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 **March 31, 2021**

or

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

For the transition period from _____ to _____

Commission File Number: **001-36374**

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

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

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

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

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

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. ☒ Yes No ☐

Indicate by check mark whether the registrant has submitted electronically every Interactive Data File required to be submitted pursuant to Rule 405 of Regulation S-T (§232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit such files). ☒ Yes No ☐

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, 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 May 14, 2021: 20,194,869

Actinium Pharmaceuticals, Inc.
FORM 10-Q
For the Three months ended March 31, 2021

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PART I - FINANCIAL INFORMATION

ITEM 1. FINANCIAL STATEMENTS

The accompanying consolidated financial statements have been prepared by the Company and are unaudited. In the opinion of management, all adjustments (which include only normal recurring adjustments) necessary to present fairly the financial position at March 31, 2021 and December 31, 2020, and the results of operations and cash flows for the three months ended March 31, 2021 and 2020, 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, 2020 in the Company's Annual Report on Form 10-K. The results of operations for the three months ended March 31, 2021 are not necessarily indicative of the operating results for the full year.

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

	March 31, 2021 (Unaudited)	December 31, 2020
Assets		
Current Assets:		
Cash and cash equivalents	$ 72,253	$ 63,560
Restricted cash – current	48	48
Prepaid expenses and other current assets	1,446	1,317
Total Current Assets	73,747	64,925
Property and equipment, net of accumulated depreciation of $314 and $291	293	312
Operating leases right-of-use assets	496	579
Finance leases right-of-use assets	119	140
Security deposit	50	50
Restricted cash	392	391
Total Assets	**$ 75,097**	**$ 66,397**
Liabilities and Stockholders' Equity		
Current Liabilities:		
Accounts payable and accrued expenses	$ 3,727	$ 4,340
Operating leases current liability	349	342
Finance leases current liability	88	85
Total Current Liabilities	4,164	4,767
Long-term operating leases obligations	154	245
Long-term finance leases obligations	43	66
Total Liabilities	4,361	5,078
Commitments and contingencies		
Stockholders' Equity:		
Preferred stock, $0.001 par value; 50,000,000 shares authorized, 0 shares issued and outstanding	-	-
Common stock, $0.001 par value; 1,000,000,000 shares authorized; 19,245,638 and 17,532,893 shares issued and outstanding, respectively	19	18
Additional paid-in capital	307,011	292,275
Accumulated deficit	(236,294)	(230,974)
Total Stockholders' Equity	70,736	61,319
Total Liabilities and Stockholders' Equity	**$ 75,097**	**$ 66,397**

See accompanying notes to the consolidated financial statements.

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

	For the Three Months Ended March 31	
	2021	**2020**
Revenue:		
Revenue	$ -	$ -
Other revenue	622	-
Total revenue	622	-
Operating expenses:		
Research and development, net of reimbursements	4,276	4,151
General and administrative	1,718	1,532
Total operating expenses	5,994	5,683
Loss from operations	(5,372)	(5,683)
Other income:		
Interest income - net	52	13
Total other income	52	13
Net loss	**$ (5,320)**	**$ (5,670)**
Net loss per share of common stock – basic and diluted	$ (0.29)	$ (0.98)
Weighted average shares of common stock outstanding – basic and diluted	18,375,442	5,799,040

See accompanying notes to the consolidated financial statements.

Actinium Pharmaceuticals, Inc.
Consolidated Statement of Changes in Stockholders' Equity
For the Period from January 1, 2021 to March 31, 2021
(Unaudited)
(amounts in thousands, except share amounts)

	Common Stock		Additional Paid-In	Accumulated	Stockholders'
	Shares	Amount	Capital	Deficit	Equity
Balance, January 1, 2021	**17,532,893**	**$ 18**	**$ 292,275**	**$ (230,974)**	**$ 61,319**
Stock-based compensation	-	-	376	-	376
Sale of common stock, net of costs	1,712,745	1	14,360	-	14,361
Net loss	-	-	-	(5,320)	(5,320)
Balance, March 31, 2021	**19,245,638**	**$ 19**	**$ 307,011**	**$ (236,294)**	**$ 70,736**

See accompanying notes to the consolidated financial statements.

