of 2009, or HITECH, which imposes criminal and civil liability for, among other things, executing a scheme to defraud any healthcare benefit program or making false statements relating to healthcare matters and also imposes obligations, including mandatory contractual terms, on covered entities, including certain healthcare providers, health plans, and healthcare clearinghouses, and their respective business associates that create, receive, maintain or transmit individually identifiable health information for or on behalf of the covered entity as well as their covered subcontractors, with respect to safeguarding the privacy, security and transmission of individually identifiable health information;

- the federal Civil Monetary Penalties Law, which prohibits, among other things, the offering or transfer of remuneration to a Medicare or state healthcare program beneficiary if the person knows or should know it is likely to influence the beneficiary's selection of a particular provider, practitioner, or supplier of services reimbursable by Medicare or a state healthcare program, unless an exception applies;

- the federal Physician Payments Sunshine Act, created under the Affordable Care Act, and its implementing regulations, which requires certain manufacturers of drugs, devices, biologicals and medical supplies for which payment is available under Medicare, Medicaid or the Children's Health Insurance Program (with certain exceptions) to report annually information related to certain payments or other transfers of value provided to physicians and any ownership and investment interests held by physicians or their immediate family members. Beginning in 2022, applicable manufacturers also will be required to report such information regarding payments and other transfers of value to physician assistants, nurse practitioners, clinical nurse specialists, anesthesiologist assistants, certified registered nurse anesthetists and certified nurse midwives during the previous year; and

- analogous state laws and regulations, including (among others) state anti-kickback and false claims laws, which may apply to our business practices, including, but not limited to, research, distribution, sales and marketing arrangements and claims involving healthcare items or services reimbursed by any third-party payor, including private insurers; state laws that require pharmaceutical companies to comply with the pharmaceutical industry's voluntary compliance guidelines and the relevant compliance guidance promulgated by the United States federal government, or otherwise restrict payments that may be made to healthcare providers and other potential referral sources; state laws and regulations that require drug manufacturers to file reports relating to pricing and marketing information and that require tracking gifts and other remuneration and items of value provided to healthcare professionals and entities; state and local laws that require the registration of pharmaceutical sales representatives; and state laws governing the privacy and security of health information in certain circumstances, many of which differ from each other in significant ways and often are not preempted by federal law, thus complicating compliance efforts.

Efforts to comply with applicable healthcare laws and regulations will involve substantial costs. Interpretations of standards of compliance under these laws and regulations are rapidly changing and subject to varying interpretations and 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 laws that may apply to us, we may be subject to significant civil, criminal and administrative penalties, damages, fines, exclusion from government funded healthcare programs, such as Medicare and Medicaid, reputational harm, imprisonment, additional reporting obligations and oversight (if we become subject to a corporate integrity agreement or other agreement to resolve allegations of non-compliance with these laws), and the curtailment or restructuring of our operations, any of which could diminish our future profits or earnings. If any of the physicians or other providers or entities with whom we expect to do business are found to be not in compliance with applicable laws, they may be subject to criminal, civil or administrative sanctions, including exclusions from government funded healthcare programs.

Third-party payors may not adequately reimburse customers for any of our products that we may commercialize or promote and may impose coverage restrictions or limitations such as prior authorizations and step edits that affect their use.

Our ability to commercialize any product candidates successfully also will depend in part on the extent to which coverage and adequate reimbursement for these products and related treatments will be available from government health programs, private health insurers, integrated delivery networks and other third-party payors. Third-party payors decide which medications they will pay for and establish reimbursement levels. A significant trend in the United States healthcare industry and elsewhere is cost containment. Government authorities and third-party payors have attempted to control costs by limiting coverage and the amount of payment for particular medications. Increasingly, third-party payors are requiring that drug companies provide predetermined discounts from list prices and are challenging the prices charged for medical products. Coverage and reimbursement may not be available for any product that we commercialize and, if reimbursement is available, the level of reimbursement may not be sufficient for commercial success. Coverage and reimbursement may impact the demand for, or the price of, any product candidate for which we obtain marketing approval. If coverage and reimbursement is not available or is available only to limited levels, we may not be able to successfully commercialize any product candidate for which we obtain marketing approval.

Obtaining reimbursement approval for any product candidate for which we obtain marketing approval from any government or other third-party payor is a time-consuming and costly process. There may be significant delays in obtaining coverage and adequate reimbursement for newly approved products. Moreover, eligibility for coverage and reimbursement does not imply that any product will be paid for in all cases or at a rate that covers our costs, including research, development, manufacture, sale and distribution. Even when a payor determines that a product that we may commercialize or promote is eligible for reimbursement under its criteria, the payor may impose coverage limitations that preclude payment for some uses that are approved by the FDA, or may impose restrictions, such as prior authorization requirements, or may simply deny coverage altogether. Interim reimbursement levels for new drugs, if applicable, may also not be sufficient to cover our costs and may not be made permanent. Coverage and reimbursement rates may vary according to the use of the drug and the medical circumstances under which it is used may be based on reimbursement levels already set for lower cost products or procedures or may be incorporated into existing payments for other services. Net prices for drugs may be reduced by mandatory discounts or rebates required by government healthcare programs or private payors and by any future relaxation of laws that presently restrict imports of drugs from countries where they may be sold at lower prices than in the United States. Furthermore, the Centers for Medicare and Medicaid Services frequently change product descriptors, coverage policies, product and service codes, payment methodologies and reimbursement values. Commercial third-party payors often rely upon Medicare coverage policies and payment limitations in setting their own reimbursement policies. Our inability to promptly obtain and maintain coverage and profitable payment rates from both government-funded programs and private payors for any approved products that we develop could have a material adverse effect on our operating results, our ability to raise capital needed to commercialize our approved products and our overall financial condition.

Risks Related to Third Parties

We rely on third parties to conduct our clinical trials. If these third parties do not successfully carry out their contractual duties or meet expected deadlines or comply with regulatory requirements, we may not be able to obtain regulatory approval for or commercialize our product candidates.

