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 **June 30, 2025**

or

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

For the transition period from _____ to _____

Commission File Number: **001-36374**

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.)
100 Park Ave., 23rd Floor New York, NY	**10017**
(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 August 8, 2025: 31,195,891

Actinium Pharmaceuticals, Inc.

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PART I - FINANCIAL INFORMATION

ITEM 1. UNAUDITED FINANCIAL STATEMENTS

The accompanying condensed consolidated financial statements have been prepared by Actinium Pharmaceuticals, Inc., or 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 June 30, 2025 and December 31, 2024, and the results of operations and cash flows for the three months and six months ended June 30, 2025 and 2024, 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, 2024 in the Company's Annual Report on Form 10-K. The results of operations for the three months and six months ended June 30, 2025 are not necessarily indicative of the operating results for the full year.

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

	June 30, 2025	December 31, 2024
	(Unaudited)	
Assets		
Current Assets:		
Cash and cash equivalents	$ 59,928	$ 72,904
Prepaid expenses and other current assets	1,101	1,602
Total Current Assets	61,029	74,506
Property and equipment, net of accumulated depreciation of $985 and $891	271	364
Restricted cash – long term	329	324
Operating leases right-of-use assets	1,373	1,685
Finance leases right-of-use assets	15	20
Total Assets	**$ 63,017**	**$ 76,899**
Liabilities and Stockholders' Equity		
Current Liabilities:		
Accounts payable and accrued expenses	$ 7,714	$ 7,568
Operating leases current liability	589	569
Finance leases current liability	11	11
Total Current Liabilities	8,314	8,148
Long-term license revenue deferred	35,000	35,000
Long-term operating lease obligations	685	984
Long-term finance lease obligations	5	9
Total Liabilities	44,004	44,141
Commitments and contingencies		
Stockholders' Equity:		
Preferred stock, $0.001 par value; 50,000,000 shares authorized, 0 shares issued and outstanding	-	-
Common stock, $0.001 par value; 1,000,000,000 shares authorized; 31,195,891 and 31,195,891 shares issued and outstanding, respectively	31	31
Additional paid-in capital	417,624	408,553
Accumulated deficit	(398,642)	(375,826)
Total Stockholders' Equity	19,013	32,758
Total Liabilities and Stockholders' Equity	**$ 63,017**	**$ 76,899**

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 June 30,		For the Six Months Ended June 30,	
	2025	**2024**	**2025**	**2024**
Revenue				
Revenue	$ -	$ -	$ -	$ -
Other revenue	-	-	-	-
Total revenue	-	-	-	-
Operating expenses:				
Research and development, net of reimbursements	4,879	8,825	12,579	15,460
General and administrative	2,624	3,593	11,562	6,555
Total operating expenses	7,503	12,418	24,141	22,015
Loss from operations	(7,503)	(12,418)	(24,141)	(22,015)
Other income:				
Interest income - net	625	1,065	1,325	1,992
Total other income	625	1,065	1,325	1,992
Net loss	**$ (6,878)**	**$ (11,353)**	**$ (22,816)**	**$ (20,023)**
Net loss per common share – basic and diluted	$ (0.22)	$ (0.38)	$ (0.73)	$ (0.69)
Weighted average common shares outstanding – basic and diluted	31,195,891	30,103,063	31,195,891	28,994,775

See accompanying notes to the condensed consolidated financial statements.

Actinium Pharmaceuticals, Inc.
Condensed Consolidated Statement of Changes in Stockholders' Equity
For the Period from January 1, 2025 to June 30, 2025
(Unaudited)
(amounts in thousands, except share amounts)

	Common Stock		Additional Paid-In	Accumulated	Stockholders'
	Shares	Amount	Capital	Deficit	Equity
Balance, January 1, 2025	**31,195,891**	**$ 31**	**$ 408,553**	**$ (375,826)**	**$ 32,758**
Stock-based compensation	-	-	8,874	-	8,874
Net loss	-	-	-	(15,938)	(15,938)
Balance, March 31, 2025	**31,195,891**	**$ 31**	**$ 417,427**	**$ (391,764)**	**$ 25,694**
Stock-based compensation	-	-	197	-	197
Net loss	-	-	-	(6,878)	(6,878)
Balance, June 30, 2025	**31,195,891**	**$ 31**	**$ 417,624**	**$ (398,642)**	**$ 19,013**

See accompanying notes to the condensed consolidated financial statements.

Actinium Pharmaceuticals, Inc.
Condensed Consolidated Statement of Changes in Stockholders' Equity
For the Period from January 1, 2024 to June 30, 2024
(Unaudited)
(amounts in thousands, except share amounts)

	Common Stock		Additional Paid-In	Accumulated	Stockholders'
	Shares	Amount	Capital	Deficit	Equity
Balance, January 1, 2024	**27,634,213**	**$ 28**	**$ 373,934**	**$ (337,583)**	**$ 36,379**
Stock-based compensation	-	-	1,378	-	1,378
Sale of common stock, net of offering costs	1,752,050	1	14,694	-	14,695
Issuance of common stock from exercise of stock options	10,148	-	75	-	75
Net loss	-	-	-	(8,670)	(8,670)
Balance, March 31, 2024	**29,396,411**	**$ 29**	**$ 390,081**	**$ (346,253)**	**$ 43,857**
Stock-based compensation	-	-	1,374	-	1,374
Sale of common stock, net of offering costs	1,154,191	2	9,955	-	9,957
Net loss	-	-	-	(11,353)	(11,353)
Balance, June 30, 2024	**30,550,602**	**$ 31**	**$ 401,410**	**$ (357,606)**	**$ 43,835**

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

	For the Six Months Ended June 30,	
	2025	**2024**
Cash flows used in operating activities:		
Net loss	$ (22,816)	$ (20,023)
Adjustments to reconcile net loss to net cash used in operating activities:		
Stock-based compensation expense	9,071	2,752
Depreciation and amortization expenses	409	405
Changes in operating assets and liabilities:		
Prepaid expenses and other current assets	501	555
Accounts payable and accrued expenses	147	1,224
Operating lease liabilities	(278)	(259)
Net cash used in operating activities	**(12,966)**	**(15,346)**
Cash flows used in investing activities:		
Purchase of property and equipment	-	(11)
Net cash used in investing activities	**-**	**(11)**
Cash flows used in/provided by financing activities:		
Payments on finance leases	(5)	(5)
Sales of shares of common stock, net of costs	-	24,652
Proceeds from the exercise of stock options	-	75
Net cash used in/provided by financing activities	**(5)**	**24,722**
Net change in cash, cash equivalents, and restricted cash	(12,971)	9,365
Cash, cash equivalents, and restricted cash at beginning of period	73,228	76,990
Cash, cash equivalents, and restricted cash at end of period	**$ 60,257**	**$ 86,355**
Supplemental disclosure of cash flow information:		
Cash paid for interest	$ -	$ -
Cash paid for income taxes	$ -	$ -

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. ("Actinium", the "Company", or "we") is a pioneer in the development of targeted radiotherapies intended to meaningfully improve outcomes for patients with advanced cancers. Our goal is to create a specialty radiopharmaceutical company with capabilities across radioisotope production, final drug product manufacturing, preclinical research and development ("R&D") and clinical development. We are deploying our technologies, capabilities and intellectual property with approximately 240 issued and pending patents worldwide, to develop next-generation radiotherapies. We are focused on developing highly differentiated and innovative first-in-class product candidates. Our current pipeline of clinical and preclinical stage targeted radiotherapy product candidates are directed against validated cancer targets for indications in hematology, solid tumors and conditioning for cell and gene therapies, which we believe have high unmet needs that are not addressed by currently available treatment options.

Basis of Presentation - Unaudited Interim Financial Information - The accompanying unaudited interim 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 interim financial information, and in accordance with 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 interim condensed consolidated financial statements furnished 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 interim periods presented. Interim results are not necessarily indicative of the results for the full year. These unaudited interim 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, 2024.

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 Annual Report on Form 10-K for the year ended December 31, 2024. 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 interim 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 unaudited interim condensed consolidated financial statements and the reported amounts of expenses during the reporting period. Actual results could differ from those estimates.

Segment Information - The Company operates as a single operating and reportable segment for the purposes of assessing performance and allocating resources. The Company's chief operating decision maker is its Chief Executive Officer, who reviews total assets in the consolidated balance sheets and net loss and its components in the consolidated statements of operations; research and development expenses, general and administrative expenses, and interest income, for the purposes of making operating decisions, assessing financial performance, and allocating resources. All assets are in the United States.

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. The Company holds most of its cash equivalents in a money market account comprised of US Treasury notes. 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 June 30, 2025 and December 31, 2024:

(in thousands)	June 30, 2025	December 31, 2024
Cash and cash equivalents	$ 59,928	$ 72,904
Restricted cash – long-term	329	324
Cash, cash equivalents and restricted cash	$ 60,257	$ 73,228

Restricted cash relates to a certificate of deposit held as collateral for a letter of credit issued in connection with the Company's lease of corporate office space.

Leases – The Company has an operating lease for corporate office space and a finance lease for office equipment 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.

Fair Value Measurement - Fair value is defined as the price that would be received to sell an asset, or paid to transfer a liability, in an orderly transaction between market participants. A fair value hierarchy has been established for valuation inputs that gives the highest priority to quoted prices in active markets for identical assets or liabilities and the lowest priority to unobservable inputs.

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. There was no revenue for the three and six months ended June 30, 2025 and June 30, 2024, respectively.

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 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 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. There was no revenue for the six months ended June 30, 2025 and June 30, 2024, respectively.

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 included overhead and general and administrative costs as well as an administrative fee. The Company recognizes revenue from grants as it performed services 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. There was no grant revenue for the six months ended June 30, 2025 and June 30, 2024, respectively.

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. There was no revenue for the six months ended June 30, 2025 and June 30, 2024, respectively.

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 six months ended June 30, 2025 and 2024, 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.

(in thousands)	June 30, 2025	June 30, 2024
Stock Options	240	5,420
Restricted Stock Units	300	305
Warrants	7	9
Total	547	5,734

Recently Adopted Accounting Pronouncements

In December 2023, the Financial Accounting Standards Board, (the "FASB"), issued ASU 2023-09, *Income Taxes (Topic 740): Improvements to Income Tax Disclosures*, to enhance the transparency and decision usefulness of income tax disclosures. The amendments in ASU 2023-09 provide improvements primarily related to the rate reconciliation and income taxes paid information included in income tax disclosures. The Company is required to disclose additional information regarding reconciling items equal to or greater than five percent of the amount computed by multiplying pretax income (loss) by the applicable statutory tax rate. Similarly, the Company is required to disclose income taxes paid (net of refunds received) equal to or greater than five percent of total income taxes paid (net of refunds received). The amendments in ASU 2023-09 are effective January 1, 2025. Early adoption is permitted for annual financial statements that have not yet been issued or made available for issuance. The Company adopted this standard effective January 1, 2025 and will report on it in the Company's Annual Report on Form 10-K for the year ended December 31, 2025. The Company will update all required disclosures pursuant to ASU 2023-09 at that time.

Recently Issued Accounting Pronouncements

In May 2025, FASB issued ASU 2025-04, *Compensation—Stock Compensation (Topic 718) and Revenue from Contracts with Customers (Topic 606): Clarifications to Share-Based Consideration Payable to a Customer*, which revises the Master Glossary definition of the term "performance condition" for share-based consideration payable to a customer to include conditions, such as vesting conditions, that are based on the volume or monetary amount of a customer's purchases or potential purchases of goods or services from the grantor, including over a specified period of time. The revised definition also incorporates performance targets based on purchases made by other parties that purchase the grantor's goods or services from the grantor's customers. The revised definition of the term performance condition cannot be applied by analogy to awards granted to employees and non-employees in exchange for goods or services to be used or consumed in the grantor's own operations. ASU 2025-04 eliminates the policy election permitting a grantor to account for forfeitures as they occur for share-based awards granted to a customer. Separate policy elections for forfeitures remain available for share-based payment awards with service conditions granted to employees and non-employees in exchange for goods or services to be used or consumed in the grantor's own operations. ASU 2025-04 further clarifies that a grantor should not apply the guidance in Topic 606 on constraining estimates of variable consideration to share-based consideration payable to a customer. ASU 2025-04 permits a grantor to apply the new guidance on either a modified retrospective or a retrospective basis. The amendments in ASU 2024-04 are effective January 1, 2027, for annual for annual reporting periods, including interim periods within annual reporting periods. Early adoption is permitted as of the beginning of an interim or annual reporting period. The Company is evaluating the impact of ASU 2024-03 on its financial statements.

In November 2024, FASB issued ASU 2024-03, *Income Statement-Reporting Comprehensive Income-Expense Disaggregation Disclosures* (Subtopic 220-40), to improve the disaggregation of expenses within the consolidated statement of operations. The amendments in ASU 2024-03 require disclosures in the notes to the consolidated financial statements and specified information about certain costs and expenses. The amendments require that at each interim and annual reporting period an entity disclose (a) employee compensation, (b) depreciation, and (c) intangible asset amortization included in each relevant expense caption; include certain amounts that are already required to be disclosed under current GAAP in the same disclosure as the other disaggregation requirements; and disclose a qualitative description of the amounts remaining in relevant expense captions that are not separately disaggregated quantitatively. The amendments in ASU 2024-03 are effective January 1, 2027 and effective for interim periods beginning January 1, 2028. The Company is evaluating the impact of ASU 2024-03 on its financial statements.

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.

On March 27, 2025, a putative class action complaint (the "Securities Complaint") was filed by alleged stockholder Nitin Kohil against the Company and executives Sandesh Seth, Avinash Desai, Madhuri Vusirikala, and Sergio Giralt (the "Defendants"), styled *Kohil v. Actinium Pharmaceuticals, Inc., et al*., Case No. 1:25-cv-02553 in the United States District Court for the Southern District of New York. The Securities Complaint alleges that the Defendants made material misrepresentations and omissions concerning the Iomab-B Phase 3 Sierra Trial and the plaintiff asserts claims against all Defendants pursuant to section 10(b) of the Securities Exchange Act (the "Exchange Act") and Rule 10b-5 promulgated thereunder, as well as additional claims against the individual Defendants pursuant to Section 20(a) of the Exchange Act. The Complaint purports to assert class action claims on behalf of all persons and entities that purchased or otherwise acquired Actinium securities between October 31, 2022 and August 2, 2024. Plaintiff seeks unspecified damages. On June 24, 2025, the court in the securities action appointed lead plaintiffs who intend to file an amended Securities Complaint on or before August 25, 2025. The Defendants have not yet responded to the Securities Complaint.

On May 5, 2025, a derivative shareholder complaint (the "*Georges* Complaint") was filed against the Company and certain of the Company's directors and officers alleging derivative liability for the allegations made in the Securities Complaint. On May 13, 2025, a second derivative shareholder complaint (the "*Robinson* Complaint" and, together with the *Georges* Complaint, the "Derivative Complaints") was filed against the Company and certain of the Company's directors also alleging derivative liability for the allegations made in the Securities Complaint. On June 24, 2025, the Court consolidated the Derivative Complaints (the "Derivative Action"). On July 29, 2025, the parties to the Derivative Action filed a stipulation with the Court to stay the Derivative Action pending resolution of any motion to dismiss the Securities Complaint. The Court has not yet entered that stipulation.

The Company and other Defendants intend to defend vigorously against such claims, however, there can be no assurances as to the outcome.

Note 3 - Leases

The Company determines if an arrangement is a lease at inception. This determination generally depends on whether the arrangement conveys to the Company the right to control the use of a fixed asset for a period of time in exchange for consideration. Control of an underlying asset is conveyed to the Company if the Company obtains the rights to direct the use of and to obtain substantially all of the economic benefits from using the underlying asset. The Company has lease agreements which include lease and non-lease components, which the Company has elected to account for as a single lease component for all classes of underlying assets. Lease expense for variable lease components are recognized when the obligation is probable. The Company made an accounting policy election to exclude from balance sheet reporting those leases with initial terms of 12 months or less.

Right-of-use assets and liabilities are recognized at commencement date based on the present value of lease payments over the lease term. ASC 842 requires a lessee to discount its unpaid lease payments using the interest rate implicit in the lease or, if that rate cannot be readily determined, its incremental borrowing rate. As an implicit interest rate was not readily determinable in the Company's leases, the incremental borrowing rate was used based on the information available at commencement date in determining the present value of lease payments.

The lease term for all of the Company's leases includes the non-cancellable period of the lease plus any additional periods covered by either a Company option to extend (or not to terminate) the lease that the Company is reasonably certain to exercise, or an option to extend (or not to terminate) the lease controlled by the lessor. Options for lease renewals have been excluded from the lease term (and lease liability) for the majority of the Company's leases as the reasonably certain threshold is not met.

At June 30, 2025, the Company has two leases which have been capitalized in accordance with ASC 842, one for corporate office space and one for office equipment. 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 current annual rent of $0.6 million. The Company is also responsible for certain other costs, such as insurance, utilities and maintenance.