Actinium Pharmaceuticals, Inc.
Consolidated Statement of Changes in Stockholders' Equity
For the Period from January 1, 2020 to March 31, 2020
(Unaudited)
(amounts in thousands, except share amounts)

	Common Stock		Additional Paid-In	Accumulated	Stockholders'
	Shares	Amount	Capital	Deficit	Equity
Balance, January 1, 2020	**5,490,038**	**$ 5**	**$ 214,397**	**$ (208,758)**	**$ 5,644**
Stock-based compensation	-	-	372	-	372
Sale of common stock, net of costs	337,944	1	2,673	-	2,674
Net loss	-	-	-	(5,670)	(5,670)
Balance, March 31, 2020	**5,827,982**	**$ 6**	**$ 217,442**	**$ (214,428)**	**$ 3,020**

See accompanying notes to the consolidated financial statements.

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

	For the Three Months Ended March 31,	
	2021	**2020**
Cash Flows From Operating Activities:		
Net loss	$ (5,320)	$ (5,670)
Adjustments to reconcile net loss to net cash used in operating activities:		
Stock-based compensation expense	376	372
Depreciation & amortization expenses	125	108
Changes in operating assets and liabilities:		
Prepaid expenses and other current assets	(128)	(30)
Accounts payable and accrued expenses	(612)	(558)
Operating lease liabilities	(83)	(76)
Net Cash Used In Operating Activities	**(5,642)**	**(5,854)**
Cash Flows Used In Investing Activities:		
Purchase of property and equipment	(4)	-
Net Cash Used In Investing Activities	**(4)**	**-**
Cash Flows From Financing Activities:		
Payments on note payable	-	(113)
Payments on finance leases	(21)	(19)
Sales of shares of common stock, net of costs	14,361	2,674
Proceeds from exercise of warrants	-	-
Net Cash Provided By Financing Activities	**14,340**	**2,542**
Net change in cash, cash equivalents, and restricted cash	8,694	(3,312)
Cash, cash equivalents, and restricted cash at beginning of period	63,999	9,693
Cash, cash equivalents, and restricted cash at end of period	**$ 72,693**	**$ 6,381**
Supplemental disclosure of cash flow information:		
Cash paid for interest on note payable	$ -	$ 4
Cash paid for income taxes	$ -	$ -

See accompanying notes to the consolidated financial statements.

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

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

Nature of Business - Actinium Pharmaceuticals, Inc. (the "Company", "Actinium", or "We") is a clinical-stage, biopharmaceutical company applying its proprietary platform technology and deep understanding of radiobiology to the development of novel targeted therapies known as ARCs or Antibody Radiation-Conjugates. Radiation is an effective therapeutic modality that is used in the treatment of over fifty percent of all cancer patients and often combined with chemotherapy and immunotherapy for greater therapeutic effect. ARCs combine the cell-killing ability of a radioisotope payload with a targeting agent, such as a monoclonal antibody, or mAb, to deliver radiation inside the body to specific cells, to potentially generate greater efficacy and less toxicity. ARCs usage is broader than externally delivered radiation as they can be used for both solid tumors and blood cancers. Blood or hematologic cancers are highly sensitive to radiation and our clinical pipeline is focused on ARCs targeting the antigens CD45 and CD33, both of which are expressed in multiple hematologic cancers. The Company's clinical programs are focused on two primary areas: targeted conditioning prior to bone marrow transplant, adoptive cell or gene therapies and therapeutics, in combination with other therapeutic modalities. The Company's product development strategy is actively informed by clinical data with its ARCs in over 500 patients, including the ongoing pivotal Phase 3 SIERRA trial for the Company's lead asset Iomab-B. The clinical pipeline has emanated from its Antibody Warhead Enabling ("AWE") technology platform, which is protected by over 140 issued and pending patents, trade secrets and know-how and is being utilized in a collaborative research partnership with Astellas Pharma, Inc., ("Astellas"). The AWE technology platform is also being used to advance Actinium's research objectives focused on developing next-generation targeted radiotherapies. To accelerate development efforts the Company is undertaking an expansion of its R&D organization and research laboratories to enable it to more effectively leverage its drug development experience to advance candidates to clinical trials.