We do not have the ability to independently conduct our clinical trials for our product candidates and we must rely on third parties, such as contract research organizations, medical institutions, clinical investigators and contract laboratories to conduct such trials. Our reliance on these third parties for clinical development activities results in reduced control over these activities. Moreover, the FDA requires us to comply with regulations and standards, commonly referred to as GCPs (good clinical practices), for conducting, recording and reporting the results of clinical trials to assure that data and reported results are credible and accurate and that the trial participants are adequately protected. Our reliance on third parties does not relieve us of these responsibilities and requirements. If we or any of our third-party contractors fail to comply with applicable GCPs, the clinical data generated in our clinical trials may be deemed unreliable and the FDA or comparable foreign regulatory authorities may require us to perform additional clinical trials before approving our marketing applications. We cannot assure you that upon inspection by a given regulatory authority, such regulatory authority will determine that any of our clinical trials complies with GCP regulations. In addition, our clinical trials must be conducted with product produced under current good manufacturing practice, or ("cGMP") regulations. Our failure to comply with these regulations may require us to repeat clinical trials, which would delay the regulatory approval process.

If our consultants, contract research organizations and other similar entities with which we are working do not successfully carry out their contractual duties, meet expected deadlines, or comply with applicable regulations, we may be required to replace them. Although we believe that there are a number of other third-party contractors we could engage to continue these activities, we may not be able to enter into arrangements with alternative third-party contractors or to do so on commercially reasonable terms, which may result in a delay of our planned clinical trials and delayed development of our product candidates.

In addition, our third-party contractors are not our employees, and except for remedies available to us under our agreements with such third-party contractors, we cannot control whether or not they devote sufficient time and resources to our programs. If these third parties do not successfully carry out their contractual duties or regulatory obligations or meet expected deadlines, or if the quality or accuracy of the data they obtain is compromised due to the failure to adhere to our clinical protocols or regulatory requirements or for other reasons, our pre-clinical development activities or clinical trials may be extended, delayed, suspended or terminated, and we may not be able to obtain regulatory approval for, or successfully commercialize, our product candidates on a timely basis, if at all, and our business, operating results and prospects would be adversely affected.

The antibodies we use in our targeted radiotherapy product candidates may be subject to generic competition.

We are not aware of any existing or pending regulations or legislation that pertains to generic radiopharmaceutical products such as antibody radiation-conjugate product candidates. Our product candidates are regulated by the FDA as biologic products and we intend to seek approval for these products pursuant to the BLA pathway. The Biologics Price Competition and Innovation Act of 2009, or BPCIA, created an abbreviated pathway for the approval of biosimilar and interchangeable biologic products. The abbreviated regulatory pathway establishes legal authority for the FDA to review and approve biosimilar biologics, including the possible designation of a biosimilar as "interchangeable" based on its similarity to an existing brand product. Under the BPCIA, an application for a biosimilar product cannot be approved by the FDA until 12 years after the original branded product was approved under a BLA. 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. Even if a biosimilar gets approved for one of the antibodies that we use, the final constructs of our drug candidates consist of an antibody, radioisotope and in some cases a linker. Therefore, we do not believe that the final drug product of our candidates can be subject to competition from a biosimilar as outlined in BPCIA.

Our product candidates may never achieve market acceptance.

Iomab-B, CD33 program candidates and future product candidates that we may develop may never gain market acceptance among physicians, patients and the medical community. The degree of market acceptance of any of our products will depend on a number of factors, including the actual and perceived effectiveness and reliability of the product; the results of any long-term clinical trials relating to use of the product; the availability, relative cost and perceived advantages and disadvantages of alternative technologies; the degree to which treatments using the product are approved for reimbursement by public and private insurers; the strength of our marketing and distribution infrastructure; and the level of education and awareness among physicians and hospitals concerning the product.

We believe that oncologists and other physicians will not widely adopt a product candidate unless they determine, based on experience, clinical data, and published peer-reviewed journal articles, that the use of that product candidate provides an effective alternative to other means of treating specific cancers. Patient studies or clinical experience may indicate that treatment with our product candidates does not provide patients with sufficient benefits in extension of life or quality of life. We believe that recommendations and support for the use of each product candidate from influential physicians will be essential for widespread market acceptance. Our product candidates are still in the development stage and it is premature to attempt to gain support from physicians at this time. We can provide no assurance that such support will ever be obtained. If our product candidates do not receive such support from these physicians and from long-term data, physicians may not use or continue to use, and hospitals may not purchase or continue to purchase, them.

Failure of Iomab-B, CD33 program candidates or any of our other product candidates to significantly penetrate current or new markets would negatively impact our business financial condition and results of operations.

We may be subject to claims that our third-party service providers, consultants or current or former employees have wrongfully used or disclosed confidential information of third parties.

We have received confidential and proprietary information from third parties. In addition, we employ individuals who were previously employed at other biotechnology or pharmaceutical companies. We may be subject to claims that we or our employees, consultants or independent contractors have inadvertently or otherwise used or disclosed confidential information of these third parties or our employees' former employers. Litigation may be necessary to defend against these claims. Even if we are successful in defending against these claims, litigation could result in substantial cost and be a distraction to our management and employees.

We currently depend on single third-party manufacturers to produce our pre-clinical and clinical trial drug supplies. Any disruption in the operations of our current third-party manufacturers, or other third-party manufacturers we may engage in the future, could adversely affect our business and results of operations.

We do not currently operate manufacturing facilities for pre-clinical or clinical production of any of our product candidates. We rely on third-party manufacturers to supply, store, and distribute pre-clinical and clinical supply of the components of our drug product candidates including monoclonal antibodies, linkers and radioisotopes, as well as the final construct which comprises our drug product candidates. We expect to continue to depend on third-party manufacturers for the foreseeable future. Any performance failure on the part of our existing or future manufacturers could delay clinical development, cause us to suspend or terminate development or delay or prohibit regulatory approval of our product candidates or commercialization of any approved products. Further avenues of disruption to our clinical or eventual commercial supply may also occur due to the sale, acquisition, business reprioritization, bankruptcy or other unforeseen circumstances that might occur at any of our suppliers or contract manufacturing partners including an inability to come to terms on renewal of existing contracts or new contracts.

We currently rely on single manufacturers to manufacture our pre-clinical and clinical trial drug supplies. With a view to maintaining business continuity we are evaluating alternatives and second and even third sources of supply or manufacturing for our core suppliers and manufacturing partners, however there can be no assurances that we will be able to identify such suppliers or partners and assuming we did, that we would be able to enter into contracts that are on favorable terms or on terms that will enable sufficient supply to ensure business continuity and support our growth plans.