The components of lease expense are as follows:

	Three months ended		Six months ended	
(in thousands)	**June 30, 2025**	**June 30, 2024**	**June 30, 2025**	**June 30, 2024**
Operating lease expense	$ 173	$ 173	$ 346	$ 346
Finance lease cost				
Amortization of right-to-use assets	$ 2	$ 3	$ 5	$ 5
Interest on lease liabilities	$ -	$ -	$ 1	$ 1
Total finance lease cost	$ 2	$ 3	$ 6	$ 6

Supplemental cash flow information related to leases are as follows:

Cash flow information:

(in thousands)	Six months ended June 30, 2025	June 30, 2024
Cash paid for amounts included in the measurement of lease liabilities:		
Operating cash flow use from operating leases	$ 313	$ 306
Operating cash flow use from finance leases	$ 5	$ 5
Financing cash flow use from finance leases	$ 5	$ 5
Non-cash activity:		
Right-of-use assets obtained in exchange for lease obligations:		
Operating leases	$ -	$ -
Finance Leases	$ -	$ -

Weighted average remaining lease terms are as follows at June 30, 2025:

Weighted average remaining lease term:	
Operating leases	2.1 years
Finance Leases	1.5 years

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 reflects 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	6.2%

Maturities of lease liabilities are as follows:

(in thousands) Year ending December 31,	Operating Leases	Finance Leases
2025 (excluding six months ended June 30, 2025)	318	6
2026	643	11
2027	380	-
Total lease payments	$ 1,341	$ 17
Less imputed interest	(67)	(1)
Present value of lease liabilities	$ 1,274	$ 16

Note 4 - Other revenue

The Company has a grant from a government-sponsored entity for research and development related activities that provides payments for reimbursed costs, which included overhead and general and administrative costs, as well as an administrative fee. The Company recognizes revenue from grants as it performed services under this arrangement. Associated expenses are recognized when incurred as research and development expense. There was no grant revenue recognized for the six months ended June 30, 2025 and 2024, respectively.

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, non-refundable 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 certain regulatory and commercial milestone payments and royalties on net sales of the product in certain countries that may result from the License Agreement. The Company continues to 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 interim unaudited condensed consolidated balance sheets, depending on the short-term or long-term nature of the payments to be recognized. The Company's contract liabilities consist of advanced payments from licensees. Long-term license revenue deferred was $35 million at June 30, 2025 and December 31, 2024; this deferred revenue will be recognized upon European Union's regulatory approval of Iomab-B or provision of definitive feedback that Iomab-B will not receive approval in the European Union.

Note 5 - Equity

In August 2020, the Company entered into the Capital on Demand™ Sales Agreement with JonesTrading Institutional Services LLC, "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. On June 28, 2022, the Company entered into an Amended and Restated Capital on Demand™ Sales Agreement (the "A&R Sales Agreement") with JonesTrading and B. Riley Securities, Inc. ("B. Riley"). The A&R Sales Agreement modifies the original Capital on Demand™ Sales Agreement to include B. Riley Securities as an additional sales agent thereunder. Shares of common stock are offered pursuant to a shelf registration statement on Form S-3 (File No. 333-242322) filed with the SEC on August 7, 2020 (the "Prior Shelf Registration Statement"). On August 11, 2023, the Company filed a new registration statement on Form S-3 (File No. 333-273911), which registration statement was amended on February 2, 2024, and declared effective on February 5, 2024, to replace the Prior Shelf Registration Statement, including a base prospectus which covers the offering, issuance and sale of up to $500 million of common stock, preferred stock, warrants, units and/or subscription rights; and a sales agreement prospectus covering the offering, issuance and sale of up to a maximum aggregate offering price of $200 million of common stock that may be issued and sold under the Amended Sales Agreement. On March 31, 2025, upon filing of the Company's Annual Report on Form 10-K for the year ended December 31, 2024, the Company became subject to General Instruction I.B.6 of Form S-3, pursuant to which in no event will the Company sell its common stock in a registered primary offering using Form S-3 with a value exceeding more than one-third of its public float in any 12 calendar month period so long as its public float remains below $75 million.

The Company did not sell any shares of common stock during the six months ended June 30, 2025. During the six months ended June 30, 2024, the Company sold 2.9 million shares of common stock, resulting in gross proceeds of $25.2 million and net proceeds of $24.7 million.

Stock Options

The following is a summary of stock option activity for the six months ended June 30, 2025:

(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, 2025	5,137	$ 6.48	7.04	$ -
Granted	26	1.43		
Exercised	-	-		
Cancelled	(4,923)	6.44		
Outstanding, June 30, 2025	240	6.66	6.04	-
Exercisable, June 30, 2025	166	7.36	5.14	-

During the six months ended June 30, 2025, the Company granted newly hired employees options to purchase 26 thousand shares of common stock with an exercise price ranging from $1.06 to $1.43 per share, a term of 10 years, and a vesting period of 4 years. The stock options had an aggregated fair value of $29 thousand 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 4.0% to 4.5% (2) expected life of 6 years, (3) expected volatility range from 90.1% to 90.7%, and (4) zero expected dividends. During the six months ended June 30, 2024, the Company granted options to purchase 1,000 shares.

On March 31, 2025, the Board of Directors approved of the cancellation of stock options to purchase an aggregate of 4.9 million shares of common stock held by certain current employees and directors that were initially granted under the Amended and Restated 2013 Stock Plan and the 2019 Amended and Restated Stock Plan. Such cancellations were subject to the consent of the applicable holders of the stock options, which the Company received. The cancellation of these stock options resulted in the recording of $8.8 million in stock option compensation expense for the six months ended June 30, 2025. During the six months ended June 30, 2024, the Company recorded stock option compensation expense of $2.4 million.

The fair values of all options issued and outstanding are being amortized over their respective vesting periods. The unrecognized compensation expense at June 30, 2025 was $0.3 million related to unvested stock options, which is expected to be expensed over a weighted average of 2.2 years.

Restricted Stock Units

The following is a summary of restricted stock unit ("RSU") activity for the six months ended June 30, 2025:

(in thousands, except for per-share amount)	**RSUs**	**Weighted Average Grant date Fair Value Per Share ($)**
Outstanding, January 1, 2025	300	5.85
Granted	-	-
Vested	-	-
Cancelled	-	-
Outstanding, June 30, 2025	300	5.85

The RSUs vest at the earliest 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 and 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 on the dates of the grant and is being recognized over three years. The unrecognized compensation expense at June 30, 2025 of $0.1 million is expected to be expensed over 0.1 years. During the six months ended June 30, 2025 and 2024, the Company recorded compensation expense related to RSUs of $0.3 million and $0.3 million, respectively.

Warrants

Following is a summary of warrant activity for the six months ended June 30, 2025:

(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, 2025	7	$ 17.33	4.46	$ -
Granted	-	-		
Expired	-	-		
Outstanding, June 30, 2025	7	$ 17.33	4.00	$ -
Exercisable, June 30, 2025	7	$ 17.33	4.00	$ -

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

CAUTIONARY STATEMENT REGARDING FORWARD-LOOKING STATEMENT NOTICE

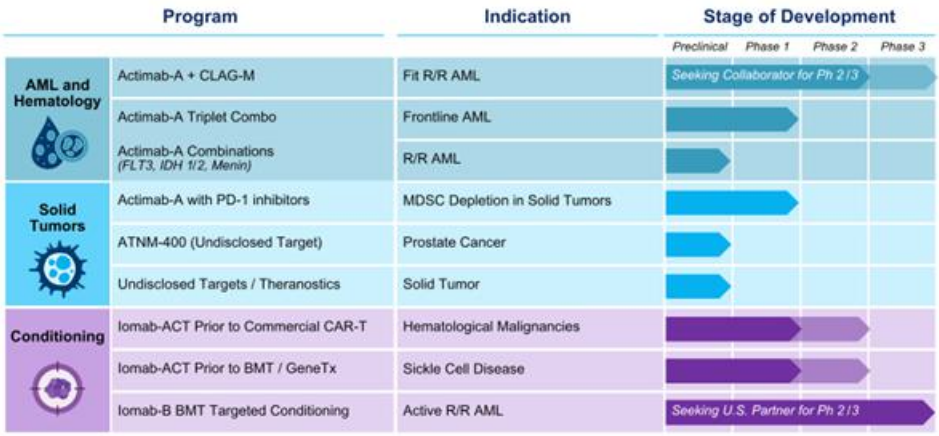
This Quarterly Report on Form 10-Q and other reports filed by the Company from time to time with the Securities and Exchange Commission contains or may contain certain forward-looking statements and information that are based upon beliefs of, and information currently available to, the Company's management as well as estimates and assumptions made by Company's management. Readers are cautioned not to place undue reliance on these forward-looking statements, which are only predictions and speak only as of the date hereof. For this purpose, any statements contained in this Quarterly Report on 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. Although we believe that the expectations reflected in the forward-looking statements are reasonable, we cannot guarantee future results, levels of activity, performance, or achievements. Except as required by applicable law, including the securities laws of the United States, we do not intend to update any of the forward-looking statements to conform these statements to actual results.

Description of Business

Actinium Pharmaceuticals, Inc. is a pioneer in the development of targeted radiotherapies intended to meaningfully improve outcomes for patients with advanced cancers. Our goal is to create a specialty radiopharmaceutical company with capabilities across radioisotope production, final drug product manufacturing, preclinical research and development ("R&D") and clinical development. We are deploying our technologies, capabilities and intellectual property with approximately 240 issued and pending patents worldwide, to develop next-generation radiotherapies. We are focused on developing highly differentiated and innovative first-in-class product candidates. Our current pipeline of clinical and preclinical stage targeted radiotherapy product candidates are directed against validated cancer targets for indications in hematology, solid tumors and conditioning for cell and gene therapies, which we believe have high unmet needs that are not addressed by currently available treatment options.

Our Targeted Radiotherapy Candidate Pipeline

We are advancing two clinical stage product candidates and one preclinical stage product candidate that are directed against validated cancer targets. Actimab-A is our most advanced clinical-stage product candidate that we are actively developing and is intended to address the significant unmet medical needs of patients with myeloid malignancies, including acute myeloid leukemia ("AML") and myelodysplastic syndromes ("MDS"). We are also evaluating Actimab-A's potential to synergize with PD-1 immune checkpoint inhibitors ("ICIs") in solid tumor indications through the depletion of immune cells known as myeloid derived suppressor cells ("MDSCs"). We recently announced our ATNM-400 program, a novel preclinical, non-prostate specific-membrane antigen ("non-PSMA") targeting, first-in-class radiotherapy utilizing the Actinium-225 ("Ac-225") radioisotope payload intended for patients with prostate cancer directed against a novel radiotherapy target and thereby differentiated from Lu-177-PSMA-617, the active agent used in Pluvicto®, a blockbuster approved prostate cancer radiotherapy and the majority of radiotherapies in development for prostate cancer. Iomab-ACT is a next-generation targeted conditioning agent we are developing with the intent to improve patient access to, and outcomes with, cellular therapies such as CAR-T for various blood cancer indications and gene therapies for non-malignant hematologic disorders such as sickle cell disease ("SCD").



Strategic Pipeline Prioritization

We currently intend to commit a significant portion of our current and future resources to the development and advancement of our targeted radiotherapy solid tumor pipeline candidates as well as solid tumor focused R&D efforts. In the first quarter of 2025, we announced ATNM-400, our first solid tumor focused program, which we are developing for prostate cancer. In addition, we announced our solid tumor initiative with Actimab-A in combination with PD-1 immune checkpoint inhibitors for head and neck squamous cell carcinoma ("HNSCC") and non-small cell lung cancer ("NSCLC"). We believe solid tumors represent large addressable markets and there remains high unmet needs in several indications that are not addressed by currently available therapies. We will continue to advance Actimab-A in a focused manner as a therapeutic for hematology indications including supporting our CRADA with the NCI and Iomab-ACT as a targeted conditioning agent for cell and gene therapies while simultaneously seeking strategic development partners or collaborators for these programs. There have been significant changes in senior leadership at the United States Food & Drug Administration ("FDA") and other government agencies including the Center for Biologics Evaluation and Research ("CBER"). We believe these changes could impact the FDA's approach toward approving therapies in part based on their perception of value and their cost benefit profile. There have also been funding cuts to healthcare spending and at governmental healthcare agencies such as the National Institutes of Health ("NIH") and National Cancer Institute ("NCI"). We have a Cooperative Research and Development Agreement ("CRADA") with the NCI for the development of Actimab-A, and while currently not the case, in the future there could be funding cuts to the NCI may cause delays, and/or pauses or termination of clinical trials under our CRADA. As previously announced, we are actively seeking a strategic partner for Iomab-B in the U.S. As part of our strategic pipeline prioritization, we may seek to partner, divest, spin-out, or out-license Iomab-B, Actimab-A and Iomab-ACT individually or collectively for all non-solid tumor indications. We believe, in aggregate, the clinical data from these hematology and cellular therapy focused programs is supportive of a partnering approach, which if successful, may yield greater value as the Company focuses on its solid tumor development efforts utilizing existing resources.

Recent Developments

- Presented first ever preclinical data for ATNM-400, a novel, first-in-class non-Prostate Specific Mature Antigen ("PSMA") Ac-225 targeted radiotherapy at the American Association for Cancer Research ("AACR") Annual Meeting in April 2025 highlighting that ATNM-400's target is implicated in prostate cancer biology, disease progression and resistance to therapies. The data also showed that ATNM-400 was more efficacious than Lu-177-PSMA-617, the active agent used in Pluvicto®, an FDA approved targeted radiotherapy, in prostate cancer models, and is highly efficacious in overcoming Lu-177-PSMA-617 resistance;

- Presented data at AACR in April 2025 highlighting the mutation agnostic antileukemic activity of Actimab-A against the most prevalent and actionable mutations in AML including FLT3, NPM1, KMT2A and TP53;

- Presented additional ATNM-400 preclinical data at the Society of Nuclear Medicine and Molecular Imaging ("SNMMI") Annual Meeting in June 2025 showing superior efficacy to enzalutamide (Xtandi®), an androgen receptor inhibitor ("ARPI") therapy, ATNM-400's ability to overcome resistance to enzalutamide and synergistic potential in combination with enzalutamide;

- Enrolled first patient in the Iomab-ACT commercial CAR-T investigator sponsored trial at the University of Texas Southwestern Medical Center;

- Finalized protocol for Phase 2/3 trial for Iomab-B in agreement with the FDA with approval to initiate the Phase 2 portion of the trial; and

- Presented additional ATNM-400 preclinical data at the Targeted Radiopharmaceuticals Summit ("TRP") in July 2025 showing tumor-specific uptake of ATNM-400 via PET images and enhanced, robust tumor control and improved survival compared to Lu-177-PSMA-617, the active agent used in Pluvicto®. Additionally, ATNM-400 showed enhanced and tumor control in enzalutamide resistance prostate cancer models and enhanced efficacy in combination with enzalutamide with follow-up ongoing.

Hematology Therapeutic Program

Actimab-A is being developed as a targeted radiotherapeutic to leverage the Ac-225 isotope payload directed against CD33, a target expressed ubiquitously in patients with AML, MDS and other myeloid malignancies. We are attempting to leverage the mutation-agnostic ability of Ac-225 to establish Actimab-A as a backbone therapy in myeloid malignancies, which are extremely heterogenous and radiosensitive, as a single agent or in combinations with chemotherapy, targeted agents, cellular therapy and immunotherapy. Actimab-A has been studied in over 150 patients as a single agent and in combination with other modalities. This clinical experience is informing our current clinical development strategy for Actimab-A. We plan to initiate a Phase 2/3 trial with Actimab-A in combination with the chemotherapy regimen CLAG-M in patients with r/r AML based on promising results with this combination in a Phase 1b trial. In addition to our internal development efforts, we entered into a Cooperative Research and Development Agreement ("CRADA") with the National Cancer Institute ("NCI") in February 2023 for the development of Actimab-A for AML and other myeloid malignancies. The first Actimab-A trial initiated under the CRADA is being conducted in patients with frontline AML in combination with Venetoclax, an oral Bcl-2 inhibitor and ASTX-727, an oral hypomethylating agent ("HMA") developed by Taiho Oncology, an Otsuka Holdings company. To date, there has been broad interest from investigators through the NCI CRADA to study Actimab-A in a variety of hematology indications that we believe may support our partnering efforts given the potential to expand the addressable market opportunity for Actimab-A.

Solid Tumor Programs

ATNM-400 is our newest targeted radiotherapy program that we are advancing for prostate cancer. We believe ATNM-400 is uniquely positioned to overcome key limitations of current standards of care in prostate cancer, including Lu-177-PSMA-617 (Pluvicto®) and the ARPI therapy enzalutamide (Xtandi®). Pluvicto® is a PSMA directed targeted radiotherapy that uses the beta-particle emitting radioisotope Lutetium-177 ("Lu-177") that is approved for patients with metastatic prostate cancer. Pluvicto® is marketed and sold by Novartis and generated sales of approximately $1.39 billion in 2024. ATNM-400 is differentiated from Lu-177-PSMA-617 such as Pluvicto® as it targets a different marker than PSMA, which has been shown to be overexpressed in patients with prostate cancer and its expression is sustained post- Lu-177-PSMA-617 treatment. In addition, ATNM-400 uses the alpha-particle emitter Ac-225, which is more potent than Lu-177 but has a shorter path length, which could result in fewer off-target effects such as xerostomia or dry mouth as PSMA is expressed in the salivary glands. ATNM-400's target is also implicated in resistance to androgen receptor ("AR") inhibition. Our preclinical data has shown that ATNM-400 is effective in preclinical prostate cancer models resistant to the ARPI enzalutamide and has additive efficacy when used in combination with enzalutamide, suggesting flexibility in sequencing or combination regimens. Enzalutamide (Xtandi®) is approved for three stages of prostate cancer and is marketed and sold by Astellas and Pfizer with sales of $5.9 billion in 2024. Given the biology of the antigen targeted by ATNM-400, the precise and potent cell-killing of Ac-225 and our preclinical data to date, we believe ATNM-400 has transformative potential to address unmet needs in prostate cancer for Lu-177-PSMA-617 and enzalutamide ineligible patients, after patients become resistant to Lu-177-PSMA-617 or enzalutamide, in combination and even as an alternative treatment option.