Basis of Presentation - Unaudited Interim Financial Information - The accompanying unaudited interim 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 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 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, 2020.

Principles of Consolidation - The consolidated financial statements include the Company's accounts and those of the Company's wholly owned subsidiaries.

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

Impact of COVID–19 Pandemic on Financial Statements - In December 2019, a novel strain of COVID-19 was reported in China. Since then, COVID-19 has spread globally. The spread of COVID-19 from China to other countries has resulted in the World Health Organization ("WHO") declaring the outbreak of COVID-19 as a "pandemic," or a worldwide spread of a new disease, on March 11, 2020. Many countries around the world have imposed quarantines and restrictions on travel and mass gatherings to slow the spread of the virus and have closed non-essential businesses, and as of the date of this report, many local jurisdictions continue to have such restrictions in place.

As local jurisdictions continue to put restrictions in place, the Company's ability to continue to operate its business may also be limited. Such events may result in a period of business, supply and drug product manufacturing disruption, and in reduced operations, any of which could materially affect the Company's business, financial condition and results of operations. In response to COVID-19, the Company implemented remote working and thus far, has not experienced a significant disruption or delay in its operations as it relates to the clinical development or drug production of our drug candidates.

The spread of COVID-19, which has caused a broad impact globally, may materially affect the Company economically. While the ultimate economic impact brought by, and the duration of, the COVID-19 pandemic may be difficult to assess or predict, including new information which may emerge concerning the severity of COVID-19 and the actions to contain COVID-19 or treat its impact, among others, the pandemic has resulted in significant disruptions in the general commercial activity and the global economy and caused financial market volatility and uncertainty in significant and unforeseen ways in the recent months. A continuation or worsening of the levels of market disruption and volatility seen in the recent past could have an adverse effect on the Company's ability to access capital, which could in the future negatively affect the Company's liquidity. In addition, a recession or market correction resulting from the spread of COVID-19 could materially affect the Company's business and the value of the Company's common stock.

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

To date, COVID-19 has not had a financial impact on the Company. However, COVID-19 has caused severe disruptions in transportation and limited access to the Company's facility, resulting in limited support from its staff and professional advisors. The Company continues to monitor the impacts of COVID-19 on the global economy and on its business operations. However, at this time, it is difficult to predict how long the potential operational impacts of COVID-19 will last or to what degree further disruption might impact the Company's operations and financial results.

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

The following is a summary of cash, cash equivalents and restricted cash at March 31, 2021 and December 31, 2020:

(in thousands)	**March 31, 2021**	**December 31, 2020**
Cash and cash equivalents	$ 72,253	$ 63,560
Restricted cash – current	48	48
Restricted cash – long-term	392	391
Cash, cash equivalents and restricted cash	$ 72,693	$ 63,999

Current restricted cash relates to credit card accounts, while long-term restricted cash relates to a certificate of deposit held as collateral for a letter of credit issued in connection with the Company's lease for corporate office space.

Leases – The Company has operating and finance leases for corporate office space, office equipment and furniture located at the corporate office space. Leases with an initial term of 12 months or less are not recorded on the balance sheet; lease expense for these leases is recognized on a straight-line basis over the lease term.

Fair Value of Financial Instruments - 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.