Our product candidates require precise, high-quality manufacturing. Failure by our current contract manufacturer or other third-party manufacturers we may engage in the future to achieve and maintain high manufacturing standards could result in patient injury or death, product recalls or withdrawals, delays or failures in testing or delivery, cost overruns, or other problems that could seriously hurt our business. Contract manufacturers may encounter difficulties involving production yields, quality control, and quality assurance. These manufacturers are subject to ongoing periodic and unannounced inspections by the FDA and corresponding state and foreign agencies to ensure strict compliance with cGMPs and other applicable government regulations and corresponding foreign standards; we do not have control over third-party manufacturers' compliance with these regulations and standards.

We may elect to build or purchase a manufacturing facility or facilities in the future to operate for the purposes of manufacturing our own products. We have never built, owned or operated a manufacturing facility. There can be no assurances that we will be able to successfully accomplish this and in doing so we may experience delays, cost overruns, or other problems that could seriously hurt our business. Even if we successfully build or purchase a manufacturing facility, we may not realize the expected benefits of these efforts.

We depend on vendors with specialized operations, equipment and know-how to manufacture the respective components of our drug candidates. We have entered into manufacturing and supply agreements with these third-parties, and in some instances, we have agreed that such vendor be the exclusive manufacturer and supplier. If any of the third-parties we depend on encounter difficulties in their operations, fail to comply with required regulations or breach their contractual obligations it may be difficult, or we may be unable to identify suitable alternative third-party manufacturers. While we identify and evaluate third-party manufacturers from time to time, even if we do identify suitable alternative third-parties, we may fail to reach agreement on contractual terms, it may be prohibitively expensive and there can be no assurance that we can successfully complete technology transfer and development work necessary or complete the necessary work in a timely manner. Any of which could prevent us from commencing manufacturing with third-parties which could cause delays or suspension of our clinical trials and pre-clinical work that may have a negative impact on our business.

Furthermore, these third-party contractors, whether foreign or domestic, may experience regulatory compliance difficulty, mechanical shutdowns, employee strikes, or any other unforeseeable acts that may delay or limit production. Our inability to adequately establish, supervise and conduct (either ourselves or through third parties) all aspects of the formulation and manufacturing processes, and the inability of third-party manufacturers to consistently supply quality product when required would have a material adverse effect on our ability to develop or commercialize our products. We have faced delays and risks associated with reliance on key third party manufacturers in the past and may be faced with such delays and risks in the future. Any future manufacturing interruptions or related supply issues could have an adverse effect on our company, including delays in clinical trials.

If we are successful in obtaining marketing approval from the FDA and/or other regulatory agencies for any of our product candidates, we anticipate continued reliance on third-party manufacturers.

To date, our product candidates have been manufactured in small quantities for preclinical and clinical testing by third-party manufacturers. If the FDA or other regulatory agencies approve any of our product candidates for commercial sale, we expect that we would continue to rely, at least initially, on third-party specialized manufacturers to produce commercial quantities of approved products. These manufacturers may not be able to successfully increase the manufacturing capacity for any approved product in a timely or economic manner, or at all. Significant scale-up of manufacturing may require additional validation studies, which the FDA must review and approve. Scale-up for commercial product may require financial commitment or investment by us, which we may not have sufficient capital for or may elect not to undertake. If third party manufacturers are unable to successfully increase the manufacturing capacity for a product candidate, or we are unable to establish our own manufacturing capabilities, the commercial launch of any approved products may be delayed or there may be a shortage in supply, which in turn could have a material adverse effect on our business.

In addition, the facilities used by our contract manufacturers to manufacture our product candidates must be approved by the FDA pursuant to inspections that will be conducted after we submit a BLA to the FDA. We do not control the manufacturing process of, and are completely dependent on, our contract manufacturing partners for compliance with cGMPs. If our contract manufacturers cannot successfully manufacture material that conforms to our specifications and the strict regulatory requirements of the FDA or other regulatory authorities, they will not be able to secure and/or maintain regulatory approval for their manufacturing facilities. If the FDA or a comparable foreign regulatory authority does not approve these facilities for the manufacture of our product candidates or if it withdraws any such approval in the future, we may need to find alternative manufacturing facilities, which would significantly impact our ability to develop, obtain regulatory approval for or market our product candidates, if approved.

We may have conflicts with our partners that could delay or prevent the development or commercialization of our product candidates.

We may have conflicts with our partners, such as conflicts concerning the interpretation of preclinical or clinical data, the achievement of milestones, the interpretation of contractual obligations, payments for services, development obligations or the ownership of intellectual property developed during our collaboration. If any conflicts arise with any of our partners, such partner may act in a manner that is averse to our best interests. Any such disagreement could result in one or more of the following, each of which could delay or prevent the development or commercialization of our product candidates, and in turn prevent us from generating revenues: unwillingness on the part of a partner to pay us milestone payments or royalties we believe are due under a collaboration; uncertainty regarding ownership of intellectual property rights arising from our collaborative activities, which could prevent us from entering into additional collaborations; unwillingness by the partner to cooperate in the development or manufacture of the product, including providing us with product data or materials; unwillingness on the part of a partner to keep us informed regarding the progress of its development and commercialization activities or to permit public disclosure of the results of those activities; initiating litigation or alternative dispute resolution options by either party to resolve the dispute; or attempts by either party to terminate the agreement.

If in the future we are unable to establish U.S. or global sales and marketing capabilities or enter into agreements with third parties to sell and market our product candidates, we may not be successful in commercializing our product candidates if they are approved and we may not be able to generate any revenue.

We currently do not have a marketing or sales team for the marketing, sales and distribution of any of our product candidates that may receive regulatory approval. In order to commercialize any product candidates after approval, we must build on a territory-by-territory basis marketing, sales, distribution, managerial and other non-technical capabilities or make arrangements with third parties to perform these services, and we may not be successful in doing so. If our product candidates receive regulatory approval, we may decide to establish an internal sales or marketing team with technical expertise and supporting distribution capabilities to commercialize our product candidates, which will be expensive and time-consuming and will require significant attention of our executive officers to manage. Any failure or delay in the development of our internal sales, marketing and distribution capabilities would adversely impact the commercialization of any of our product candidates that we obtain approval to market.