In addition to ATNM-400, we have active R&D efforts leveraging our in-house preclinical development and translational research capabilities that are primarily focused on supporting our ATNM-400 preclinical program, the Actimab-A and Iomab-ACT clinical programs and advancing several preclinical programs for solid tumor indications.

We have also initiated our Actimab-A solid tumor program that will combine Actimab-A with PD-1 checkpoint inhibitors. We initiated this program to evaluate if Actimab-A can deplete CD33 expressing MDSCs and hence improve patient outcomes in combination with PD-1 ICIs such as KEYTRUDA® and OPDIVO®. The Actimab-A solid tumor program is comprised of several controlled, head-to-head clinical trials that will evaluate the combination of Actimab-A with KEYTRUDA® versus KEYTRUDA® alone, and Actimab-A with OPDIVO® versus OPDIVO® alone. The initial tumors that are being targeted are Head and Neck Squamous Cell Carcinoma ("HNSCC") and Non-Small Cell Lung Cancer ("NSCLC") with a separate trial for each indication.

Targeted Conditioning Programs

Iomab-ACT is our next-generation targeted conditioning agent directed against CD45, a target expressed widely across the hematopoietic system including normal nucleated immune cells such as lymphocytes that are relevant to this program and uses the Iodine-131("I-131") radioisotope payload. We are developing Iomab-ACT as conditioning for cell and gene therapies in both malignant and non-malignant hematologic indications. Iomab-ACT utilizes non-myeloablative doses of I-131, to not fully deplete the patient's bone marrow and immune system with the goal of improving patient access and outcomes for potentially curative cell and gene therapies by replacing the need for the non-targeted, chemotherapy-based conditioning regimens that are currently used. Iomab-ACT is currently being studied in three clinical trials. These trials include Iomab-ACT with a commercial CAR-T therapy, Iomab-ACT prior to allogeneic bone marrow transplant for patients with SCD, which could potentially inform a trial design with gene therapy for SCD, and Iomab-ACT with a novel investigational CD19 CAR-T therapy. In May 2025, we announced that the first patient was enrolled in the Iomab-ACT commercial CAR-T trial at the University of Texas Southwest Medical Center ("UTSW").

We previously advanced our targeted conditioning program Iomab-B through the Phase 3 Study of Iomab-B in Elderly Relapsed and Refractory AML ("SIERRA") trial, a 153 patient, randomized multi-center trial conducted in the United States and Canada. Iomab-B is comprised of the anti-CD45 monoclonal antibody apamistamab with myeloablative doses of I-131 intended to enable patient access to bone marrow transplant ("BMT"), the only potentially curative treatment option for patients with r/r AML. At this time, we are seeking a strategic partner for Iomab-B to conduct an additional clinical trial based on feedback from the FDA. We have finalized the protocol for this additional Phase 2/3 trial in agreement with the FDA and have authorization to initiate the Phase 2 portion of this trial. As previously disclosed and noted above, Actinium also has a License Agreement with Immedica, granting Immedica the exclusive product rights for commercialization of Iomab-B in certain countries in the EUMENA region.

Our Targeted Radiotherapy Candidates

Actimab-A: Mutation Agnostic Mechanism of Action with Backbone Therapy Potential in Myeloid Malignancies including AML and high-risk MDS

Actimab-A *(Ac-225-lintuzumab satetraxetan)* is our most advanced radiotherapeutic product candidate in development for patients with myeloid malignancies. To our knowledge, Actimab-A is the only CD33 targeting radiotherapy in clinical development. We are focused on developing Actimab-A as both a monotherapy and in combination with other treatment regimens to leverage both the potential mechanistic synergies of radiation and its mutation agnostic cell-killing ability. In addition to our internal development efforts, we entered into a CRADA with the NCI in February 2023 for the development of Actimab-A for AML and other myeloid malignancies.

We intend to establish Actimab-A as a backbone therapy, leveraging the broad expression of CD33 in myeloid malignancies such as AML and MDS, which, like most blood cancers, are highly sensitive to radiation. AML is a highly heterogenous, mutation-rich cancer with over 70 identified driver genetic mutations. However, there are only approved therapies for four mutations including FLT3, IDH1 & IDH2, and KMT2A. CD33 is expressed regardless of other mutations being present. The Ac-225 isotope payload that we utilize with Actimab-A emits potent alpha-particles with high linear energy that kill cells via double strand DNA breaks for which there is no known resistance or repair mechanism.

Our development strategy is to exploit these properties of Actimab-A to address the unmet needs of patients with myeloid malignancies across the treatment journey including the frontline, relapsed/refractory and maintenance settings. To accomplish this, we are leveraging our clinical development experience, clinical data and preclinical work supporting Actimab-A's mutation agnostic capabilities.

Actimab-A + CLAG-M Pivotal Phase 2/3 Trial

We have aligned with the FDA on a randomized pivotal Phase 2/3 trial to compare Actimab-A + CLAG-M to CLAG-M alone in patients with r/r AML. Based on our interactions with the FDA, this trial will first complete a Phase 2 portion where the Actimab-A dose will be optimized in combination with CLAG-M. Once the optimized Actimab-A dose is determined, we expect the trial will advance to the Phase 3 portion of the study, which may reduce time and resources required compared to separate Phase 2 and Phase 3 studies.

The primary endpoint of the Phase 3 trial will be Overall Survival. Event-Free Survival ("EFS") and other efficacy measures as well as safety also being evaluated. We are actively seeking potential strategic partners or collaborators to advance this trial.

Actimab-A NCI CRADA Trials

In 2023, we entered into a CRADA with NCI to develop Actimab-A for the treatment of patients with AML and other hematologic malignancies. The NCI will serve as the regulatory sponsor for any clinical trials mutually approved by both parties to study Actimab-A. The CRADA will provide support for and may accelerate the development of Actimab-A alone or in combination with chemotherapy, immunotherapy, targeted agents and other novel combinations. The CRADA studies will be overseen by the NCI in collaboration with Actinium's clinical development team, where we have the right to review and approve all protocols and have full rights to all data. The NCI CRADA provides for us to supply Actimab-A and for NCI to cover all clinical trial execution and development expenses, which we believe will be a cost-efficient approach as opposed to a Company sponsored trial and may therefore spare our balance sheet. The NCI Cancer Therapy Evaluation Program ("CTEP"), which sponsors approximately two thirds of all combination cancer studies, will accept Letters of Intent ("LOIs") or concepts for Phase 1, 2 or 3 studies of Actimab-A in AML and other hematological malignancies.

In October 2024, the NCI announced that its myeloMATCH program was officially open to patient enrollment across the U.S. and Canada. MyeloMATCH is a portfolio of clinical trials to test precision medicine treatments for adults with AML or MDS being designed and led by four leading cancer research organizations including the Alliance for Clinical Trials in Oncology, Canadian Cancer Trials Group, ECOG-ACRIN Cancer Research Group, and SWOG Cancer Research Network in collaboration with the NCI National Clinical Trials Network ("NCTN"). Collectively, the myeloMATCH program expects to open trials at hundreds of cancer care sites across the U.S. and Canada with the goal of enrolling 5,000 or more patients over the next several years. Under our CRADA with the NCI, Actimab-A is part of the myeloMATCH program and may be included in future clinical trials.

Actimab-A, Venetoclax & ASTX-727 – Frontline AML Triplet Phase 1b Combination Trial

In March 2025, we announced the initiation of the first clinical trial to be conducted under our CRADA by NCI. The trial will evaluate the triplet combination comprised of Actimab-A, Venetoclax and ASTX-727, a novel oral HMA developed by Taiho Oncology, an Otsuka Holdings company, in frontline AML patients. Venetoclax in combination with HMAs (Ven-HMA) is approved for patients with newly diagnosed AML. We believe this trial is supported by our Actimab-A + Venetoclax combination trial that showed that the combination was well-tolerated and showed supportive anti-leukemic activity. The frontline AML triplet trial is expected to enroll up to 48 patients who are newly diagnosed with AML that are age 75 and above and not eligible for intensive chemotherapy. The trial will evaluate various dose levels of Actimab-A along with dosing regimens.

Additional clinical trial concepts for Actimab-A have been submitted through our CRADA. We believe this supports the differentiated profile of Actimab-A for hematologic and solid tumor indications and presents an opportunity to expand Actimab-A's addressable market for a potential partner or collaborator.

Data Supporting Actimab-A's Mutation Agnostic Profile

To leverage Actimab-A's mutation agnostic capabilities and support its broad development, we have conducted preclinical experiments studying Actimab-A in combination with targeted agents including Bcl-2 inhibitors, FLT-3 inhibitors, IDH inhibitors, menin inhibitors for NPM1 and KMT2A AML, chemotherapies such as azacitidine and in cell lines expressing TP53 mutations.

On April 27, 2025, we presented data at the AACR annual meeting preclinical data demonstrating that the combination of Actimab-A with standard of care targeted AML therapies including menin and FLT3 inhibitors and the HMA azacitidine resulted in significant antileukemic activity in AML cells lines with FLT3, NPM1, KMT2A and TP53 mutations. Additionally, in animal models, Actimab-A significantly enhanced tumor growth inhibition, prolonged the duration of response and survival when combined with the menin inhibitor revumenib, and potentiated AML cell killing in combination with the FLT3 inhibitor gilteritinib and HMA azacitidine. We expect to present additional data supporting Actimab-A's mutation agnostic capabilities and backbone potential at future scientific and medical conferences. In addition, we will continue to explore potential clinical trials under our CRADA with NCI, investigator-initiated trials or under our sponsorship.

ATNM-400 Program: Novel, First-in-Class, Non-PSMA Targeting Ac-225 Radiotherapy for Prostate Cancer

ATNM-400 is a novel antibody radioconjugate designed to deliver the potent alpha-emitter Ac-225 to prostate cancer cells by targeting a non-PSMA, disease-driving protein overexpressed in advanced and treatment-resistant disease. Unlike PSMA-targeted agents that primarily serve as imaging and targeting tools, the ATNM-400 target is directly implicated in tumor progression, survival signaling, and resistance to AR inhibition. This target is markedly overexpressed in advanced, treatment-refractory prostate cancer and is associated with faster progression to castration resistance and poorer overall survival in metastatic castrate resistant prostate cancer ("mCRPC").

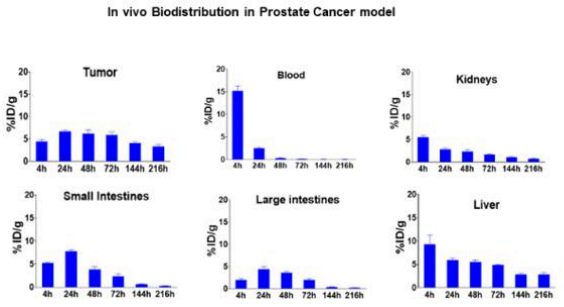
We believe that ATNM-400 is uniquely positioned to overcome key limitations of current standards of care in prostate cancer, including Lu-177-PSMA-617 (Pluvicto®) and the ARPI enzalutamide (Xtandi®). By selectively targeting ARPI-resistant tumor populations and delivering potent Ac-225 alpha radiation, we believe that ATNM-400 has the potential to achieve deep, durable responses in patients with limited treatment options. With a differentiated mechanism of action, we believe that ATNM-400 represents a potential first-in-class targeted radiotherapy designed to extend survival and address the significant unmet need in mCRPC.

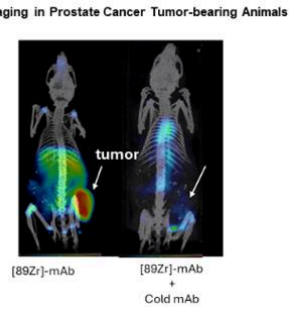
Preclinical Highlights

In vitro and in vivo studies have established ATNM-400's robust therapeutic activity and unique resistance-overcoming potential:

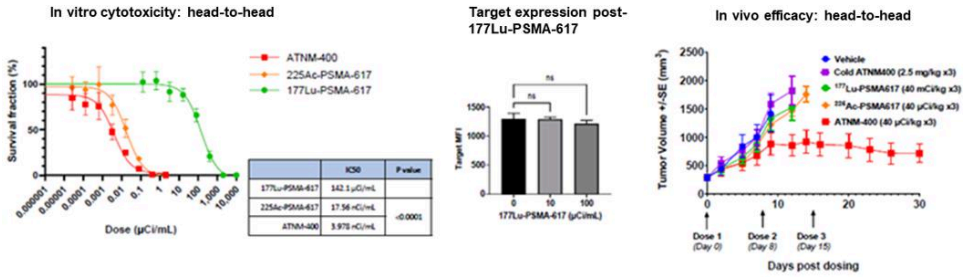
Mechanism of Action: ATNM-400 selectively binds and internalizes in human prostate cancer cells expressing the target protein, inducing potent cytotoxicity via alpha radiation from the Ac-225 isotope, which causes irreversible double-stranded DNA breaks and targeted tumor cell death.

Sustained and specific tumor uptake: The ATNM-400 antibody showed sustained tumor uptake up to 216 hours with rapid clearance from normal tissues in prostate cancer in vivo models. PET imaging confirmed tumor-specific uptake, which was blocked with unlabeled cold antibody.

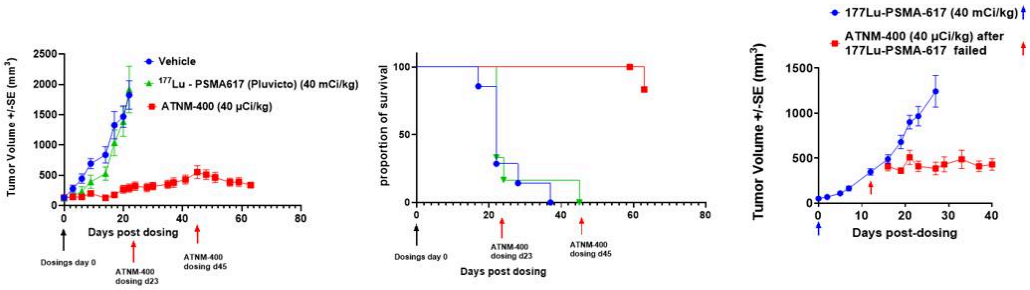




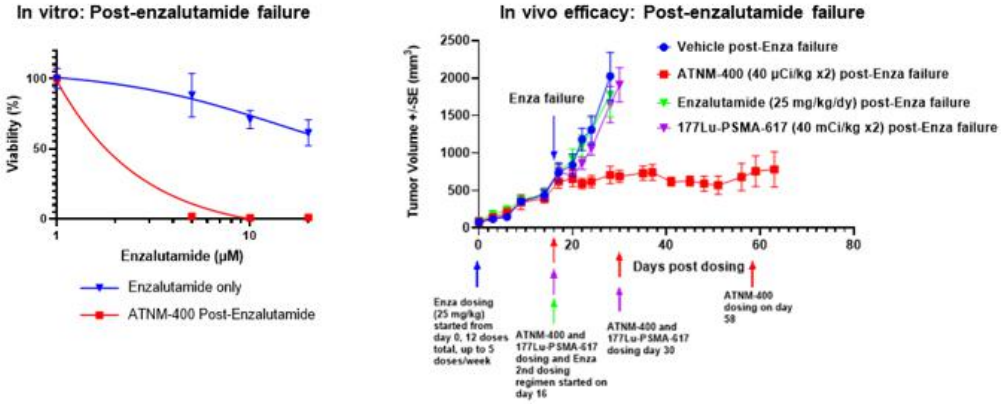
Superior to PSMA-targeted Therapies: In direct head-to-head studies, ATNM-400 demonstrated greater in vitro cytotoxicity and in vivo tumor growth inhibition compared to both Lu-177-PSMA-617 and 225Ac-PSMA-617 in prostate cancer preclinical models. Unlike PSMA, which loses target expression upon treatment with Lu-177-PSMA-617 (the active agent in Pluvicto®), the target for ATNM-400 is sustained post-Lu-177-PSMA-617 treatment.