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

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

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

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

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 income, and when the effects are not anti-dilutive, diluted earnings per share is computed by dividing net income available to common stockholders by the weighted-average number of shares outstanding plus the impact of all potential dilutive common shares, consisting primarily of common shares underlying common stock options and warrants using the treasury stock method. 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 months ended March 31, 2021 and 2020, the Company's potentially dilutive shares, which include outstanding common stock options 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)	March 31, 2021	March 31, 2020
Options	843	368
Warrants	2,114	2,871
Total	2,957	3,239

Accounting Standards Recently Adopted - In August 2020, FASB issued ASU 2020-06, *Debt—Debt with Conversion and Other Options (Subtopic 470-20) and Derivatives and Hedging—Contracts in Entity's Own Equity (Subtopic 815-40): Accounting for Convertible Instruments and Contracts in an Entity's Own Equity*, which, among other things, provides guidance on how to account for contracts on an entity's own equity. This ASU simplifies the accounting for certain financial instruments with characteristics of liabilities and equity. Specifically, the ASU eliminated the need for the Company to assess whether a contract on the entity's own equity (1) permits settlement in unregistered shares, (2) whether counterparty rights rank higher than shareholder's rights, and (3) whether collateral is required. In addition, the ASU requires incremental disclosure related to contracts on the entity's own equity and clarifies the treatment of certain financial instruments accounted for under this ASU on earnings per share. This ASU may be applied on a full retrospective of modified retrospective basis. This ASU is effective January 1, 2022 and interim periods presented, although early adoption of this ASU was permitted effective January 1, 2021. The Company early adopted this standard effective January 1, 2021 and the standard did not have a significant impact on the Company's financial statements.

Note 2 - Commitments and Contingencies

Agreements

The Company has entered into agreements with third parties for the rights to certain intellectual property, manufacturing and clinical trial services under which the Company may incur obligations to make payments including upfront payments as well as milestone and royalty payments. A notable inclusion in this category is:

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 BC8 (licensed antibody). FHCRC has completed both a Phase 1 and Phase 2 clinical trial with BC8. The Company has been granted exclusive rights to the BC8 antibody and related master cell bank developed by FHCRC. A milestone payment of $1 million will be due to FHCRC upon FDA approval of the first drug utilizing the licensed BC 8 antibody. Upon commercial sale of the drug, royalty payments of 2% of net sales will be due to FHCRC.

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.

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 is not readily determinable in the Company's leases, the incremental borrowing rate is 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 March 31, 2021, the Company has an operating lease for corporate office space and two finance leases for office equipment and furniture located in the corporate office space. In addition, the Company has auxiliary corporate office space that it rents on a month-to-month basis; this rental is accounted for as an operating lease with the same term as the Company's main office in the same building.

The components of lease expense are as follows:

	Three months ended	
(in thousands)	**March 31, 2021**	**March 31, 2020**
Operating lease expense	$ 93	$ 93
Finance lease cost		
Amortization of right-to-use assets	$ 20	$ 20
Interest on lease liabilities	$ 3	$ 4
Total finance lease cost	$ 23	$ 24

Supplemental cash flow information related to leases are as follows:

Cash flow information:	**Three months ended**	
(in thousands)	**March 31, 2021**	**March 31, 2020**
Cash paid for amounts included in the measurement of lease liabilities:		
Operating cash flow use from operating leases	$ 94	$ 94
Operating cash flow use from finance leases	$ 3	$ 4
Financing cash flow use from finance leases	$ 21	$ 19
Non-cash activity:		
Right-of-use assets obtained in exchange for lease obligations:		
Operating leases	$ -	$ 83
Finance Leases	$ -	$ -

Weighted average remaining lease terms are as follows at March 31, 2021:

Weighted average remaining lease term:	
Operating leases	1.4 years
Finance Leases	1.5 years

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

Weighted average discount rates:	
Operating leases	8%
Finance Leases	8%

Maturities of lease liabilities are as follows:

(in thousands)