With respect to the commercialization of all or certain of our product candidates, we may choose to collaborate, either globally or on a territory-by-territory basis, with third parties that have direct sales forces and established distribution systems, either to augment our own sales force and distribution systems or in lieu of our own sales force and distribution systems. In particular, we have and expect to continue to partner with third parties to commercialize Iomab-B outside the United States. In April 2022, we entered into a licensing agreement with Immedica, in which Immedica acquired the product rights for commercialization of Iomab-B for certain territories outside the U.S. If we are unable to enter into or maintain such arrangements when needed on acceptable terms, or at all, we may not be able to successfully commercialize any of our product candidates that receive regulatory approval or any such commercialization may experience delays or limitations. If we are not successful in commercializing our product candidates, 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.

We face significant competition from other biotechnology and pharmaceutical companies.

Our product candidates face, and will continue to face, intense competition from large pharmaceutical and biotechnology companies, as well as academic and research institutions. We compete in an industry that is characterized by (i) rapid technological change, (ii) evolving industry standards, (iii) emerging competition and (iv) new product introductions. Our competitors have existing products and technologies that will compete with our product candidates and technologies and may develop and commercialize additional products and technologies that will compete with our product candidates and technologies. Because several competing companies and institutions have greater financial resources than us, they may be able to (i) provide broader services and product lines, (ii) make greater investments in research and development, or R&D, and (iii) carry on broader R&D initiatives. Our competitors also have greater development capabilities than we do and have substantially greater experience in undertaking preclinical and clinical testing of product candidates, obtaining regulatory approvals, and manufacturing and marketing pharmaceutical products. They also have greater name recognition and better access to customers than us.

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

Undesirable side effects caused by our product candidates could cause us or regulatory authorities to interrupt, delay or halt clinical trials and could result in a more restrictive label or the delay or denial of regulatory approval by the FDA or other comparable foreign authorities. The drug-related side effects could 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 harm our business, financial condition and prospects significantly. Even if any of our product candidates receives marketing approval, as greater numbers of patients use a product following its approval, an increase in the incidence of side effects or the incidence of other post-approval problems that were not seen or anticipated during pre-approval clinical trials could result in a number of potentially significant negative consequences, including:

- regulatory authorities may withdraw their approval of the product;
- regulatory authorities may require the addition of labeling statements, such as warnings or contraindications;
- we may be required to change the way the product is administered, conduct additional clinical trials or change the labeling of the product;
- we may elect, or we may be required, to recall or withdraw product from the market;
- we could be sued and held liable for harm caused to patients; and
- our reputation may suffer.

Any of these events could substantially increase the costs and expenses of developing, commercializing and marketing any such product candidates or could harm or prevent sales of any approved products.

Risks Related to Our Intellectual Property

We depend upon securing and protecting critical intellectual property.

We are dependent on obtaining and maintaining patents, trade secrets, copyright and trademark protection of our technologies in the United States and other jurisdictions, as well as successfully enforcing this intellectual property and defending this intellectual property against third-party challenges. The degree of future protection of our proprietary rights is uncertain for product candidates that are currently in the early stages of development because we cannot predict which of these product candidates will ultimately reach the commercial market or whether the commercial versions of these product candidates will incorporate proprietary technologies.

Our patent position is highly uncertain and involves complex legal and factual questions.

Accordingly, we cannot predict the breadth of claims that may be allowed or enforced under our patents or in third-party patents. For example, we or our licensors might not have been the first to make the inventions covered by each of our pending patent applications and issued patents; we or our licensors might not have been the first to file patent applications for these inventions; others may independently develop similar or alternative technologies or duplicate any of our technologies; it is possible that none of our pending patent applications or the pending patent applications of our licensors will result in issued patents; our issued patents and issued patents of our licensors may not provide a basis for commercially viable technologies, or may not provide us with any competitive advantages, or may be challenged and invalidated by third parties; and, we may not develop additional proprietary technologies that are patentable.

As a result, our owned and licensed patents may not be valid, and we may not be able to obtain and enforce patents and to maintain trade secret protection for the full commercial extent of our technology. The extent to which we are unable to do so could materially harm our business.

We or our licensors have applied for and will continue to apply for patents for certain products. Such applications may not result in the issuance of any patents, and any patents now held or that may be issued may not provide us with adequate protection from competition. Furthermore, it is possible that patents issued or licensed to us may be challenged successfully. In that event, if we have a preferred competitive position because of such patents, such preferred position would be lost. If we are unable to secure or to continue to maintain a preferred position, we could become subject to competition from the sale of generic products. Failure to receive, inability to protect, or expiration of our patents for medical use, manufacture, conjugation and labeling of Ac-225, the antibodies that we license from third parties, or subsequent related filings, would adversely affect our business and operations.

Patents issued or licensed to us may be infringed by the products or processes of others. The cost of enforcing our patent rights against infringers, if such enforcement is required, could be significant, and we do not currently have the financial resources to fund such litigation. Further, such litigation can go on for years and the time demands could interfere with our normal operations. There has been substantial litigation and other proceedings regarding patent and other intellectual property rights in the pharmaceutical industry. We may become a party to patent litigation and other proceedings. The cost to us of any patent litigation, even if resolved in our favor, could be substantial. Some of our competitors may be able to sustain the costs of such litigation more effectively than we can because of their substantially greater financial resources. Litigation may also absorb significant management time.

Unpatented trade secrets, improvements, confidential know-how and continuing technological innovation are important to our scientific and commercial success. Although we attempt to and will continue to attempt to protect our proprietary information through reliance on trade secret laws and the use of confidentiality agreements with our partners, collaborators, employees and consultants and other appropriate means, these measures may not effectively prevent disclosure of our proprietary information, and, in any event, others may develop independently, or obtain access to, the same or similar information.

Certain of our patent rights are licensed to us by third parties. If we fail to comply with the terms of these license agreements, our rights to those patents may be terminated, and we will be unable to conduct our business.

If we are found to be infringing on patents or trade secrets owned by others, we may be forced to cease or alter our product development efforts, obtain a license to continue the development or sale of our products, and/or pay damages.