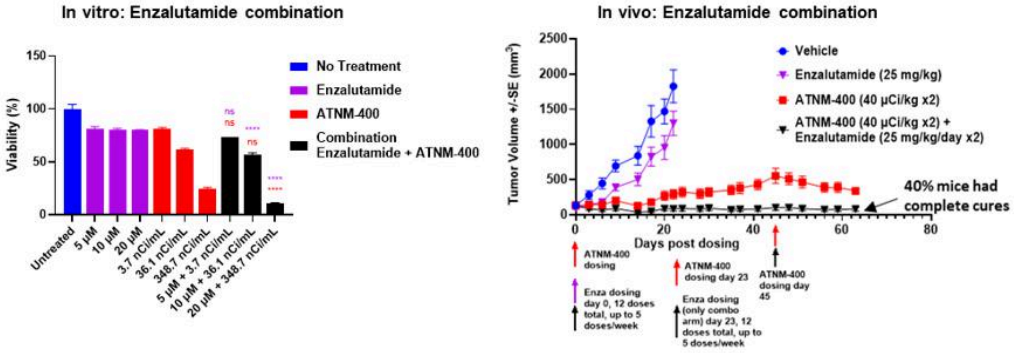
Robust Tumor Control, Improved Survival and Superior Efficacy After Lu-177-PSMA-617 Resistance: ATNM-400 outperformed Lu-177-PSMA-617, the active agent in Pluvicto®, significantly improved survival and had robust anti-tumor activity in preclinical prostate cancer models. It remained effective in both in vitro and in vivo models with acquired Lu-177-PSMA-617 resistance, highlighting its potential in resistant disease settings.



Superior Tumor Control Activity Post-Enzalutamide: ATNM-400 remained effective in preclinical prostate cancer models resistant to the ARPI enzalutamide, highlighting its utility post-AR pathway treatment failure.



Enhanced Efficacy Supports Combination Therapy Potential: ATNM-400 demonstrated additive efficacy when used in combination with AR-targeting agents such as enzalutamide in both in vitro and in vivo preclinical studies in prostate cancer models, suggesting flexibility in sequencing or combination regimens. Also 40% of prostate cancer tumor-bearing animals had complete cures.



We are continuing to study and advance ATNM-400 and expect to have further updates on this program in the second half of 2025. We intend to demonstrate ATNM-400's potential to treat prostate cancer that has become resistant to commonly used therapies such as Lu-177-PSMA-617 (the active agent in Pluvicto®) and enzalutamide to improve outcomes with mCRPC.

ATNM-400 Market Opportunity in Prostate Cancer

Approximately 313,780 men in the United States are expected to be diagnosed with prostate cancer in 2025, accounting for approximately 30% of all cancer diagnoses in men according to the American Cancer Society. Prostate cancer is by far the most diagnosed cancer in men in the United States and is the same in 118 of 185 countries. Of those diagnosed with prostate cancer, approximately 5-7% exhibited metastatic disease at initial diagnosis, and among those exhibiting localized prostate cancer, approximately 20-30% will progress to metastatic disease. A majority of metastatic prostate cancer patients receive hormone therapy such as ARPI therapy, as prostate cancer cells rely on androgen hormones for growth. In the U.S., approximately 40,000–60,000 mCRPC patients annually progress after ARPI therapy, which as a class generated sales of greater than $10 billion in 2024 including Xtandi® (>$5.9 billion) Erleada® (>$2.9 billion), and Nubeqa® (>$1.7 billion), highlighting a significant unmet need. Unlike localized diseased, there are currently no known cures for metastatic prostate cancer – there are only treatments to slow the progression of disease.

With the approval of the targeted radiotherapy Pluvicto® (lutetium Lu 177 vipivotide tetraxetan; active agent: Lu-177-PSMA-617) for post-taxane mCRPC in March 2022, targeted-radiotherapy has become a prominent component of the metastatic prostate cancer treatment paradigm. Pluvicto®, marketed globally by Novartis, generated approximately $1.39 billion in sales in 2024 and approximately $825M in the first half of 2025. In March 2025, the total addressable market for Pluvicto® essentially doubled to approximately 44,000 patients with its approval in mCRPC after treatment with ARPI therapy and prior to taxane. Subsequently, in June 2025, Novartis announced that Pluvicto® reached the primary endpoint in the Phase 3 PSMAddition study in metastatic hormone sensitive prostate cancer (“mHSPC”) and expects to file an FDA submission in the second half of 2025. An approval would add approximately 42,500 additional patients to the addressable market for Pluvicto®.

With the only approved targeted radiotherapy moving up in the prostate cancer treatment paradigm and very few differentiated products in clinical development, a significant opportunity exists in the post-Pluvicto® setting. Currently, over 20 PSMA-targeted radiotherapies are in various stages of development, of which few offer a substantial efficacy advantage compared to Pluvicto®. Re-treatment with PSMA-targeting agents has not yet been supported substantially in clinical trials and could be less effective than targeting a different antigen due to potential reduction of PSMA surface expression as well as increased tumor heterogeneity following initial PSMA-targeted therapy.

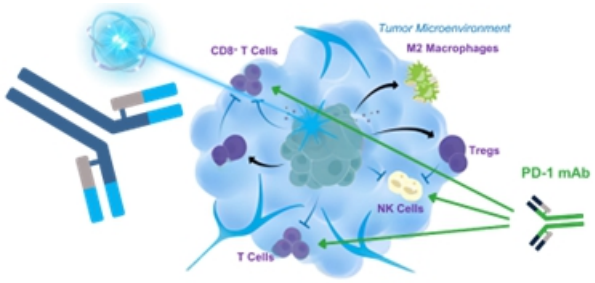
ATNM-400 targets a non-PSMA tumor antigen that is implicated in disease progression, shorter time to hormone therapy resistance such as ARPI therapy and poorer survival outcomes. We have demonstrated that ATNM-400’s differentiated target is expressed and druggable following ARPI therapy and PSMA radiotherapy. We believe ATNM-400 can therefore target a significant subset of the mCRPC patient population with aggressive disease who progressed on second generation ARPIs or have had no response to or progressed on Lu-177 labelled PSMA-targeted therapy. ATNM-400 utilizes the alpha-particle emitter Ac-225, which is more potent than Lu-177, and due to Ac-225’s short path length, could result in fewer off-target effects. As ATNM-400 does not target PSMA, xerostomia or dry mouth, which can be a significant quality of life issue for patients with metastatic prostate cancer receiving PSMA-targeted radiotherapies as PSMA is expressed on salivary glands, would not be expected. Additionally, the antigen targeted by ATNM-400 is implicated in a pathway leading to ARPI-resistance in mCRPC patients; therefore, along with the tumor suppressing ability of Ac-225, ATNM-400 displays a compelling mechanism for synergy with ARPIs. As a result, we believe ATNM-400 has the potential to address critical gaps in prostate cancer treatment as a monotherapy or in combination or sequenced with other therapeutic modalities.

Actimab-A Solid Tumor Program: Potential Pan Solid Tumor Therapy in Combination with PD-1 Checkpoint Inhibitors Including KEYTRUDA® and OPDIVO® by Depleting Myeloid Derived Suppressor Cells

Given the significant number of patients treated with PD-1 ICIs, there is extensive data in the medical literature on outcomes in these patients. PD-1 ICIs have significantly improved patient outcomes across several solid tumor indications, however, not all patients have robust or durable responses. Multiple therapeutic modalities have been studied in combination with PD-1 ICIs in attempt to improve patient outcomes, but few combinations have produced a sufficient clinical benefit or have been approved. To our knowledge, our Actimab-A solid tumor program is the only CD33 targeted radiotherapy being evaluated in combination with PD-1 ICIs. The rationale for studying Actimab-A in combination with either KEYTRUDA® or OPDIVO® is based on the premise that depleting MDSCs with Actimab-A may improve the efficacy of these drugs.

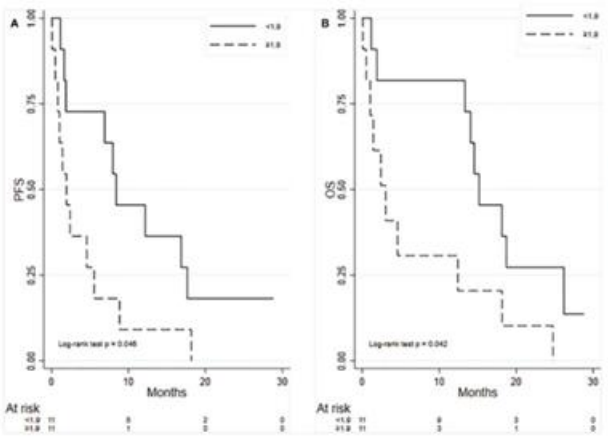
MDSCs are immune-suppressive cells that help tumors evade immune detection and promote disease progression. They are overexpressed in the tumor microenvironment in several different solid tumors and associated with poor outcomes. They work by multiple mechanisms but most relevant to PD-1 inhibitors which work by keeping T-cells active is that MDSCs prevent T-cells from recognizing and attacking cancer cells.

Potential Mechanistic Synergy of Actimab-A with PD-1 ICI’s



Studies have shown that MDSCs are overexpressed in patients with cancers. For instance, a study by Bronte et al., in patients with NSCLC receiving ICIs evaluated the role of immune cells on patient outcomes. In this study, MDSCs were the only immune cell subtype to show a statistically significant association with tumor response. The median level of MDSCs was determined to be 1.9% with patients above that level being classified as "High-MDSC" and patients below that level being classified as "Low-MDSC". In this study, only Low-MDSC patients had a clinical response, with no responses observed in High-MDSC patients and over 80% of High-MDSC patients having progressive disease. In addition, Low-MDSC patients had a statistically significantly improvement in progression-free survival ("PFS") of 8.39 months compared to 1.94 months in High-MDSC patients and OS of 15.15 months compared to 3.03 months in High-MDSC patients.

Low MDSC's Associated with Statistically Significant Improvement in PFS and OS



	Low MDSCs	High MDSCs
PFS	8.39	1.94
OS	15.15	3.03

There is considerable preclinical scientific evidence in the literature that depleting MDSCs could be a viable strategy in improving the outcomes of PD-1 directed immunotherapy, however, there have been no viable clinical approaches that have been tried successfully to our knowledge. MDSCs are known to express the CD33 antigen which is the target of Actimab-A. Actinium has also generated published and unpublished preclinical data showing that Actimab-A can selectively deplete MDSCs in solid tumors.

We believe there is strong scientific rationale supporting the potential for Actimab-A to deplete CD33 expressing MDSCs and hence improve patient outcomes with PD-1 ICIs such as KEYTRUDA® and OPDIVO®. Our Actimab-A solid tumor program is expected to be comprised of several controlled, head-to-head clinical trials that will evaluate the combination of Actimab-A with KEYTRUDA® versus KEYTRUDA® alone, and Actimab-A with OPDIVO® versus OPDIVO® alone. The initial tumors that are being targeted are HSNCC and NSCLC with a separate trial for each indication.

The patient population for these trials will be adults with PD-L1 expression and locally advanced metastatic HNSCC or NSCLC randomized to either Actimab-A alone or Actimab-A with a specific checkpoint inhibitor. The objective of each trial would be to evaluate the safety and tolerability as well as following endpoints including ORR, PFS and OS. Further, the following biomarker data would be collected including the pattern of depletion of CD33+ MDSCs and T-cell activity in peripheral blood. We are advancing these trials and expect initial proof of concept data in the first half of 2026.

Iomab-ACT Program: Potential Universal Targeted Conditioning Agent for Cell & Gene Therapies to Improve Patient Access and Outcomes

The opportunity exists for better conditioning regimens in the area of cellular therapies beyond the non-targeted chemotherapy-based regimens that are used currently. We are working on a next-generation targeted conditioning program, Iomab-ACT, for the rapidly growing cell and gene therapy market, as well as BMT conditioning for non-malignant hematologic indications such as SCD.

We are studying Iomab-ACT in collaboration with Memorial Sloan Kettering Cancer Center ("MSKCC"), for conditioning prior to CAR-T therapy for patients with relapsed or refractory B-cell acute lymphoblastic leukemia ("B-ALL") or diffuse large B-cell lymphoma ("DLBCL"). This study, funded by a NIH grant, is the first study of its kind to use CD45 targeted radiotherapy conditioning with CAR-T therapy. At the 2024 Tandem Meetings | Transplantation & Cellular Therapy Meetings of ASTCT and CIBMTR, we presented results from the ongoing Phase 1 trial. No patients (0/4) developed Immune Effector Cell-Associated Neurotoxicity Syndrome ("ICANS") of any grade, a major safety measure of the study, as ICANS is observed in 25% or more of patients with r/r B-ALL and DLBCL treated with various CAR T-cell products and negligible incidence of cytokine release syndrome ("CRS"). Additionally, Iomab-ACT demonstrated transient depletion of peripheral blood lymphocytes and monocytes. Persistence of CAR T-cells up to 8 weeks and minimal non-hematologic toxicities have been observed to date. These results prompted us to explore additional clinical trials with Iomab-ACT.

We have initiated an investigator-sponsored trial studying Iomab-ACT as targeted conditioning prior to patients receiving an FDA approved commercial CAR-T therapy at UTSW. To our knowledge, this is the first trial to study a targeted radiotherapy conditioning agent with a commercial CAR-T therapy. Given the robust clinical data that exists with commercial CAR-T therapies, we believe this trial may demonstrate the potential for Iomab-ACT to improve outcomes over current chemotherapy conditioning regimens, which we are seeking to replace and provide patients better access to CAR-T. In May 2025, we announced that the first patient was enrolled in this trial, which will enroll up to 30 patients. The primary objectives of this study are safety, tolerability and efficacy. Secondary objectives will evaluate incidences of CRS and ICANS as well as the persistence and expansion of CAR-T cells, which has been associated with improved efficacy and patient outcomes. If successful, we believe this Phase 1b/2 trial could support a pivotal trial, which could be initiated as early as 2026.

Iomab-ACT is also being studied in an investigator-led clinical trial as targeted conditioning prior to a BMT for patients with SCD in collaboration with Columbia University. SCD is a rare, debilitating and life-threatening blood disorder with significant unmet need that affects approximately 100,000 people in the U.S. Patients with sickle cell disease have a mutation that causes red blood cells to develop a crescent or "sickle" shape, which restrict the flow in blood vessels and limit oxygen delivery to the body's tissues, leading to severe pain and organ damage called vaso-occlusive events ("VOEs") or vaso-occlusive crises ("VOCs"). The recurrence of these events or crises can lead to life-threatening disabilities and/or early death. A BMT is a potentially curative treatment option for patients with sickle cell disease, particularly in patients who have had complications such as strokes, acute chest crises or recurring pain crises due to their disease. Patient recruitment for the Phase 1 trial has commenced and this trial can enroll up to 24 patients with interim data updates expected. If safety is demonstrated, the trial is expected to inform a clinical trial to evaluate Iomab-ACT as a targeted conditioning agent prior to gene therapy for which there are two approved agents for patients with sickle cell disease, Casgevy® (Vertex Pharmaceuticals, Inc.) and Lyfgenia™ (Bluebird Bio, Inc.).

We plan to continue to develop Iomab-ACT based on early encouraging results, ultimately with the value proposition of improving overall access and outcomes for patients who need cellular or gene therapies. We believe an opportunity exists for Iomab-ACT to potentially generate significant revenue, if it can provide one or more clinical benefits related to lower CRS, less ICANS (neurotoxicity), longer duration of response or a higher overall success rate of cellular therapy due to benefits of targeted conditioning.

Iomab-B

In February 2023, Actinium announced that the SIERRA trial met the primary endpoint with statistical significance, as 22% of patients (13/76) on the Iomab-B arm achieved durable Complete Remission ("dCR") compared to 0% of patients (0/77) on the control arm resulting in a p-value of <0.0001. The SIERRA trial met the secondary endpoint of Event-Free Survival ("EFS") with a 78% reduction in the probability of an event (Hazard Ratio=0.22, p<0.0001 for both per protocol and ITT basis). EFS at 180 days for the Iomab-B arm was 28% compared to 0.2% for the control arm. In the SIERRA trial, an event was defined as one of the following: a patient not achieving CR/CRp or crossing over, patient not receiving BMT, a patient relapsing or death. The SIERRA trial did not, however, meet the secondary endpoint in achieving a statistically significant improvement in OS in the intent to treat ("ITT") population.

On August 5, 2024, Actinium announced that it concluded both its clinical and Chemistry, Manufacturing and Controls ("CMC") interactions with the FDA regarding the BLA pathway for Iomab-B based on the SIERRA trial results. As previously disclosed, we had received positive feedback from the FDA regarding our CMC package for Iomab-B and were also assigned a BLA number. However, in the third quarter of 2024, the FDA provided definitive feedback that the SIERRA trial alone is not adequate to support a BLA filing for Iomab-B, despite (a) the SIERRA trial meeting the primary endpoint of dCR with statistical significance (p-value<0.0001) and other positive secondary endpoints including Event Free Survival ("EFS") and safety, and (b) our presentation of several additional analyses from the SIERRA study, including long-term follow-up demonstrating a trend towards improved overall survival and evidence of survival benefit in patients with high-risk TP53 mutations, to support Iomab-B's impact on overall survival. The FDA indicated that demonstrating an overall survival benefit in a randomized head-to-head trial is necessary and has advised us to conduct a study to evaluate allogeneic BMT using Iomab-B plus a reduced intensity conditioning regimen of fludarabine and total body irradiation ("Flu/TBI") versus allogeneic BMT using reduced intensity conditioning comprised of cyclophosphamide plus Flu/TBI. This proposed additional study differs from the SIERRA trial, which allowed physician's choice of salvage chemotherapies and heterogenous conditioning regimens in the control arm. Additionally, the proposed new study will not allow patients to cross over from the control arm, which was allowed in the SIERRA trial and confounded the overall survival analysis in the ITT patient population, as nearly 60% of patients crossed over from the control arm.