Year ending December 31,	**Operating Leases**	**Finance Leases**
2021 (excluding three months ended March 31, 2021)	$ 282	$ 71
2022	252	64
2023	-	4
Total lease payments	$ 534	$ 139
Less imputed interest	(30)	(9)
Present value of lease liabilities	$ 504	$ 130

Note 4 – Other revenue

The Company determined that certain collaborations with a third-party are within the scope of ASC 606. The collaboration agreement is made up of multiple modules related to various research activities. While the Company identified a single performance obligation to provide research services within each module for which the Company receives monetary consideration, as the promises included in each module are similar in nature, the third-party can choose to proceed with each module or can terminate the agreement at any time. The consideration is recognized to revenue over each module and revenue recognized during the three months ended March 31, 2021 of $0.6 million was due to the recognition of revenue from nonrefundable payments received from the third-party.

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. Shares of common stock are offered pursuant to the Company's shelf registration statement on Form S-3 filed with the SEC on August 7, 2020. As of December 31, 2020, the Company had sold 2.1 million shares of common stock, resulting in gross proceeds of $22.6 million and net proceeds of $21.7 million. For the three months ended March 31, 2021, the Company sold 1.7 million shares of common stock, resulting in gross proceeds of $14.8 million and net proceeds of $14.4 million.

In December 2018, the Company entered into the Amended and Restated At Market Issuance Sales Agreement with B. Riley FBR, Inc. and JonesTrading, pursuant to which the Company conducted its at-the market program. During the three months ended March 31, 2020, the Company sold 0.3 million shares of common stock through its at-the-market program, resulting in net proceeds of $2.5 million.

In October 2018, the Company and Lincoln Park Capital Fund, LLC ("Lincoln Park") entered into a purchase agreement and a registration rights agreement, pursuant to which the Company has the right to sell to Lincoln Park shares of the Company's common stock having an aggregate value of up to $32.5 million, subject to certain limitations and conditions set forth in the agreement. During the three months ended March 31, 2020, the Company elected to sell to Lincoln Park 27 thousand shares and received $0.2 million.

Stock Options

The following is a summary of stock option activity for the three months ended March 31, 2021:

(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, 2021	815	$ 21.53	8.51	$ 120
Granted	50	9.25		
Cancelled	(22)	11.96		
Outstanding, March 31, 2021	843	21.05	8.21	92
Exercisable, March 31, 2021	293	41.57	6.41	38

The fair values of all options issued and outstanding are being amortized over their respective vesting periods. The unrecognized compensation expense at March 31, 2021 was $3.8 million related to unvested options, which is expected to be expensed over a weighted average of 3.2 years. During the three months ended March 31, 2021 and 2020, the Company recorded compensation expense related to stock options of $0.4 million and $0.4 million, respectively.

Warrants

Following is a summary of warrant activity for the three months ended March 31, 2021:

(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, 2021	2,113	$ 20.55	2.76	$ 362
Granted	1	9.80		
Exercised	-	-		
Cancelled/Expired	-	-		
Outstanding, March 31, 2021	2,114	$ 20.54	2.52	$ 354
Exercisable, March 31, 2021	2,111	$ 20.56	2.51	$ 354

Subsequent Event

Since March 31, 2021, the Company has sold 0.9 million shares of common stock under its Capital on Demand™ Sales Agreement with JonesTrading, resulting in net proceeds of $7.2 million.