Our manufacturing processes and potential products may violate proprietary rights of patents that have been or may be granted to competitors, universities or others, or the trade secrets of those persons and entities. As the pharmaceutical industry expands and more patents are issued, the risk increases that our processes and potential products may give rise to claims that they infringe the patents or trade secrets of others. These other persons could bring legal actions against us claiming damages and seeking to enjoin clinical testing, manufacturing and marketing of the affected product or process. If any of these actions are successful, in addition to any potential liability for damages, we could be required to obtain a license in order to continue to conduct clinical tests, manufacture or market the affected product or use the affected process. Required licenses may not be available on acceptable terms, if at all, and the results of litigation are uncertain. If we become involved in litigation or other proceedings, it could consume a substantial portion of our financial resources and the efforts of our personnel.

In addition to infringement or other intellectual property claims against us, we may become a party to other patent litigation or proceedings before regulatory agencies, including post-grant review, inter parties review, interference or re-examination proceedings filed with the U.S. Patent and Trademark Office (or similar proceedings before corresponding tribunals in other jurisdictions) that challenge our patent rights or the patent rights of our licensors. The costs and efforts of defending our patents or enforcing our proprietary rights in post-issuance administrative proceedings can be substantial and the outcome can be uncertain. An adverse determination in these proceedings could weaken or invalidate the patent claims that cover our technology, which adverse determination could harm our business significantly and dissuade companies from collaborating with us or permit third parties to directly compete with the same technology.

Our ability to protect and enforce our patents does not guarantee that we will secure the right to commercialize our patents.

A patent is a limited monopoly right conferred upon an inventor, and his successors in title, in return for the making and disclosing of a new and non-obvious invention. This monopoly is of limited duration but, while in force, allows the patent holder to prevent others from making and/or using its invention. While a patent gives the holder this right to exclude others, it is not a license to commercialize the invention where other permissions may be required for commercialization to occur. For example, a drug cannot be marketed without the appropriate authorization from the FDA, regardless of the existence of a patent covering the product. Further, the invention, even if patented itself, cannot be commercialized if it infringes the valid patent rights of another party.

We rely on confidentiality agreements to protect our trade secrets. If these agreements are breached by our employees or other parties, our trade secrets may become known to our competitors.

We rely on trade secrets that we seek to protect through numerous measures, including non-compete and confidentiality agreements with our employees and other parties. If these agreements are breached, our competitors may obtain and use our trade secrets to gain a competitive advantage over us. Any remedies that may be available to us may not be adequate to protect our business or compensate us for the damaging disclosure. In addition, we may have to expend resources to protect our interests from possible infringement by others. We have learned that a former employee violated the non-compete provision of their employment agreement by working for a direct competitor. This employee, who had access to materials containing proprietary information and trade secrets, may have been solicited, and until recently, pursuant to actions taken by Actinium, was employed by a direct competitor. We intend to fully investigate this matter and, if appropriate, pursue litigation against all parties that may be involved to protect our confidential information and trade secrets.

Risks Related to Our Operations

We expect to expand our development and regulatory capabilities and potentially implement sales, marketing and distribution capabilities, and, as a result, we may encounter difficulties in managing our growth, which could disrupt our operations.

We expect to experience significant growth in the number of our employees and the scope of our operations, particularly in the areas of product candidate development, regulatory affairs and, if any of our product candidates receives marketing approval, sales, marketing and distribution.

We currently do not have a marketing or sales team for the marketing, sales and distribution of any of our product candidates that are potentially able to obtain regulatory approval. In order to commercialize any product candidates, we must build on a territory-by-territory basis marketing, sales, distribution, managerial and other non-technical capabilities or make arrangements with third parties to perform these services, and we may not be successful in doing so. If our product candidates receive regulatory approval, we intend to establish an internal sales or marketing team with technical expertise and supporting distribution capabilities to commercialize our product candidates, which will be expensive and time consuming and will require significant attention of our executive officers to manage. We will also have to compete with other pharmaceutical and biotechnology companies to recruit, hire, train and retain marketing and sales personnel. Any failure or delay in the development of our internal sales, marketing and distribution capabilities would adversely impact the commercialization of any of our product candidates that we obtain approval to market.

To manage our anticipated future growth, we must continue to implement and improve our managerial, operational and financial systems, expand our facilities and continue to recruit and train additional qualified personnel. Due to our limited financial resources and the limited experience of our management team in managing a public company with such anticipated growth, we may not be able to effectively manage the expansion of our operations or recruit and train additional qualified personnel. The expansion of our operations may lead to significant costs and may divert our management and business development resources. Any inability to manage growth could delay the execution of our business plans or disrupt our operations.

The use of hazardous materials, including radioactive and biological materials, in our research and development efforts imposes certain compliance costs on us and may subject us to liability for claims arising from the use or misuse of these materials.

Our research, development and manufacturing activities involve the controlled use of hazardous materials, including chemicals, radioactive and biological materials, such as radioactive isotopes. We are subject to federal, state, local and foreign environmental laws and regulations governing, among other matters, the handling, storage, use and disposal of these materials and some waste products. We cannot completely eliminate the risk of contamination or injury from these materials and we could be held liable for any damages that result, which could exceed our financial resources. We currently maintain insurance coverage for injuries resulting from the hazardous materials we use; however, future claims may exceed the amount of our coverage. Also, we do not have insurance coverage for pollution cleanup and removal. Currently the costs of complying with such federal, state, local and foreign environmental regulations are not significant, and consist primarily of waste disposal expenses. However, they could become expensive, and current or future environmental laws or regulations may impair our research, development, production and commercialization efforts.

We may undertake international operations, which will subject us to risks inherent with operations outside of the United States.

Although we do not have any international operations at this time, we intend to seek market clearances in foreign markets that we believe will generate significant opportunities. However, even with the cooperation of a commercialization partner, conducting drug development in foreign countries involves inherent risks, including, but not limited to difficulties in staffing, funding and managing foreign operations; unexpected changes in regulatory requirements; export restrictions; tariffs and other trade barriers; difficulties in protecting, acquiring, enforcing and litigating intellectual property rights; fluctuations in currency exchange rates; and potentially adverse tax consequences.