Actinium continued interactions with the FDA in 2024 to further discuss the specifics of the additional head-to-head clinical trial required by the FDA, including the patient population, which the FDA had suggested could include all adult r/r AML patients. The FDA also requires that a Phase 2 dose optimization trial demonstrating safety and efficacy be completed to calculate the dose of Iomab-B based on absorbed dose by the bone marrow, rather than the maximum tolerable dose of 24 Gy of radiation to the liver as was done in the SIERRA trial based on several interactions we had with the FDA before starting the SIERRA trial. In the second quarter of 2025, Actinium conducted another meeting with the FDA. Based on this meeting, Actinium has reached agreement with the FDA on a Phase 2/3 clinical trial protocol and has been authorized by FDA to initiate the Phase 2 portion of the trial. We are actively seeking a strategic partner for Iomab-B in the U.S. to execute the Phase 2/3 clinical trial. This planned study will be conducted to establish dose optimization and evaluate allogeneic BMT using Iomab-B plus a reduced intensity conditioning regimen of Flu/TBI versus allogeneic BMT using reduced intensity conditioning comprised of cyclophosphamide plus Flu/TBI. The study population will be all adult patients aged 18 and above with active AML with blasts counts between 5 and 20 percent. This is a broader patient population than the patients enrolled on the SIERRA trial, which only enrolled patients aged 55 and above and with blast counts that exceeded 20 percent.

On April 7, 2022, we entered into a License Agreement with Immedica Pharma AB ("Immedica"), pursuant to which Immedica licensed the exclusive product rights for commercialization of Iomab-B in certain countries in the EUMENA region. Upon signing, we were entitled to an upfront, non-refundable payment of $35.0 million from Immedica, which was received in May 2022. Under the terms of the License Agreement, we are eligible to receive certain regulatory and commercial milestone payments and royalties on net sales of the product in certain countries that may result from the License Agreement. Immedica is responsible for regulatory submissions in the EUMENA region, and we continue to retain commercialization rights in the U.S. and rest of the world.

R&D and Platform Technology

Our R&D capabilities have the potential to yield differentiated, high-value targeted radiotherapy programs that demonstrate our experience across multiple validated cancer targets and isotopes and cover broad areas of focus leveraging our clinical development experience across hematology, targeted conditioning, solid tumors, and next-generation radiotherapies. We have internal R&D capabilities with our research laboratory capable of executing in vitro and in vivo experiments and translational research. We are working on several preclinical programs which include novel approaches to validated cancer targets, as well as novel targets that we believe show immense potential for radiotherapeutic approaches. Preclinical pharmacology studies with our targeted radiotherapeutics, such as HER2, CD33 and CD38, have shown strong improvement in tumor growth inhibition in various preclinical tumor models.

We currently believe that our targeted radiotherapies, which utilize biologic molecules, are less likely than small molecules to face pricing pressure and negotiation from the Inflation Reduction Act of 2022 ("IRA"), given that small molecules are at risk for pricing negotiations seven years after approval compared to eleven years for biologics with negotiated prices taking effect two years after selection. Further, a drug or biological product that has an orphan drug designation, which our Actimab-A and Iomab-B programs both have, for only one rare disease or condition will be excluded from the IRA's price negotiations requirements until such time the biological products has designations for more than one rare disease or condition, or if is approved for an indication that is not within that single designated rare disease or condition, unless such additional designation or such disqualifying approvals are withdrawn by the time CMS evaluates the drug for selection for negotiation. In addition, regulatory barriers for generic large molecule biologic based targeted radiotherapies are much higher than for small molecule radioligands such as those under development or approved, namely, Pluvicto®, Lutathera®, and Xofigo®. Generic versions of certain radiopharmaceuticals utilizing peptides, which are considered small molecules, have been submitted to the FDA via the Abbreviated New Drug Application ("ANDA") pathway. To our knowledge, only the biosimilar approach pertains to large molecule biologic-based radiotherapies filed under 351(k) BLA pathway. The regulatory pathway for a biosimilar is much more comprehensive than the pathway for generics, and it has not been proven that biosimilars are interchangeable with the innovator's large molecule biologic targeted radiotherapy. In addition, we are not aware of any regulations that would require us to provide Actimab-A or Iomab-ACT, including their respective mAbs, lintuzumab and apamistamab, to any third party or potential competitor. Despite the above, we are aware that one or more of the policies or regulations that afford our pipeline candidates market protections may change in the future and that one or more of our product candidates may be disadvantaged by such change.

We seek to expand our capabilities and technologies across therapeutic modalities, linker technologies and in vivo cancer models, and build visibility through presentations at key conferences and publications in journals of high impact. Our R&D efforts are centered on the advancement of key programs with a robust "fast-to-clinic" approach. Underpinning our development programs is our expanded patent portfolio of approximately 240 issued patents and pending patent applications worldwide.

Our Proprietary Ac-225 Cyclotron Manufacturing Technology

With our in-depth, long-term experience in clinical development of Ac-225 based radiopharmaceuticals, we have developed an end-to-end technology solution for producing Ac-225 that has demonstrated radiochemical and radionuclidic purity identical to current gold-standard methods. This patented technology has been used to produce Ac-225 in a cyclotron that is essentially identical to that derived from a Th-229 generator and has the potential to be a lower-cost, commercially scalable higher-yielding approach. Importantly, the Ac-225 material produced by our proprietary method contains no long-lived contaminants and less than 0.001% Actinium-227 ("Ac-227"). Using the cyclotron-produced Ac-225 technology may allow for large commercial scale production with estimated cost of goods sold including capital expenditures and operational costs for a single cyclotron facility to be several times less expensive than the price of currently available Ac-225 material.

Our extensive know-how related to this production technology is supported by 5 issued patents in the U.S. and 33 issued patents internationally and covers:

- End-to-end solution including processing and recycling of Radium-226 starting material
- Production of up to 100 mCi of Ac-225 per production cycle
- Utilization of a medium energy cyclotron
- Expected cost 10 to 20 times lower than currently available material
- Radiochemical purity > 99%
- Radioisotopic purity 99.8% with no long-lived contaminants and <0.001% Ac-227

With our Ac-2225 based Actimab-A and ATNM-400 programs and the rapidly increasing number of Ac-225 based programs in development, we believe that we are well positioned to leverage this technology to produce Ac-225 to address the growing clinical and potential commercial demand.

Manufacturing and Supply Chain

Actinium has established significant manufacturing and supply chain expertise, having delivered over 500 doses for 18 clinical trials at 45 large cancer hospitals and have never missed a dose.

We believe this experience provides us with insights that are highly relevant to the unique manufacturing and distribution requirements of radiotherapeutics. Due to the short half-life of radioisotopes, our finished drug products are shipped "hot" and must be administered within days. Actinium has established core competencies in the process of manufacturing radiotherapeutics, coordinating with the hospital's care team, and delivering "just-in-time" doses.

We plan to establish our own manufacturing capabilities and intend to commence the build-out of a facility in the second half of 2025. We believe that having in-house manufacturing will provide enhanced control, flexibility and scalability to serve our current and planned clinical trials and R&D efforts as well as potential future activity.

Isotope supply is critical for the manufacturing of radiotherapeutics, and we have engaged several sources for the procurement of alpha (e.g., Ac-225) and beta (e.g., I-131 and Lu-177) emitters. We also have multiple isotope supply agreements and qualified vendors in place to supply isotopes for our active and planned clinical trials. In March 2025, we announced that we entered into Ac-225 supply agreement with Eckert & Ziegler, a leading specialist in isotope-related components for nuclear medicine and radiation therapy, to support our comprehensive development including U.S. and international clinical trials.

Actinium has commercial agreements with Contract Development and Manufacturing Organizations ("CDMOs") with significant experience in mAb and final radio-labeled drug products. Our finished drug product CDMOs are located in the U.S. and have experience in the international supply of radiotherapies. We have scaled deliberately for manufacturing flexibility and are currently qualifying additional CDMOs to ensure readily available drug product upon FDA approval and the ability to ramp up rapidly to meet commercial demand.

We have established an actively managed end-to-end supply chain that encompasses isotope sourcing through drug administration at the point of care to execute our clinical trials. Our end-to-end supply chain did not miss a patient dose in our international, 24-site SIERRA Phase 3 clinical trial, including 40 additional patients that crossed over from the control arm to receive Iomab-B. We believe we have a thorough understanding and working knowledge of the intricacies required to manufacture and distribute radiotherapies. Through our clinical experience with Iomab-B and Actimab-A, we have developed a wealth of proprietary knowledge to enable coordination between Actinium and all key stakeholders including, but not limited to hematologists/oncologists, infusion center and in patient rooms, nuclear medicine and radiology, hot labs and radio-pharmacies, and radiation safety committees, among others.

Intellectual Property

Our proprietary technology platform is supported by IP, know-how and trade secrets that cover the generation, development, methods of use and manufacture of targeted radiotherapies and their select components. Our IP covers various methods of use in multiple diseases, including indication, dose and scheduling, radionuclide warhead, and therapeutic combinations.

As of August 2025, our patent portfolio is comprised of approximately 240 issued patents and pending patent applications worldwide, which we believe constitutes a valuable business asset. Our IP includes 48 patent families, including key patents that relate primarily to our radiotherapeutic candidates. Our patent portfolio includes 20 issued patents and 51 pending patent applications in the U.S., and 173 that 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 2026 and 2046.

For our Iomab-B product candidate, we have four issued patents in the U.S. and issued patents in Canada, Europe and Japan that relate to the composition. The basic patent terms of these patents expire in 2036 and 2037. Related patent applications are also currently pending in the U.S. and internationally. In addition, we own both U.S. and international pending patent applications that relate to the use of Iomab-B or Iomab-ACT in the treatment of cancers and non-malignant conditions.

Our patents also cover key areas of our business such as manufacturing key components of our product candidate, Actimab-A, including Ac-225 in a cyclotron. We have 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 U.S. and 33 issued patents internationally related to the manufacturing of Ac-225 in a cyclotron, which we believe has the potential to produce higher quantities of Ac-225 than currently utilized methods. In addition, we also own U.S. and international patents and pending patent applications that relate to the manufacturing of Actimab-A and its use in the treatment of cancers.

Human Capital

As of August 8, 2025, we had 27 full-time employees, 12 of whom have Ph.D. or M.D. degrees and 20 of whom are engaged in research and development and clinical development activities. In the second quarter of 2025, we conducted a workforce optimization aligned with our strategic pipeline prioritization that reduced our headcount by approximately fourteen percent. Also in the second quarter of 2025, Dr. Avinash Desai resigned from his position as Chief Medical Officer. There were no disagreements with the Company that contributed to Dr. Desai's resignation. We do not expect the aforementioned workforce optimization or departures to have a material impact on our operations or ability to execute our operating plan. We believe that we have been successful to date in attracting skilled and experienced personnel despite the competitive hiring marketing in the industry. Our employees are not covered by a collective bargaining agreement, and we believe that our relationship with our employees is excellent. We continue to engage external consultants on an as-needed basis to temporarily supplement existing staff.

Stock Option Compensation Expense

On March 31, 2025, our Board of Directors approved the cancellation of certain stock options to purchase an aggregate of 4.9 million shares of common stock held by certain current employees and directors that were initially granted under our Amended and Restated 2013 Stock Plan and 2019 Amended and Restated Stock Plan. Such cancellations were subject to the consent of the applicable holders of the stock options.

Stock option expense for the three months ended March 31, 2025 and March 31, 2024, respectively and stock option expense for the three months and six months ended June 30,2025 and June 30,2024, respectively, is presented below:

	3 months ended March 31		3 months ended June 30		6 months ended June 30	
$ in thousands	**2025**	**2024**	**2025**	**2024**	**2025**	**2024**
Research & Development	$ 2,070	$ 340	$ 16	$ 337	$ 2,086	$ 677
General & Administrative	6,657	887	33	885	6,690	1,772
Total	$ 8,727	$ 1,227	$ 49	$ 1,222	$ 8,776	$ 2,449

Results of Operations – Three Months Ended June 30, 2025 Compared to Three Months Ended June 30, 2025

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

	For the Three Months Ended June 30,	
(in thousands)	**2025**	**2024**
Revenue:		
Revenue	$ -	$ -
Other revenue	-	-
Total revenue	-	-
Operating expenses:		
Research and development, net of reimbursements	4,879	8,825
General and administrative	2,624	3,593
Total operating expenses	7,503	12,418
Other income:		
Interest income – net	625	1,065
Total other income	625	1,065
Net loss	$ (6,878)	$ (11,353)

Revenue

We recorded no commercial revenue for the three months ended June 30, 2025 and June 30, 2024, respectively.

Other revenue

The National Institutes of Health 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, our CD45-targeting Antibody Radio-Conjugate, for targeted conditioning to achieve lymphodepletion prior to administration of a CD19-targeted CAR T-cell therapy developed at MSK. There was no other revenue recognized for the three months ended June 30, 2025 and 2024, respectively.

As noted above, on April 7, 2022, we entered into a License Agreement with Immedica, pursuant to which Immedica licensed the exclusive product rights for commercialization of Iomab-B in certain countries in the EUMENA region. Upon signing, we were entitled to an upfront, non-refundable payment of $35 million from Immedica, which was received in May 2022. Under the terms of the License Agreement, we are eligible to receive certain regulatory and commercial milestone payments and royalties on net sales of the product in certain countries that may result from the License Agreement. We continue to retain commercialization rights in the U.S. and rest of the world.

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. There was no Other revenue deferred-current liability at June 30, 2025 and December 31, 2024. Long-term license revenue deferred was $35 million at June 30, 2025 and December 31, 2024, resulting from the receipt from Immedica; this deferred revenue will be recognized upon the European Union's regulatory approval of Iomab-B or provision of definitive feedback that Iomab-B will not receive approval in the European Union.

Stock-Based Compensation Expense

As noted above, the cancellation of stock options in March 2025 resulted in a significant decrease in non-cash stock compensation expense for the three months ended June 30, 2025. During the three months ended June 30, 2025 and June 30, 2024, total non-cash stock-based compensation expense, including stock option compensation expense, was $0.2 million and $1.4 million, respectively.

Research and Development Expense, net of reimbursements

Research and development expenses of $4.9 million for the three months ended June 30, 2025 decreased by $3.9 million from $8.8 million for the three months ended June 30, 2024. The decrease was primarily a result of lower compensation of $1.6 million due to lower headcount and lower non-cash stock-based compensation expense of $0.3 million due to the cancellation of stock options in March 2025. In the second quarter of 2025, we conducted a workforce optimization that reduced our headcount by approximately fourteen percent. In addition, there was a decline in Chemistry, manufacturing and controls, or CMC, expenses and clinical expenses of $1.4 million due to lower activity related to Iomab-B and preclinical expenses decreased $0.7 million.

General and administrative expense

General and administrative expense of $2.6 million for the three months ended June 30, 2025 decreased by $1.0 million from $3.6 million for the three months ended June 30, 2024. The cancellation of stock options in March 2025 described above resulted in lower non-cash stock-based compensation expense of $0.9 million for the three months ended June 30, 2025 compared with the three months ended June 30, 2024.

Other income

Other income is comprised of net interest income in both reporting periods. The amount for the three months ended June 30, 2025 of $0.6 million decreased from $1.1 million for the three months ended June 30, 2024 primarily due to a lower average cash balance during the respective time periods.

Net loss

Net loss of $6.9 million for the three months ended June 30, 2025 decreased by $4.5 million from $11.4 million for the three months ended June 30, 2024 primarily due to lower research and development expenses and lower general administrative expenses, partially offset by lower other income.

Results of Operations – Six Months Ended June 30, 2025 Compared to Six Months Ended June 30, 2025

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

(in thousands)	For the Six Months Ended June 30, 2025	2024
Revenue:		
Revenue	$ -	$ -
Other revenue	-	-
Total revenue	-	-
Operating expenses:		
Research and development, net of reimbursements	12,579	15,460
General and administrative	11,562	6,555
Total operating expenses	24,141	22,015
Other income:		
Interest income – net	1,325	1,992
Total other income	1,325	1,992
Net loss	$ (22,816)	$ (20,023)

Revenue

We recorded no commercial revenue for the six months ended June 30, 2025 and June 30, 2024, respectively.

Other revenue

We recorded no other revenue recognized for the six months ended June 30, 2025 and 2024, respectively.

Stock-Based Compensation Expense

The cancellation of stock options on March 31, 2025, described above, resulted in a significant increase in non-cash stock-based compensation for the six months ended June 30, 2025 compared to its prior-year period due to recognition of previously unrecognized stock-based compensation cost at the cancellation. During the six months ended June 30, 2025 and June 30, 2024, total non-cash stock-based compensation expense, including stock option compensation expense, was $9.1 million and $2.8 million, respectively.