If we were to experience any of the difficulties listed above, or any other difficulties, any international development activities and our overall financial condition may suffer and cause us to reduce or discontinue our international development and registration efforts.

We are highly dependent on our key personnel, and if we are not successful in attracting and retaining highly qualified personnel, we may not be able to successfully implement our business strategy.

Our future operations and successes depend in large part upon the continued service of key members of our senior management team whom we are highly dependent upon to manage our business. If any member of our current senior management terminates his or her employment with us and we are unable to find a suitable replacement quickly, the departure could have a material adverse effect on our business. An overall tightening and increasingly competitive labor market has been observed in the U.S. employment market generally, especially in response to the COVID-19 pandemic. Specific to the biotechnology industry in which we operate, there is significant demand and competition for highly specialized talent that we require. A sustained labor shortage or increased turnover rates within our employee base, caused by the COVID-19 pandemic, as a result of general macroeconomic factors, or due to dynamics within our industry, could lead to increased costs, such as increased wage rates to attract and retain employees, and could negatively affect our ability to efficiently conduct our clinical development, R&D, business development and potential regulatory and commercial activities. If we are unable to hire and retain employees capable of performing at a high-level, or if mitigation measures we may take to respond to a decrease in labor availability, have unintended negative effects, our business could be adversely affected. An overall labor shortage, lack of skilled labor, increased turnover or labor inflation, caused by the COVID-19 pandemic, general macroeconomic factors or as a result of biotechnology industry dynamics could have a material adverse impact on our operations, results of operations, liquidity or cash flows.

Our future success also depends on our ability to identify, attract, hire or engage, retain and motivate other well-qualified managerial, technical, clinical and regulatory personnel. This activity is likely to create additional demands on the time and attention of our senior management personnel as they identify, hire, and train external and internal candidates to fill the sizable number of positions required to execute our business plans including submit a BLA and build a commercial organization. The market for talent in our industry is very competitive. Many of the other biopharmaceutical companies we compete against for qualified personnel have greater financial and other resources, more favorable risk profiles and a longer operating history in the biopharmaceutical industry than we do. They also may provide more diverse opportunities and better chances for career advancement. Some of these opportunities may be more appealing to high-quality candidates than what we have to offer.

It is particularly difficult to recruit and hire new employees during the COVID-19 pandemic as the uncertainty created by the COVID-19 pandemic makes it less likely potential candidates will be willing to leave a stable job to explore a new opportunity. There can be no assurance that such professionals will be available in the market, or that we will be able to retain existing professionals or meet or continue to meet their compensation requirements. Furthermore, the cost base in relation to such compensation, which may include equity compensation, may increase significantly, which could have a material adverse effect on us. Failure to establish and maintain an effective management team and workforce could adversely affect our ability to operate, grow and manage our business.

Managing our growth as we expand operations may strain our resources.

We expect to need to grow rapidly in order to support additional, larger, and potentially international, pivotal clinical trials of our product candidates as well as potential commercial operations, which will place a significant strain on our financial, managerial and operational resources. In order to achieve and manage growth effectively, we must continue to improve and expand our operational and financial management capabilities. Moreover, we will need to increase staffing and to train, motivate and manage our employees. All of these activities will increase our expenses and may require us to raise additional capital sooner than expected. Failure to manage growth effectively could materially harm our business, financial condition or results of operations.

We may expand our business through the acquisition of rights to new product candidates that could disrupt our business, harm our financial condition and may also dilute current stockholders' ownership interests in our company.

Our business strategy includes expanding our products and capabilities, and we may seek acquisitions of product candidates, antibodies or technologies to do so. Acquisitions involve numerous risks, including substantial cash expenditures; potentially dilutive issuance of equity securities; incurrence of debt and contingent liabilities, some of which may be difficult or impossible to identify at the time of acquisition; difficulties in assimilating acquired technologies or the operations of the acquired companies; diverting our management's attention away from other business concerns; risks of entering markets in which we have limited or no direct experience; and the potential loss of our key employees or key employees of the acquired companies.

We can make no assurances that any acquisition will result in short-term or long-term benefits to us. We may incorrectly judge the value or worth of an acquired product, company or business. In addition, our future success would depend in part on our ability to manage the rapid growth associated with some of these acquisitions. We cannot assure that we will be able to make the combination of our business with that of acquired products, businesses or companies work or be successful. Furthermore, the development or expansion of our business or any acquired products, business or companies may require a substantial capital investment by us. We may not have these necessary funds, or they might not be available to us on acceptable terms or at all. We may also seek to raise funds by selling shares of our preferred or common stock, which could dilute each current stockholder's ownership interest in the Company.

Risks Related to Ownership of Our Common Stock

The sale of securities by us in any equity or debt financing could result in dilution to our existing stockholders and have a material adverse effect on our earnings.

We have financed our operations primarily through sales of stock and warrants. It is likely that during the next twelve months we will seek to raise additional capital through the sales of stock and warrants in order to expand our level of operations to continue our research and development efforts.

Any sale of common stock by us in a future offering could result in dilution to our existing stockholders as a direct result of our issuance of additional shares of our capital stock. In addition, our business strategy may include expansion through internal growth or by establishing strategic relationships with targeted customers and vendors. In order to do so, or to finance the cost of our other activities, we may issue additional equity securities that could dilute our stockholders' stock ownership. We may also assume additional debt and incur impairment losses related to goodwill and other tangible assets if we acquire another company and this could negatively impact our earnings and results of operations.

Our common stock is subject to price volatility which could lead to losses by stockholders and potential costly security litigation.

The trading volume of our common stock has been and may continue to be extremely limited and sporadic. We expect the market price of our common stock to fluctuate substantially due to a variety of factors, including market perception of our ability to achieve our planned growth, quarterly operating results of other companies in the same industry, trading volume in our common stock, changes in general conditions in the economy and the financial markets or other developments affecting our competitors or us. This volatility has had a significant effect on the market price of securities issued by many companies for reasons unrelated to their operating performance and could have the same effect on our common stock.