Research and Development Expense, net of reimbursements

Research and development expenses of $12.6 million for the six months ended June 30, 2025 decreased by $2.9 million from $15.5 million for the six months ended June 30, 2024. The decrease was primarily a result of lower compensation of $2.3 million due to lower headcount. In the second quarter of 2025, we conducted a workforce optimization that reduced our headcount by approximately fourteen percent. In addition, there was a decline in clinical expenses of $1.2 million due to lower activity related to Iomab-B and preclinical expenses decreased $0.4 million. These decreases were partially offset by higher non-cash stock-based compensation of $1.4 million, due to the cancellation of stock options described above.

General and administrative expense

General and administrative expenses of $11.6 million for the six months ended June 30, 2025 increased by $5.0 million from $6.6 million for the six months ended June 30, 2024, as a result of higher non-cash stock-based compensation expense of $4.9 million, due to the cancellation of stock options described above.

Other income

Other income is comprised of net interest income in both reporting periods. The amount for the six months ended June 30, 2025 of $1.3 million decreased from $2.0 million for the six months ended June 30, 2024 primarily due to a lower average cash balance during the respective time periods.

Net loss

Net loss of $22.8 million for the six months ended June 30, 2025 increased by $2.8 million from $20.0 million for the six months ended June 30, 2024 primarily due to higher research and development expenses and higher general administrative expenses as a result of non-cash stock-based compensation expense of $9.1 million for the six months ended June 30, 2025 compared to $2.8 million in the prior-year period due to the cancellation of stock options described above, along with lower other income.

Liquidity and Capital Resources

The following table sets forth selected cash flow information for the periods indicated:

	For the Six Months Ended June 30,	
(in thousands)	**2025**	**2024**
Cash used in operating activities	$ (12,966)	$ (15,346)
Cash used in investing activities	-	(11)
Cash used in/provided by financing activities	(5)	24,722
Net change in cash, cash equivalents and restricted cash	$ (12,971)	$ 9,365

Net cash used in operating activities for the six months ended June 30, 2025 was $13.0 million, a decrease of $2.3 million from $15.3 million in the prior-year period. In the six months ended June 30, 2025, our net loss of $22.8 million excluding non-cash stock-based compensation expense of $9.1 million was $13.7 million. In the prior-year period, net loss of $20.0 million excluding non-cash stock-based compensation expense of $2.8 million was $17.2 million. This decrease in net cash used in operating activities of $3.5 million was offset by an increase in net operating assets and liabilities of $1.2 million.

There was no cash used in investing activities for the six months ended June 30, 2025. Cash used in investing activities was $11 thousand for the six months ended June 30, 2024 due to the purchase of equipment.

Cash used in financing activities for the six months ended June 30, 2025 was not material. Net cash provided by financing activities of $24.7 million for the six months ended June 30, 2024 was primarily from the sale of shares of common stock.

In August 2020, we entered into the Capital on Demand™ Sales Agreement with JonesTrading Institutional Services LLC, or JonesTrading, pursuant to which we are able to sell, from time to time, through or to JonesTrading, up to an aggregate of $200 million of our common stock. On June 28, 2022, we entered into an Amendment and Restated Capital on Demand™ Sales Agreement, or the Amended Sales Agreement, with JonesTrading and B. Riley Securities, Inc. The Amended Sales Agreement modifies the original Capital on Demand™ Sales Agreement to include B. Riley as an additional sales agent thereunder. Shares of common stock are offered pursuant to a shelf registration statement on Form S-3 (File No. 333-273911), which was declared effective February 5, 2024, including a base prospectus covering the offering, issuance and sale of up to $500 million of common stock, preferred stock, warrants, units and/or subscription rights; and a sales agreement prospectus covering the offering, issuance and sale of up to a maximum aggregate offering price of $200 million of common stock that may be issued and sold under the Amended Sales Agreement. During the six months ended June 30, 2025, there were no sales of shares of common stock. For the six months ended June 30, 2024, we sold 2.9 million shares of common stock, resulting in gross proceeds of $25.2 million and net proceeds of $24.7 million.

On March 31, 2025, upon filing of our Annual Report on Form 10-K for the year ended December 31, 2024, we became subject to General Instruction I.B.6 of Form S-3, pursuant to which in no event will we sell our common stock in a registered primary offering using Form S-3 with a value exceeding more than one-third of our public float in any 12 calendar month period so long as our public float remains below $75 million.

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

Critical Accounting 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. The Company does not have any critical accounting estimates.

Recently Adopted Accounting Pronouncements

In December 2023, the Financial Accounting Standards Board ("FASB") issued ASU 2023-09, Income Taxes (Topic 740): Improvements to Income Tax Disclosures, to enhance the transparency and decision usefulness of income tax disclosures. The amendments in ASU 2023-09 provide improvements primarily related to the rate reconciliation and income taxes paid information included in income tax disclosures. We would be required to disclose additional information regarding reconciling items equal to or greater than five percent of the amount computed by multiplying pretax income (loss) by the applicable statutory tax rate. Similarly, we would be required to disclose income taxes paid (net of refunds received) equal to or greater than five percent of total income taxes paid (net of refunds received). The amendments in ASU 2023-09 are effective January 1, 2025. Early adoption is permitted for annual financial statements that have not yet been issued or made available for issuance. We adopted this standard effective January 1, 2025 and will report on it in our Annual Report on Form 10-K for the year ended December 31, 2025. We will update all required disclosures pursuant to ASU 2023-09 at that time.

Recently Issued Accounting Pronouncements

In May 2025, FASB issued ASU 2025-04, *Compensation—Stock Compensation (Topic 718) and Revenue from Contracts with Customers (Topic 606): Clarifications to Share-Based Consideration Payable to a Customer*, which revises the Master Glossary definition of the term "performance condition" for share-based consideration payable to a customer to include conditions, such as vesting conditions, that are based on the volume or monetary amount of a customer's purchases or potential purchases of goods or services from the grantor, including over a specified period of time. The revised definition also incorporates performance targets based on purchases made by other parties that purchase the grantor's goods or services from the grantor's customers. The revised definition of the term performance condition cannot be applied by analogy to awards granted to employees and nonemployees in exchange for goods or services to be used or consumed in the grantor's own operations. ASU 2025-04 eliminate the policy election permitting a grantor to account for forfeitures as they occur for share-based awards granted to a customer. Separate policy elections for forfeitures remain available for share-based payment awards with service conditions granted to employees and nonemployees in exchange for goods or services to be used or consumed in the grantor's own operations. ASU 2025-04 further clarifies that a grantor should not apply the guidance in Topic 606 on constraining estimates of variable consideration to share-based consideration payable to a customer. ASU 2025-04 permit a grantor to apply the new guidance on either a modified retrospective or a retrospective basis. The amendments in ASU 2024-04 are effective January 1, 2027, for annual for annual reporting periods, including interim periods within annual reporting periods. Early adoption is permitted as of the beginning of an interim or annual reporting period. We are evaluating the impact of ASU 2024-03 on our financial statements.

In November 2024, FASB issued ASU 2024-03, *Income Statement-Reporting Comprehensive Income-Expense Disaggregation Disclosures* (Subtopic 220-40), to improve the disaggregation of expenses within the consolidated statement of operations. The amendments in ASU 2024-03 require disclosures in the notes to the consolidated financial statements and specified information about certain costs and expenses. The amendments require that at each interim and annual reporting period an entity disclose (a) employee compensation, (b) depreciation, and (c) intangible asset amortization included in each relevant expense caption; include certain amounts that are already required to be disclosed under current GAAP in the same disclosure as the other disaggregation requirements; and disclose a qualitative description of the amounts remaining in relevant expense captions that are not separately disaggregated quantitatively. The amendments in ASU 2024-03 are effective January 1, 2027 and effective for interim periods beginning January 1, 2028. We are evaluating the impact of ASU 2024-03 on our financial statements.

Known Trends, Events and Uncertainties

The Company is subject to risks and uncertainties common to companies in the biopharmaceutical industry, including but not limited to, risks associated with completing preclinical studies and clinical trials, receiving regulatory approvals for product candidates, development by competitors of new biopharmaceutical products, dependence on key personnel, protection of proprietary technology, compliance with government regulations and the ability to secure additional capital to fund operations. In addition, the consequences of the ongoing geopolitical conflicts, such as the ongoing conflict between Russia and Ukraine and the ongoing conflict between Israel and Hamas, including related sanctions and countermeasures, and the effects of rising global inflation, are difficult to predict, and could adversely impact geopolitical and macroeconomic conditions, the global economy, and contribute to increased market volatility, which may in turn adversely affect our business and operations. Additionally, recent changes to U.S. policy implemented by the U.S. Congress, the Trump administration or any new administration have impacted and may in the future impact, among other things, the U.S. and global economy, tariffs, international trade relations, unemployment, immigration, healthcare, taxation, the U.S. regulatory environment, inflation and other areas. Although we cannot predict the impact, if any, of these changes to our business, they could adversely affect our business. For a further discussion of factors that may affect future operating results see the sections entitled “Risk Factors” and “Cautionary Statement Regarding Forward-Looking Statement Notice.”

Other than as discussed above and elsewhere in this report, we are not aware of any trends, events or uncertainties that are likely to have a material effect on our financial condition.

ITEM 3. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK.

We are a smaller reporting company as defined by Rule 12b-2 of the Exchange Act and are not required to provide the information required under this item.

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 June 30, 2025, 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 June 30, 2025, 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 internal controls over financial reporting during the period covered by this Quarterly Report on Form 10-Q 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

From time to time, we may become involved in various lawsuits and legal proceedings, which arise in the ordinary course of business. Litigation is subject to inherent uncertainties, and an adverse result in these or other matters may arise from time to time that may harm business.

On March 27, 2025, a putative class action complaint (the "Securities Complaint") was filed by alleged stockholder Nitin Kohil against the Company and executives Sandesh Seth, Avinash Desai, Madhuri Vusirikala, and Sergio Giralt (the "Defendants"), styled *Kohil v. Actinium Pharmaceuticals, Inc., et al*., Case No. 1:25-cv-02553 in the United States District Court for the Southern District of New York. The Securities Complaint alleges that the Defendants made material misrepresentations and omissions concerning the Iomab-B Phase 3 Sierra Trial and the plaintiff asserts claims against all Defendants pursuant to section 10(b) of the Securities Exchange Act (the "Exchange Act") and Rule 10b-5 promulgated thereunder, as well as additional claims against the individual Defendants pursuant to Section 20(a) of the Exchange Act. The Complaint purports to assert class action claims on behalf of all persons and entities that purchased or otherwise acquired Actinium securities between October 31, 2022 and August 2, 2024. Plaintiff seeks unspecified damages. On June 24, 2025, the court in the securities action appointed lead plaintiffs who intend to file an amended Securities Complaint on or before August 25, 2025. The Defendants have not yet responded to the Securities Complaint.

On May 5, 2025, a derivative shareholder complaint (the "*Georges* Complaint") was filed against the Company and certain of the Company's directors and officers alleging derivative liability for the allegations made in the Securities Complaint. On May 13, 2025, a second derivative shareholder complaint (the "*Robinson* Complaint" and, together with the *Georges* Complaint, the "Derivative Complaints") was filed against the Company and certain of the Company's directors also alleging derivative liability for the allegations made in the Securities Complaint. On June 24, 2025, the Court consolidated the Derivative Complaints (the "Derivative Action"). On July 29, 2025, the parties to the Derivative Action filed a stipulation with the Court to stay the Derivative Action pending resolution of any motion to dismiss the Securities Complaint. The Court has not yet entered that stipulation.

The Company and other Defendants intend to defend vigorously against such claims, however, there can be no assurances as to the outcome.

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 on Form 10-K for the year ended December 31, 2024. 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 Quarterly Report on Form 10-Q to enhance the readability and accessibility of our risk factor disclosures. We encourage you to carefully review the full risk factors contained in this Quarterly Report on Form 10-Q 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 or product commercialization and you will likely lose your entire investment;

- We are highly dependent on the clinical, regulatory and commercial success of Iomab-B, Actimab-A, Iomab-ACT, ATNM-400 and other pipeline candidates which we may never achieve;

- We continuously evaluate our business strategy and may modify our strategy as necessary to respond to developments in our business and other factors, and any such modification such as a divestiture, spin-off, spin-out, merger or acquisition, if not successful, could have a material adverse effect on our business, financial condition, and 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 could be adversely affected by the effects of future health epidemics;

- Our business is subject to cybersecurity risk;

- We have not demonstrated that any of our products are safe or 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 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 on our business, future revenue, if any, and results of operations;

- Changes in the healthcare industry and in healthcare spending could adversely affect our grant funded clinical programs, business, financial condition and results of operations;

- We may rely on third parties to conduct certain aspects of 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 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;

- 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;

- Disruptions at the FDA and other government agencies caused by leadership changes, changes to regulatory approach, layoffs, funding shortages or global health concerns could negatively impact our business;

- 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 June 30, 2025 and December 31, 2024, we had an accumulated deficit of $398.6 million and $375.8 million, respectively. We reported a net loss of $22.8 million and $20.0 million for the six months ended June 30, 2025 and 2024, 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 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 unfavorable terms.

We have limited access to the capital markets to raise funds. The capital markets have been unpredictable in the recent past for development stage radiopharmaceutical and other biotechnology 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 clinical, regulatory and commercial success of Actimab-A, Iomab-ACT, ATNM-400 and other pipeline candidates which we may never achieve

None of the drug candidates we are developing, or have developed, have received regulatory approval. Based on the current status of our pipeline candidates, it will likely take several years or additional clinical studies before we can seek approval for any drug candidate.

Our Actimab-A drug candidate was studied in a Phase 2 clinical trial as a monotherapy and we are now studying it in combination with other therapies. We believe we have aligned with the FDA on a Phase 2/3 trial that is intended to support a BLA filing. There can be no assurance that the Phase 2 portion of the trial will be successful and support advancing to the Phase 3 portion of the trial. In addition, our Iomab-ACT drug candidate has only been studied in a limited number of human subjects in a Phase 1 trial with a novel CAR-T therapy. While we believe the initial results from this trial were encouraging, there can be no assurance that future results with Iomab-ACT from the commercial CAR-T trial at UTSW or sickle cell conditioning trial at Columbia will be positive.

As for Iomab-B in particular, as previously disclosed, we completed the pivotal Phase 3 SIERRA trial (Study of Iomab-B in Elderly Relapsed or Refractory AML) and presented the trial results in February 2023, which were expected to support a BLA filing. The SIERRA trial met the primary endpoint of dCR with statistical significance (p-value<0.0001) but did not meet the secondary endpoint in achieving a statistically significant improvement in overall survival in the intent to treat population. On August 5, 2024, we announced that the FDA determined that the SIERRA trial alone is not adequate to support a BLA filing and is requiring an additional randomized head-to-head clinical trial to demonstrate an overall survival benefit in an intent to treat population. Further, the FDA is also requiring an additional dose optimization trial to calculate the dose of Iomab-B based on absorbed dose by the bone marrow, rather than the maximum tolerable dose of 24 Gy of radiation to the liver as was done in the SIERRA trial based on several interactions with the FDA prior to the start of the SIERRA trial. Based on this revised approach now required by the FDA, the safety and efficacy data generated from all Iomab-B studies, including the SIERRA trial, are inadequate to seek regulatory approval for Iomab-B, as dosing based on maximum tolerable dose of 24 Gy to the liver will lead to variable doses to the bone marrow (the target organ), result in underdosing or overdosing of patients and translate to a global patient safety risk. We are seeking a strategic partner for the U.S. in order to conduct the additional studies required by the FDA; however, we may not be successful in our efforts to find such a partner, or the trials and studies may not be successful. Further, there are no assurances that we can satisfy all of the FDA's requests, and there could be additional regulatory hurdles that may result in either non-acceptance or non-approval of a future BLA filing. The U.S. commercial opportunity for Iomab-B may thus never be realized.

As previously disclosed and noted above, Actinium has licensed to Immedica the exclusive product rights for commercialization of Iomab-B in the EUMENA region. We are evaluating the impact of the FDA's 2024 determination of the SIERRA trial results in the context of global regulatory submissions for Iomab-B. At this time, filings for regulatory approval, obtaining regulatory approvals, and successful commercialization of Iomab-B in the EUMENA region and on a global basis are highly uncertain and may never be realized.

Disruptions at the FDA and other government agencies caused by leadership changes, changes to regulatory approach, layoffs, funding shortages or global health concerns could negatively impact our business

The ability of the FDA to review proposed clinical trials or approve new products can be affected by a variety of factors, including government budget and funding levels, statutory, regulatory, and policy changes, the FDA's ability to hire and retain key personnel and accept the payment of user fees, and other events that may otherwise affect the FDA's ability to perform routine functions. In addition, government funding of other government agencies that fund research and development activities is subject to the political process, including executive and congressional priorities, the impacts of which are inherently fluid and unpredictable. Disruptions at the FDA and other agencies may slow the time necessary for new product candidates to be reviewed and/or approved, which would adversely affect our business. For example, over the last several years, including for 35 days beginning on December 22, 2018, the U.S. government has shut down several times and certain regulatory agencies, such as the FDA, have had to furlough critical FDA employees and stop critical activities. In addition, the current administration has proposed substantial reductions in force at various government agencies including the FDA, which could significantly reduce the FDA's capacity to perform its functions in a manner consistent with its past practices and could delay reviews and negatively impact our business. There has been significant turnover and recent changes in senior leadership at the FDA and other government agencies including the Center for Biologics Evaluation and Research ("CBER"), which is the division of the FDA that would oversee and review biologics-based targeted radiotherapies like those we currently develop and plan to continue to develop. We believe these changes could result in changes in the FDA's perception of the approvability of therapies, the perceived value of certain therapies or therapeutic modalities, which could create material challenges for our development efforts. At this time, there is significant uncertainty and risks associated with future FDA regulatory policies and actions that could have a material negative impact on our business. Any or all of these factors could cause us to amend, suspend or terminate the development of certain of our preclinical or clinical programs, which could have material adverse impacts on our business, our product candidates or our 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 ultimately become approved and we do not secure a commercial partner, 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 future health epidemics.