The trading price of our common stock may be highly volatile and could fluctuate in response to factors such as:

- actual or anticipated variations in our operating results;
- announcements of developments by us or our competitors;
- the timing of IND and/or BLA approval, the completion and/or results of our clinical trials;
- regulatory actions regarding our products;
- announcements by us or our competitors of significant acquisitions, strategic partnerships, joint ventures or capital commitments;
- adoption of new accounting standards affecting our industry;
- additions or departures of key personnel;
- introduction of new products by us or our competitors;
- sales of our common stock or other securities in the open market; and
- other events or factors, many of which are beyond our control.

The stock market is subject to significant price and volume fluctuations. Moreover, the COVID-19 pandemic has resulted in significant financial market volatility and uncertainty in recent months. In the past, following periods of volatility in the market price of a company's securities, securities class action litigation has often been initiated against such a company. Litigation initiated against us, whether or not successful, could result in substantial costs and diversion of our management's attention and our resources, which could harm our business and financial condition.

We do not intend to pay dividends on our common stock, so any returns will be determined by the value of our common stock.

We have never declared or paid any cash dividends on our common stock. For the foreseeable future, it is expected that earnings, if any, generated from our operations will be used to finance the growth of our business, and that no dividends will be paid to holders of our common stock. As a result, the success of an investment in our common stock will depend upon any future appreciation in its value. There is no guarantee that our common stock will appreciate in value.

Certain provisions of our Certificate of Incorporation and Bylaws and Delaware law make it more difficult for a third party to acquire us and make a takeover more difficult to complete, even if such a transaction were in our stockholders' interest.

Provisions of our certificate of incorporation and bylaws may delay or discourage transactions involving an actual or potential change in our control or change in our management, including transactions in which stockholders might otherwise receive a premium for their shares, or transactions that our stockholders might otherwise deem to be in their best interests. Therefore, these provisions could adversely affect the price of our stock. Among other things, the certificate of incorporation and bylaws:

- provide that the authorized number of directors may be changed by resolution of the board of directors;
- provide that all vacancies, including newly created directorships, may, except as otherwise required by law, be filled by the affirmative vote of a majority of directors then in office, even if less than a quorum;
- divide the board of directors into three classes; and
- provide that stockholders seeking to present proposals before a meeting of stockholders or to nominate candidates for election as directors at a meeting of stockholders must provide notice in writing in a timely manner, and meet specific requirements as to the form and content of a stockholder's notice.

In addition, we are governed by Section 203 of the Delaware General Corporation Law. In general, Section 203 prohibits a public Delaware corporation from engaging in a "business combination" with an "interested stockholder" for a period of three years after the date of the transaction in which the person became an interested stockholder, unless the business combination is approved in a prescribed manner. A "business combination" includes mergers, asset sales or other transactions resulting in a financial benefit to the stockholder. An "interested stockholder" is a person who, together with affiliates and associates, owns, or within three years, did own, 15% or more of the corporation's outstanding voting stock. These provisions may have the effect of delaying, deferring or preventing a change in our control.

Compliance with the reporting requirements of federal securities laws can be expensive.

We are subject to the information and reporting requirements of the Exchange Act and other federal securities laws, and the compliance obligations of the Sarbanes-Oxley Act. The costs of preparing and filing annual and quarterly reports and other information with the Securities and Exchange Commission and furnishing audited reports to stockholders are substantial. In addition, we will incur substantial expenses in connection with the preparation of registration statements and related documents with respect any offerings of our common stock.

Failure to establish and maintain adequate finance infrastructure and accounting systems and controls could impair our ability to comply with the financial reporting and internal controls requirements for publicly traded companies.

As a public company, we operate in an increasingly demanding regulatory environment, including with respect to more complex accounting rules. Company responsibilities required by the Sarbanes-Oxley Act of 2002, as amended, or the Sarbanes-Oxley Act, include establishing and maintaining corporate oversight and adequate internal control over financial reporting and disclosure controls and procedures. Effective internal controls are necessary for us to produce reliable financial reports and are important to help prevent financial fraud.

Our compliance with Section 404 of the Sarbanes-Oxley Act requires that we incur substantial accounting expense and expend significant management efforts. We complied with Section 404 at December 31, 2021 and 2020 and while our testing did not reveal any material weaknesses in our internal controls, any material weaknesses in our internal controls in the future would be required us to remediate in a timely manner so as to be able to comply with the requirements of Section 404 each year. If we are not able to comply with the requirements of Section 404 in a timely manner each year, we could be subject to sanctions or investigations by the SEC, NYSE American or other regulatory authorities which would require additional financial and management resources and could adversely affect the market price of our common stock. Furthermore, if we cannot provide reliable financial reports or prevent fraud, our business and results of operations could be harmed, and investors could lose confidence in our reported financial information.

If securities or industry analysts do not publish research or publish inaccurate or unfavorable research about our business, the price of our common stock and trading volume could decline.

The trading market for our common stock will depend in part on the research and reports that securities or industry analysts publish about us or our business. Multiple securities and industry analysts currently cover us. If one or more of the analysts downgrade our common stock or publish inaccurate or unfavorable research about our business, the price of our common stock would likely decline. If one or more of these analysts cease coverage of us or fail to publish reports on us regularly, demand for our common stock could decrease, which could cause the price of our common stock and trading volume to decline.

Our amended and restated bylaws, as amended, designate the U.S. federal district courts as the exclusive forum for the resolution of any complaint asserting a cause of action arising under the Securities Act of 1933, as amended.

Our amended and restated bylaws, as amended, provide that, unless we consent in writing to the selection of an alternative forum, the federal district courts of the United States of America will be the exclusive forum for resolving any complaint asserting a cause of action arising under the Securities Act of 1933, as amended. In addition, our amended and restated bylaws, as amended, state that any person purchasing or otherwise acquiring any interest in our security shall be deemed to have notice of and to have consented to such provision. Such 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, if successful, might benefit our stockholders. Stockholders who do bring a claim in the federal district courts of the United States of America could face additional litigation costs in pursuing any such claim.

ITEM 2. UNREGISTERED SALES OF EQUITY SECURITIES AND USE OF PROCEEDS.

None.

ITEM 3. DEFAULTS UPON SENIOR SECURITIES.

None.

ITEM 4. MINE SAFETY DISCLOSURES.

None.

ITEM 5. OTHER INFORMATION.

None.

ITEM 6. EXHIBITS

Copies of the following documents are included as exhibits to this report pursuant to Item 601 of Regulation S-K.

Exhibit No.	Description
3.1	Certificate of Incorporation of Actinium Pharmaceuticals, Inc. (incorporated by reference to Exhibit 3.1 of the Company's Form 8-K filed with the SEC on April 17, 2013).
3.2	Certificate of Amendment to Certificate of Incorporation, as amended, filed January 7, 2014 (incorporated by reference to Exhibit 3.5 to Form S-1 filed on January 31, 2014).
3.3	Certificate of Amendment to Certificate of Incorporation, as amended, filed February 3, 2014. (incorporated by reference to Exhibit 3.1 to Form 8-K filed on February 7, 2014).
3.4	Certificate of Amendment to Certificate of Incorporation, as amended, filed on February 26, 2015 (incorporated by reference to Exhibit 3.1 to Form 8-K filed on March 4, 2015).
3.5	Certificate of Amendment to Certificate of Incorporation, as amended, filed on February 26, 2018 (incorporated by reference to Exhibit 3.1 to Form 8-K filed on February 26, 2018).
3.6	Certificate of Amendment to Certificate of Incorporation, as amended, filed on March 6, 2019 (incorporated by reference to Exhibit 3.7 to Form 10-K filed on March 15, 2019).
3.7	Certificate of Amendment to Certificate of Incorporation, as amended, filed on June 16, 2020 (incorporated by reference to Exhibit 3.1 to Form 8-K filed on June 16, 2020).
3.8	Certificate of Amendment to Certificate of Incorporation, as amended, filed on August 10, 2020 (incorporated by reference to Exhibit 3.1 to Form 8-K filed on August 14, 2020).
3.9	Amended and Restated Bylaws, dated August 8, 2018 (incorporated by reference to Exhibit 3.1 to Form 10-Q filed on August 9, 2018).
3.10	Amendment to Amended and Restated Bylaws, dated May 7, 2020 (incorporated by reference to Exhibit 3.1 to Form 8-K filed on May 5, 2020).
10.1#	Third Amendment to the Actinium Pharmaceuticals, Inc. 2019 Stock Plan (incorporated by reference to Exhibit 99.4 to the Registration Statement on Form S-8 filed on August 19, 2022).
31.1*	Certification of the Chief Executive Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
31.2*	Certification of the Principal Financial and Accounting Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
32.1**	Certification of the Chief Executive Officer pursuant to U.S.C. Section 1350 as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002*
32.2**	Certification of the Principal Financial and Accounting Officer pursuant to U.S.C. Section 1350 as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002*
101.INS *	Inline XBRL Instance Document
101.SCH *	Inline XBRL Taxonomy Schema Document
101.CAL *	Inline XBRL Taxonomy Calculation Linkbase Document
101.DEF *	Inline XBRL Taxonomy Definition Linkbase Document
101.LAB *	Inline XBRL Taxonomy Label Linkbase Document
101.PRE *	Inline XBRL Taxonomy Presentation Linkbase Document
104*	Cover Page Interactive Data File (formatted as Inline XBRL and contained in Exhibit 101).

* Filed herewith.
** Furnished herewith.
# Indicates a management contract or compensatory plan or arrangement.

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.

ACTINIUM PHARMACEUTICALS, INC.

Date: November 14, 2022

By: */s/ Sandesh Seth*
Sandesh Seth
Chairman and Chief Executive Officer
(Duly Authorized Officer and
Principal Executive Officer)

By: */s/ Steve O'Loughlin*
Steve O'Loughlin
Chief Financial Officer
(Duly Authorized Officer and
Principal Financial and Accounting Officer)

Exhibit 31.1

CERTIFICATION OF PRINCIPAL EXECUTIVE OFFICER

PURSUANT TO

18 U.S.C. SECTION 1350,

AS ADOPTED PURSUANT TO SECTION 302 OF

THE SARBANES-OXLEY ACT OF 2002

I, Sandesh Seth, certify that:

1. I have reviewed this Form 10-Q of Actinium Pharmaceuticals, 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. I am responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13-a-15(f) and 15d-15(f)) for the registrant and have:

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

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

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

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

5. 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, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Dated: November 14, 2022

By: /s/ Sandesh Seth

Sandesh Seth
Chairman and Chief Executive Officer
(Duly Authorized Officer,
Principal Executive Officer)

Exhibit 31.2

CERTIFICATION OF PRINCIPAL FINANCIAL AND ACCOUNTING OFFICER

PURSUANT TO

18 U.S.C. SECTION 1350,

AS ADOPTED PURSUANT TO SECTION 302 OF

THE SARBANES-OXLEY ACT OF 2002

I, Steve O'Loughlin, certify that:

1. I have reviewed this Form 10-Q of Actinium Pharmaceuticals, 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. I am responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13-a-15(f) and 15d-15(f)) for the registrant and have:

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

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

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

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

5. 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, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Dated: November 14, 2022

By: /s/ Steve O'Loughlin
Steve O'Loughlin
Chief Financial Officer
(Duly Authorized Officer,
Principal Financial and Accounting Officer)

Exhibit 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

In connection with the Quarterly Report of Actinium Pharmaceuticals, Inc. (the "Company") on Form 10-Q for the period ended September 30, 2022 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, Sandesh Seth, Chairman & CEO of the Company, certify, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that:

1. The Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934, as amended; and

2. The information contained in the Quarterly Report fairly presents, in all material respects, the financial condition and result of operations of the Company.

Dated: November 14, 2022

By: /s/ Sandesh Seth

Sandesh Seth
Chairman and Chief Executive Officer
(Duly Authorized Officer,
Principal Executive Officer)

Exhibit 32.2

CERTIFICATION OF PRINCIPAL FINANCIAL AND ACCOUNTING OFFICER

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 Actinium Pharmaceuticals, Inc. (the "Company") on Form 10-Q for the period ended September 30, 2022 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, Steve O'Loughlin, Chief Financial Officer of the Company, certify, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that:

1. The Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934, as amended; and

2. The information contained in the Quarterly Report fairly presents, in all material respects, the financial condition and result of operations of the Company.

Dated: November 14, 2022

By: /s/ Steve O'Loughlin

Steve O'Loughlin
Chief Financial Officer
(Duly Authorized Officer,
Principal Financial and Accounting Officer)