Our business could be adversely impacted by the effects of future pandemics, epidemics or infectious disease outbreaks. The full impact of such an event cannot be predicted at this time, and could depend on numerous factors, including vaccination rates among the population 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 a future pandemic on our business.

A future pandemic could adversely affect our 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 a future pandemic if their geography is impacted by the pandemic. Further, future pandemics 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, or the inability of patients to comply with clinical trial protocols if quarantines or travel restrictions are implemented that 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 a future 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, a future pandemic 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.

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, EMA 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, EMA 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 regulators, 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 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 obtain 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.

For instance, as for Iomab-B, despite the Phase SIERRA 3 trial meeting the primary endpoint of durable Complete Remission (dCR) with statistical significance (p-value<0.0001), the FDA has determined that demonstrating an overall survival benefit in a randomized head-to-head trial is required for a BLA filing. In addition, the FDA is also requiring that an additional dose optimization trial demonstrating safety and efficacy be completed to calculate the dose of Iomab-B based on absorbed dose by the bone marrow, rather than the maximum tolerable dose of 24 Gy of radiation to the liver as was done in the SIERRA trial based on several interactions we had with the FDA before starting the SIERRA trial. The head-to-head Phase 3 trial will evaluate allogeneic bone marrow transplant (BMT) using Iomab-B plus a reduced intensity conditioning regimen of fludarabine and total body irradiation (Flu/TBI) versus allogeneic BMT using reduced intensity conditioning comprised of cyclophosphamide plus Flu/TBI. This is different from the SIERRA trial, which allowed physician's choice of salvage therapies and heterogenous conditioning regimens in the control arm. However, there are no assurances that the additional trials will be completed or successful or that we can satisfy all of the FDA's requests. There could also be additional regulatory hurdles that may result in either non-acceptance or non-approval of a future BLA filing.

As previously disclosed and noted above, Actinium has licensed to Immedica the exclusive product rights for commercialization of Iomab-B in the EUMENA region. We are evaluating the impact of the FDA's 2024 determination of the SIERRA trials results referred to above in the context of global regulatory submission for Iomab-B. At this time, filings for regulatory approval, obtaining regulatory approvals, and successful commercialization of Iomab-B in the EUMENA region and on a global basis are highly uncertain and may never be realized.

We are also evaluating Iomab-ACT, which uses a lower dose I-131 for conditioning prior to cellular therapies such as CAR-T and gene therapies. We are currently studying Iomab-ACT in three clinical trials including two investigator sponsored studies.

Our Actimab-A (lintuzumab-Ac-225) product candidate has also been studied in several Phase 1 and 2 trials under our sponsorship and investigator-initiated trials in patients with r/r AML and we plan to continue to study Actimab-A in clinical trials. Actimab-A is also being developed under a cooperative research and development agreement (CRADA) with the National Cancer Institute (NCI) and we expect clinical trials to be initiated that will study Actimab-A as a single agent or in combination with other therapies. 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, EMA 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, EMA 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.

Disruptions at the FDA and other agencies may slow the time necessary for new product candidates to be reviewed and/or approved, which would adversely affect our business and may cause us to amend our business strategy or. For example, over the last several years, including for 35 days beginning on December 22, 2018, the U.S. government has shut down several times and certain regulatory agencies, such as the FDA, have had to furlough critical FDA employees and stop critical activities. In addition, the current administration has proposed substantial reductions in force at various government agencies including the FDA, which could significantly reduce the FDA's capacity to perform its functions in a manner consistent with its past practices and could delay reviews and negatively impact our business. There has been significant turnover and changes in senior leadership at the FDA and other government agencies including the Center for Biologics Evaluation and Research ("CBER"), which is the division of the FDA that would oversee and review biologics based targeted radiotherapies like those we currently develop and plan to continue to develop. We believe these changes could result in changes in the FDA's perception of the approvability of therapies, the perceived value of certain therapies or therapeutic modalities, which could create material challenges for our development efforts. At this time, there is significant uncertainty and risks associated with future FDA regulatory policies and actions that could have a material negative impact on our business. Any or all of these factors could cause us to amend, suspend or terminate the development of certain of our preclinical or clinical programs, which could have material adverse impacts on our business, our product candidates or our ability to continue operations.

We have not demonstrated that any of our products are safe or 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 three 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 Federal Food, Drug, and Cosmetic Act ("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") application, 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, good clinical practices ("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 current good manufacturing practices ("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 application. Some preclinical testing may continue even after the IND application is submitted. The IND application 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 application will result in the FDA allowing clinical trials to begin or that, for those that have already commenced under an active IND application, 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 application. 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. 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, effort and expense.

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 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;
- Funding cuts to the NCI, which could delays and/or pauses or termination of our ongoing and planned clinical trials under our CRADA;
- the placement by the FDA or a foreign regulatory authority of a clinical hold on a trial; or
- delays in obtaining regulatory agency authorization for the conduct of our clinical trials.

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, Actimab-A, Iomab-ACT, ATNM-400 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.

For instance, we worked with the FDA to develop the SIERRA clinical trial to test the safety and efficacy of Iomab-B in patients with r/r AML who are aged 55 and above prior to a BMT. Even though the SIERRA trial met the primary endpoint of dCR with statistical significance (p-value<0.0001), the FDA has determined that the analyses from the SIERRA trial do not support a BLA filing for Iomab-B. The FDA now requires an additional head-to-head Phase 3 clinical study. We have further discussed the specifics of this additional clinical trial with the FDA. Based on these discussions, Actinium believes it has aligned with the FDA on the patient population for this additional clinical trial, which can include all adult patients aged 18 and above with active AML with blasts counts greater than 5% and less than 20%. This is a broader patient population than the patients enrolled on the SIERRA trial, which only enrolled patients aged 55 and above. Further, the FDA is also requiring that an additional dose optimization trial demonstrating safety and efficacy be completed to calculate the dose of Iomab-B based on absorbed dose by the bone marrow, rather than the maximum tolerable dose of 24 Gy of radiation to the liver as was done in the SIERRA trial based on several interactions we had with the FDA before starting the SIERRA trial. We are seeking a strategic partner for Iomab-B in the U.S. to advance these additional trials. Even if we are able to secure a partner, there are no assurances that the additional trials will be successful or that we can satisfy all of the FDA's requests. There could also be additional regulatory hurdles that may result in either non-acceptance or non-approval of a future BLA.

Preliminary, Interim, and "top-line" data from our preclinical studies and 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. We may 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 preclinical studies are not necessarily predictive of future success in 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.

Even if our preclinical studies or early clinical trials are favorable, later 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 preclinical studies are favorable and 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 the FDA concludes that any current or future clinical trials for Actimab-A, Iomab-ACT, Iomab-B, ATNM-400 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 the 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 Actimab-A product candidate, 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 4 issued U.S. patents, 2 issued Canadian patents, 2 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. 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. Our patent portfolio includes pending applications related to radioimmunoconjugate composition, formulation administration, and methods of use in treating 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. Further, if approved, Iomab-B would be entitled to 12 years of market exclusivity in the U.S. and 10 years in Europe, during which time no generic biologic or biosimilar product referencing Iomab-B can be granted marketing approval.

Our Actimab-A program clinical trials are testing the same drug construct.

Our Actimab-A program is comprised of several clinical trials conducted under the CRADA with NCI, Actinium sponsored trials, investigator-initiated trials in AML and other myeloid indications and solid tumors that will study the same drug construct consisting of lintuzumab-Ac-225. Negative results from any of these trials could adversely impact our ability to enroll or complete our other trials studying lintzumab-Ac-225, including future studies conducted under our CRADA with the NCI. Additionally, negative outcomes including safety concerns, may result in the FDA requiring amendment to certain clinical trials, placing a clinical hold on certain or all clinical trials or discontinuing other trials utilizing lintuzumab-Ac-225.

We are currently developing, and in the future may develop, product candidates in combination with other therapies and that may expose us to additional risks.

We are currently developing, and may develop future product candidates, for use in combination with one or more currently approved therapies. For example, Actimab-A is expected to be tested in combination with KEYTRUDA® and OPDIVO® for treating HNSCC and NSCLC. If any of the approved therapies we currently or may, in the future, use in combination with a current or future product candidate is found defective, removed from the market, or otherwise becomes unavailable, our clinical trials may face significant delays, be suspended, or terminated. Any such events would likely have a material impact on our operations and the development of the affected product candidate(s) and may ultimately prevent the approval of such product candidate or render continued development efforts too costly to proceed.

Even if a current or future product candidate were to receive FDA approval to be commercialized in the U.S. for use in combination with one or more existing therapies, we would continue to be subject to the risk that the FDA or similar foreign regulatory authorities could revoke approval of the therapy used in combination with our product candidate or that safety, efficacy, manufacturing or supply issues could arise with any such existing therapies. This could result in our own products being removed from the market or cause material delays in, or the suspension or discontinuation, of our production and/or distribution of the applicable product, as our ability to market any such product will be limited to the extent specified in the FDA's approval, if granted.

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 source medical grade I-131 from multiple suppliers, including two leading global manufacturers. Currently, we believe there is sufficient supply of I-131 to support additional trials we may undertake utilizing I-131 and for future commercialization of potential I-131 based products. We continually evaluate I-131 manufacturers and suppliers. 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 Actimab-A product candidate, technology platform, preclinical R&D programs including ATNM-400 and other drug candidates that we might consider for development with the Ac-225 payload. We have secured multiple suppliers that are expected to provide cGMP Ac-225 for our planned clinical trials. There are adequate quantities of Ac-225 available today to meet our current needs via our present supplier, the Department of Energy ("DOE"), who has been our primary supplier of Ac-225 historically. The Ac-225 currently supplied for our 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 the 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 us. 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 at a scale that would be able to satisfy commercial needs. In addition, we are aware of at least ten 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-based drug candidate.

Our contract for supply of this isotope from the DOE must be renewed yearly, and we renewed our contract to extend through the end of 2025. 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 that change its policies that allow for the sale of isotope to us. There can be no assurance that the DOE or our other suppliers will be able to supply all of the quantities of Ac-225 we request in the future. Failure to acquire sufficient quantities of medical grade Ac-225 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 the 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 and planned preclinical R&D activities and commercialization should our drug candidates receive regulatory 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 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 have or are expected to enroll, 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 the FDA or that if future modifications during the trial are necessary, that any such modifications will be acceptable to the 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, the 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 obtaining regulatory approval for Iomab-B or completion of our ongoing or planned clinical trials would adversely affect our business and prospects and could cause us to cease operations.

We have obtained orphan drug designation from the 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 Actimab-A and Iomab-B 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 on 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. The Affordable Care Act 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 judicial, administrative, executive, and legislative initiatives to modify, limit, replace, or repeal the Affordable Care Act since its enactment. For example, during his first term, 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 remained in effect in its then-current form; 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. This uncertainty has become even greater given the new Trump administration and its proposed agenda.

In addition to the Affordable Care Act, there have been numerous other Congressional initiatives 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, former 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, which began on 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.

More recently, on August 16, 2022, former President Biden signed into law the Inflation Reduction Act of 2022 (the "IRA"), which, among other provisions, included several measures intended to lower the cost of prescription drugs and related healthcare reforms. Specifically, the IRA 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 announced on August 29, 2023, and the first year of maximum price applicability to begin in 2026. The IRA 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 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.

On April 15, 2025, the Trump Administration released an executive order entitled, "Lower Drug Prices by Once Again Putting Americans First," which among other things, included multiple directives to various agencies aimed at lowering prescription drug prices. These directives included reports and proposals for new regulations related to reforming the IRA's Medicare Drug Price Negotiation Program, reducing the prices of high-cost drugs, and enhancing price transparency. On May 12, 2025, President Trump issued an executive order implementing the concept of most-favored nation pricing. Under this order, DHHS, in coordination with other federal agencies, is directed to take actions to ensure that the price of prescription drugs paid by federal health insurers, including Medicare and Medicaid, is in line with the prices paid in comparable nations. Any reduction in reimbursement from Medicare, Medicaid, or other government programs may result in a similar reduction in payments from private payors. Further, on July 4, 2025, President Trump signed the One Big Beautiful Bill Act into law which, among other things, is expected to reduce funding to federal healthcare programs, imposes additional requirements to be eligible for healthcare, and clarifies exclusions for orphan drugs under IRA's Drug Price Negotiation Program. Current and future legislative and regulatory changes to further reform healthcare or reduce healthcare costs may limit coverage of or lower reimbursement for healthcare products and treatments that could significantly impact pharmaceutical companies and the success of our product candidates. At the state level, legislatures have increasingly passed legislation and implemented regulations designed to control pharmaceutical and biological product pricing, including price or patient reimbursement constraints, discounts, restrictions on certain product access and marketing cost disclosure and transparency measures, and, in some cases, designed to encourage importation from other countries and bulk purchasing.

Changes in the healthcare industry and in healthcare spending could adversely affect our grant funded clinical programs, business, financial condition and results of operations.

Our business and research efforts rely, in part, on funding and support from U.S. government agencies such as the National Institutes of Health ("NIH"), National Cancer Institute ("NCI") and the Department of Health and Human Services ("HHS"). Government funding for these programs is subject to annual budgetary decisions, which can be unpredictable and influenced by shifting political and economic priorities. Reductions in government support for cancer research or other healthcare initiatives could limit grants, contracts, or other financial resources that we or our research collaborators depend on, potentially delaying our clinical programs and increasing our reliance on alternative funding sources. For instance, we have a CRADA with the NCI for the development of Actimab-A. While we have been informed that the funding for our CRADA is not expected to be impacted, there can be no assurances that this will remain the case and any reduction or elimination of funding can have a material adverse impact on our business.

Moreover, with the change in presidential administration that recently occurred in the United States, government spending programs have become even more difficult to predict and may be subject to greater risk. Considerable uncertainty exists regarding how future budget and program decisions will unfold, including the spending priorities of the new U.S. presidential administration and Congress and what challenges budget reductions may present for our industry generally or for our company. In particular, President Trump recently attempted to place a widespread freeze on most federal grants and loans. Any freeze on government support for our products, programs, or studies could significantly impair our research and development activities, business, and operations.

Disruptions at the FDA, the SEC and other government agencies or comparable regulatory authorities caused by funding shortages or global health concerns, in addition to substantial uncertainty regarding the new Administration's initiatives and how these might impact the FDA, its implementation of laws, regulations, policies and guidance, and its personnel, could hinder government agencies' ability to hire and retain key leadership and other personnel, or otherwise prevent new products and services from being developed or commercialized in a timely manner, or otherwise prevent those agencies from performing normal business functions on which our business operations rely, including timely reviews, which could negatively impact our business.

The ability of the FDA or comparable foreign regulatory authorities to review and approve new products can be affected by a variety of factors, including government budget and funding levels, ability to hire and retain key personnel and accept the payment of user fees, and statutory, regulatory, and policy changes that may otherwise affect the FDA's or comparable foreign regulatory authorities' ability to perform routine functions. In addition, government funding of the SEC and other government agencies or comparable foreign regulatory authorities on which our operations may rely, including those that fund research and development activities, is subject to the political process, which is inherently fluid and unpredictable.

Disruptions at the FDA and other agencies, including substantial leadership, personnel, and policy changes, may also slow the time necessary for new drugs to be reviewed and/or approved by necessary government agencies, which would harm our business. Changes in FDA staffing could result in delays in the FDA's responsiveness or in its ability to review submissions or applications, issue regulations or guidance, or implement or enforce regulatory requirements in a timely fashion or at all. Similar consequences would also result in the event of another significant shutdown of the federal government. For example, over the last several years, the U.S. government has shut down several times and certain regulatory agencies, such as the FDA, have had to furlough critical FDA employees and stop critical activities. If a prolonged government shutdown occurs, or if geopolitical or global health concerns prevent the FDA or other regulatory authorities from conducting their regular inspections, reviews, or other regulatory activities, it could significantly impact the ability of the FDA to timely review and process our regulatory submissions, which could materially adversely affect our business, financial condition, results of operations and prospects. Such changes could significantly impact the ability of the FDA to timely review and take action on our regulatory submissions, which could have a material adverse effect on our business. Further, in our operations as a public company, future government shutdowns or substantial leadership, personnel, and policy changes could impact our ability to access the public markets and obtain necessary capital in order to properly capitalize and continue our operations. If the FDA is constrained in its ability to engage in oversight and implementation activities in the normal course, our business may be negatively impacted.

With the change in the U.S. Presidential Administration in 2025, there is substantial uncertainty as to whether and how the new administration will seek to modify or revise the requirements and policies of the FDA and other regulatory agencies with jurisdiction over our product candidates. This uncertainty could present new challenges and/or opportunities as we navigate development of our product candidates. Some of these efforts have manifested to date in the form of personnel measures that could impact the FDA's ability to hire and/or retain key personnel, which could result in delays or limitations on our ability to obtain guidance from the FDA on our product candidates in development and obtain the requisite regulatory approvals in the future. Moreover, the new Administration has proposed action to freeze or reduce the budget of the National Institutes of Health, or NIH, as related to its funding for medical research, which could decrease the ability of facilities that rely on NIH funding to enroll and conduct clinical trials or increase the costs to us of conducting clinical trials. There remains general uncertainty regarding future activities. The new Administration could issue or promulgate executive orders, regulations, policies or guidance that adversely affect us or create a more challenging or costly environment to pursue the development of new therapeutic products. Alternatively, state governments may attempt to address or react to changes at the federal level with changes to their own regulatory frameworks in a manner that is adverse to our operations. If we become negatively impacted by future governmental orders, regulations, policies or guidance as a result of the new Administration, there could be a material adverse effect on us and our business.

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 product candidates 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.

In the U.S. and some jurisdictions outside the U.S., there have been a number of legislative and regulatory changes and proposed changes regarding the healthcare system that could impact our business. Generally, there has been increasing legislative and enforcement interest in the U.S. with respect to drug pricing, including specialty drug pricing practices, in light of the rising cost of prescription drugs and biologics. Specifically, there have been U.S. Congressional inquiries and federal and state legislative activity designed to, among other things, bring more transparency to drug pricing, review the relationship between pricing and manufacturer patient programs, reduce the price of drugs under Medicare, and reform government program reimbursement methodologies for drugs and biologics. In addition, the concept of most-favored nation pricing has been raised that would seek to establish drug prices in the U.S. to the lowest level paid by comparable countries. Such policy action could cause us to amend, suspend or terminate the development of any or all of our product candidates if a viable commercial market did not exist, which could have a material adverse impact on our business and ability to operate.

If future legislation were to impose direct governmental price controls and access restrictions, it could have a significant adverse impact on our business and financial results. Managed care organizations, as well as Medicaid and other government authorities, continue to seek price discounts. At the state level, legislatures have increasingly passed legislation and implemented regulations designed to control pharmaceutical and biologic product pricing, including price or patient reimbursement constraints, discounts, restrictions on certain product access and marketing cost disclosure and transparency measures, and, in some cases, to encourage importation from other countries and bulk purchasing. Due to the volatility in the current economic and market dynamics, we are unable to predict the impact of any unforeseen or unknown legislative, regulatory, payor or policy actions, which may include cost containment and healthcare reform measures. Such policy actions could have a material adverse impact on our business and ability to operate.

Risks Related to Third Parties

We may 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 protection against generic competition for our biologic drug candidates and reimbursement by CMS may be subject to future change

We are not aware of any existing or pending regulations or legislation that pertains to generic radiopharmaceutical products such as our targeted radiotherapy product candidates. Our ARC 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 and in Europe a biosimilar product cannot be approved until 10 years after the original branded product was approved. The law is complex and 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 and we are not aware of any regulations that would require us to provide the final constructs or components to third parties or potential competitors. Therefore, based on the current regulations, we do not believe that the final drug product of our candidates can be subject to competition from a biosimilar as outlined in BPCIA for at least 12 years in the U.S. and 10 years in the EU. We are aware that generic versions of certain radiopharmaceuticals utilizing peptides have been submitted to the FDA via the Abbreviated New Drug Application ("ANDA") pathway, however, those products are not covered under the BPCIA and therefore that generic pathway is not applicable to Iomab-B or Actimab-A. We expect this would also apply to other biologic drug candidates we may seek to develop in the future based on the current provisions of the BPCIA. Additionally, the Inflation Reduction Act ("IRA") that was enacted in August 2022, states that reimbursement by the Centers for Medicare& Medicaid Services ("CMS") for high-expenditure single-source biologic drugs, which we expect Iomab-B and Actimab-A to be, can only be negotiated after at least 11 years following approval compared to 7 years for non-biologic drugs with negotiated prices taking effect two years after selection. Therefore, we currently believe that our ARCs are less likely than small molecules to face pricing pressure and negotiation from IRA. Further, a drug or biological product that has an orphan drug designation, which Iomab-B and Actimab-A both have, for only one rare disease or condition will be excluded from the IRA's price negotiations requirements until such time the biological products has designations for more than one rare disease or condition, or if is approved for an indication that is not within that single designated rare disease or condition, unless such additional designation or such disqualifying approvals are withdrawn by the time CMS evaluates the drug for selection for negotiation. In August 2023, 10 initial drugs were identified with negotiated prices expected to take effect starting in 2026. In 2027 and 2028, it is expected that CMS will establish negotiated prices for 15 additional drugs in each respective year. We do not believe there is a high likelihood that Iomab-B or Actimab-A would be identified by CMS for negotiated pricing under IRA but there is potential that IRA and other additional state and federal healthcare reform measures will be adopted in the future and the implementation of cost-containment measures or other healthcare reforms may prevent us from being able to generate revenue, attain profitability or successfully commercialize our product candidates.

Our product candidates may never achieve market acceptance.

Actimab-A, Iomab-ACT, ATNM-400, Iomab-B 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 Actimab-A, Iomab-ACT, ATNM-400, Iomab-B 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 currently plan to build out a manufacturing facility 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 out our planned 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, pertaining to the global patient safety profile or efficacy results of our products, the achievement of milestones, the interpretation of contractual obligations, payments for services, development obligations or the ownership of intellectual property developed during our collaboration. We may seek to amend, modify or terminate agreements with partners, suppliers or service providers related to Iomab-B, Actimab-A or Iomab-ACT but there can be no assurance that we can do so successfully or negotiate terms that are favorable to us. Failure of which can increase the risk of or result in litigation or alternative dispute resolution options taken against us. Further, we may exercise our decision-making authority under certain circumstances pertaining to global patient safety related to our products, which our partners may disagree with and may result in potential conflicts and public disclosure of our rationale and position. If any conflicts arise with any of our partners, such partner may act in a manner that is adverse 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. Litigation or alternative dispute resolution options can be lengthy and expensive, require significant time and attention from our management and are highly uncertain. There can be no assurance that if we pursue, or a partner pursues litigation or alternative dispute resolution options, that we will prevail. Monetary and equitable damages awarded against us could have a material adverse effect on our business.

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. 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.

Furthermore, the issuance of a patent, while presumed valid and enforceable, is not conclusive as to its validity or its enforceability and it may not provide us with adequate proprietary protection or competitive advantages against competitors with similar products. Competitors may also be able to design around our patents. Other parties may develop and obtain patent protection for more effective technologies, designs or methods. We may not be able to prevent the unauthorized disclosure or use of our technical knowledge or trade secrets by consultants, vendors, former employees and current employees.

Patent rights are territorial, and patent protection extends only to those countries where we have issued patents. Filing, prosecuting and defending patents on our products and product candidates in all countries and jurisdictions throughout the world would be prohibitively expensive, and our intellectual property rights in some countries outside the United States could be less extensive than those in the United States. Many countries, however, do not protect intellectual property to the same extent as the U.S. or Europe, and their litigation processes differ. Competitors may successfully challenge or avoid our patents, or manufacture products in countries where we have not applied for patent protection. Changes in the patent laws in the U.S. or other countries may diminish the value of our patent rights. As a result of these and other factors, the scope, validity, enforceability, and commercial value of our patent rights are uncertain and unpredictable.

Indeed, several companies have encountered significant problems in protecting and defending intellectual property rights in foreign jurisdictions. The legal systems of some countries do not favor the enforcement of patents and other intellectual property rights, which could make it difficult for us to stop the infringement, misappropriation or other violation of our intellectual property rights generally. Proceedings to enforce our intellectual property rights in foreign jurisdictions could result in substantial costs and divert our efforts and attention from other aspects of our business, could put our patents at risk of being invalidated or interpreted narrowly and our patent applications at risk of not issuing and could provoke third parties to assert claims against us. We may not prevail in any lawsuits that are initiated, and the damages or other remedies awarded, if any, may not be commercially meaningful.

The patent positions of pharmaceutical companies, including our patent position, involve complex legal and factual questions, and, therefore, the issuance, scope, validity and enforceability of any patent claims that we may obtain cannot be predicted with certainty. Patents, if issued, may be challenged, deemed unenforceable, invalidated, or circumvented. A third-party may submit prior art, or we may become involved in opposition, derivation, reexamination, inter partes review, post-grant review, supplemental examination, or interference proceedings challenging our patent rights or the patent rights of our licensors or development partners. The costs of defending or enforcing our proprietary rights in these proceedings can be substantial, and the outcome can be uncertain. An adverse determination in any such submission or proceeding could reduce the scope of, or invalidate, our patent rights, allow third parties to commercialize our technology or products and compete directly with us, or reduce our ability to manufacture or commercialize products. Furthermore, if the scope or strength of protection provided by our patents and patent applications is threatened, it could discourage companies from collaborating with us to license, develop or commercialize current or future products. The ownership of our proprietary rights could also be challenged.

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 and methods. 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. Our ability to enforce our patent rights depends on our ability to detect infringement. It is difficult to detect infringers who do not advertise the components that are used in their products. Moreover, it may be difficult or impossible to obtain evidence of infringement in a competitor’s or potential competitor’s product, particularly in litigation in countries other than the U.S. that do not provide an extensive discovery procedure. Any litigation to enforce or defend our patent rights, if any, even if we were to prevail, could be costly and time-consuming and would divert the attention of our management and key personnel from our business operations. We may not prevail in any lawsuits that we initiate and the damages or other remedies awarded if we were to prevail may not be commercially meaningful.

The cost of enforcing our patent rights against infringers, if such enforcement is required, could be significant, and we may not 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. In addition, we cannot guarantee that we have executed these agreements with each party that may have or have had access to our trade secrets. Furthermore, if the employees and consultants who are parties to these agreements breach or violate the terms of these agreements, we may not have adequate remedies for any such breach or violation, and we could lose our trade secrets through such breaches or violations.

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 may be unable to conduct our business.

If we are found to be infringing 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.

We may not have identified all patents, published applications or published literature that affect our business either by blocking our ability to commercialize our products, by preventing the patentability of one or more aspects of our products to us or our licensors, or by covering the same or similar technologies that may affect our ability to market our products. For example, we (or our licensors) may not have conducted a patent clearance search sufficient to identify potentially obstructing third party patent rights. Moreover, patent applications in the United States are maintained in confidence for up to 18 months after their filing. In some cases, however, patent applications remain confidential in the U.S. Patent and Trademark Office, or the USPTO, for the entire time prior to issuance as a U.S. patent. Patent applications filed in countries outside of the United States are not typically published until at least 18 months from their first filing date. Similarly, publication of discoveries in the scientific or patent literature often lags behind actual discoveries. We cannot be certain that we or our licensors were the first to invent, or the first to file, patent applications covering our products and candidates. We also may not know if our competitors filed patent applications for technology covered by our pending applications or if we were the first to invent the technology that is the subject of our patent applications. Competitors may have filed patent applications or received patents and may obtain additional patents and proprietary rights that block or compete with our patents.

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 potential products and respective 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, using and/or selling its invention. While a patent gives the holder this right to exclude others, it is not a license to commercialize an invention covered by the patent 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 may be subject to damages resulting from claims that we or our employees have wrongfully used or disclosed alleged trade secrets of their former employers.

Our employees may have been previously employed at other companies in the industry, including our competitors or potential competitors. Although we are not aware of any claims currently pending against us, we may be subject to claims that these employees or we have inadvertently or otherwise used or disclosed trade secrets or other proprietary information of the former employers of our employees. Litigation may be necessary to defend against these claims. Even if we are successful in defending against these claims, litigation could result in substantial costs and be a distraction to management. If we fail in defending such claims, in addition to paying money claims, we may lose valuable intellectual property rights or personnel. A loss of key personnel or their work product could hamper or prevent our ability to commercialize product(s), which would materially adversely affect our commercial development efforts.

Obtaining and maintaining patent protection depends on compliance with various procedures and other requirements, and our patent protection could be reduced or eliminated in case of non-compliance with these requirements.

Periodic maintenance fees, renewal fees, annuity fees and various other governmental fees on patents and/or applications will be due to the relevant patent agencies in several stages over the lifetime of the patents and /or applications. The relevant patent agencies require compliance with a number of procedural, documentary, fee payment and other provisions during the patent application process. In many cases, an inadvertent lapse can be cured by payment of a late fee or by other means in accordance with the applicable rules. However, there are situations in which the failure to comply with the relevant requirements can result in the abandonment or lapse of the patent or patent application, resulting in partial or complete loss of patent rights in the relevant jurisdiction. In such an event, our competitors might be able to use our technologies and know-how which could have a material adverse effect on our business, prospects, financial condition and results of operation.

Risks Related to Our Operations

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.

In the third quarter of 2024, our overall headcount was reduced by approximately twenty percent, with a majority of departures coming from our clinical and CMC groups. As a result of these departures, we expect our personnel expenses to be reduced by approximately $3.7 million in 2025, which may be offset by additional hires or consultants. We do not expect these departures to have a material impact on our operations or ability to execute our operating plan and are actively seeking a strategic partner for Iomab-B in the U.S. to advance the additional studies and trials required by the FDA.

An overall tightening and increasingly competitive labor market has been observed in the U.S. employment market generally. 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 as a result of general macroeconomic factors of *force majeure* events, 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, 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 submitting a BLA and building 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. 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 in the future, 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.

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 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 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.

We continuously evaluate our business strategy and may modify our strategy as necessary to respond to developments in our business and other factors, and any such modification such as a divestiture, spin-off, spin-out, merger or acquisition, if not successful, could have a material adverse effect on our business, financial condition, and results of operations.

We continuously evaluate our business strategy and modify our plans as necessary to achieve our objectives in response to changing circumstances. As part of such a process, we may delay, modify or discontinue the development of certain of our drug candidates and choose alternative approaches if we believe such changes would be in our best interest. We may also expand or alter our research and development activities from time to time and redirect allocation of our resources. We have implemented such changes in our business strategy and may continue to do so in the future. There can be no assurances that any product development or other changes that we implement will be successful or that, after implementation of any such changes, that we will not refocus our efforts on new or different objectives.

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;
- inaccurate or unfavorable reports from securities or industry analysts; and
- other events or factors, many of which are beyond our control.

The stock market is subject to significant price and volume fluctuations. 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, such as the Securities Claims further described under "Legal Proceedings", 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;
- 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.

General Risk Factors

We face risks associated with litigation and claims.

We are subject to certain legal proceedings, as further described under "Legal Proceedings." In addition, from time to time, we may become involved in various claims, disputes and legal or regulatory proceedings that arise in the ordinary course of business and relate to contractual and other obligations. Due to the uncertainties of litigation, we can give no assurance that we will prevail on any claims made against us in any such lawsuit. Also, we can give no assurance that any other lawsuits or claims brought in the future will not have an adverse effect on our financial condition, liquidity, or operating results. Adverse outcomes in some or all of these claims may result in significant monetary damages that could adversely affect our ability to conduct our business.

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 to any offerings of our common stock.

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

Our ability to utilize our federal net operating loss and tax credit carryforwards may be limited under Sections 382 and 383 of the Internal Revenue Code of 1986, as amended, or the Code. The limitations apply if we experience an "ownership change", generally defined as a greater than 50 percentage point change in the ownership of our equity by certain stockholders over a rolling three-year period. Similar provisions of state tax law may also apply. We have not assessed whether such an ownership change has previously occurred. If we have experienced an ownership change at any time since our formation, we may already be subject to limitations on our ability to utilize our existing net operating losses and other tax attributes to offset taxable income. In addition, future changes in our stock ownership, which may be outside of our control, may trigger an ownership change and, consequently, the limitations under Sections 382 and 383 of the Code. As a result, if or when we earn net taxable income, our ability to use our pre-change net operating loss carryforwards and other tax attributes to offset such taxable income may be subject to limitations, which could adversely affect our future cash flows.

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, 2024 and 2023 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.

Tariff policies and potential countermeasures could increase our costs and disrupt our global supply chain, which could negatively impact the results of our operations.

President Trump has increased, and has indicated his willingness to continue to increase, the use of tariffs by the U.S. to accomplish certain U.S. policy goals. Such tariffs and any countermeasures could increase the cost of raw materials and components necessary for our operations, disrupt our global supply chain and create additional operational challenges. Further, it is possible that government policy changes and related uncertainty about policy changes could increase market volatility. Because of these dynamics, we cannot predict the impact of any future changes to the U.S.'s or other countries' trading relationships or the impact of new laws or regulations adopted by the U.S. or other countries on our business. Such changes in tariffs and trade regulations could have a material adverse effect on our financial condition, results of operations and cash flows.

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 9, 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).
16.1	Letter from Marcum dated May 8, 2025 (incorporated by reference to Exhibit 16.1 to Form 8-K filed on May 9, 2025).
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.

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: August 8, 2025

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.

Date: August 8, 2025

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.

Date: August 8, 2025

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 June 30, 2025 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.

Date: August 8, 2025

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 June 30, 2025 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.

Date: August 8, 2025

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