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

FORWARD-LOOKING STATEMENT NOTICE

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

Description of Business

Actinium Pharmaceuticals, Inc. is a clinical-stage, biopharmaceutical company applying its proprietary platform technology and deep understanding of radiobiology to the development of novel targeted therapies known as Antibody Radiation-Conjugates ("ARCs"). ARCs combine the cell-killing ability of radiation via a radioisotope payload with a targeting agent, such as a monoclonal antibody, to deliver radiation in a precise manner inside the body to specific, targeted cells, to potentially achieve greater efficacy with lower toxicity than with external beam radiation. ARCs enable a broader usage of radiation than external beam radiation as they can be used in the treatment of both solid tumors and blood cancers. Blood or hematologic cancers are known to be highly sensitive to radiation. Our clinical pipeline is focused on ARCs targeting the antigens CD45 and CD33, both of which are expressed in multiple hematologic cancers. Our clinical programs are focused on two primary areas: (1) targeted conditioning prior to a bone marrow transplant ("BMT"), adoptive cell therapy ("ACT") such as CAR-T or gene therapy and (2) ARC therapeutic combinations with other agents. Our product development strategy is actively informed by clinical data with our ARCs in over 500 patients, including our ongoing Pivotal Phase 3 SIERRA trial. Our clinical pipeline has emanated from our Antibody Warhead Enabling ("AWE") technology platform, which is protected by over 140 issued and pending patents, trade secrets and know-how and is being utilized in a collaborative research partnership with Astellas Pharma, Inc. ("Astellas"). We are also utilizing our AWE technology platform to advance our research objectives focused on developing next-generation targeted radiotherapies. To accelerate development efforts we are undertaking an expansion of our R&D organization and research laboratories to enable us to more effectively leverage our drug development experience to advance candidates to clinical trials.

Targeted Conditioning

To the best of our knowledge, we are advancing the only multi-target, multi-indication, clinical-stage pipeline for targeted conditioning and the only ARC-based targeted conditioning regimens in development. Our ARCs for targeted conditioning are intended to potentially enable improved access and outcomes to cell-based therapies with curative potential, including BMT, ACT, and Gene Therapy. Conditioning in the context of BMT, ACT or Gene Therapy is the act of depleting certain blood and immune-forming cells, including bone marrow stem cells and, in some cases, cancer cells prior to transplanting new cells into a patient. Currently, conditioning is accomplished using a combination of cytotoxic chemotherapeutic agents and external radiation. These non-targeted conditioning regimens are highly toxic and may prevent a patient from receiving a potentially curative therapy and hinder outcomes. ARCs have the potential to increase patient access and outcomes by way of their ability to selectively deplete targeted cells while sparing normal healthy cells, resulting in potentially lower systemic and off-target toxicities. We use our ARCs both at high isotope dose levels to achieve myeloablation, which fully depletes bone marrow stem cells and at lower isotope dose levels to achieve lymphodepletion, which spares bone marrow stem cells from depletion. In addition, dosing may be titrated downward from myeloablative doses to achieve partial myeloablation, which may be appropriate for certain gene therapy programs.

CD45 Targeted Conditioning Program

Our CD45 ARC is comprised of the anti-CD45 monoclonal antibody known as apamistamab (formerly BC8) and the radioisotope Iodine-131 ("I-131"). CD45 is an antigen expressed on leukemia, lymphoma and myeloma cancer cells, as well as nucleated immune cells including bone marrow stem cells, but is not expressed outside of the hematopoietic, or blood forming, system. This unique expression on blood cancer and immune cells enables simultaneous depletion of both cell types, making CD45 an optimal antigen for targeted conditioning applications. CD45 is a cell surface antigen with an average expression of 200,000 copies per cell, however, it only internalizes at a rate of 10-15%. We believe our ARC approach is the most effective method to target CD45 positive cells, as the radioisotope payload linear energy transfer can readily ablate a targeted cell without requiring payload internalization like an antibody drug conjugate or without relying on biological effector function processes like a naked antibody. Furthermore, since CD45 expression level varies from low to high antigen density as the immune cells become more terminally differentiated, we can selectively condition depending on the therapeutic application, from full myeloablation to transient lymphodepletion, by adjusting the dose or intensity of the I-131 isotope payload. Full myeloablation can be achieved with high doses of I-131, as its energy pathlength and crossfire effect can penetrate into bone marrow niches to target and deplete blood and immune system forming bone marrow stem cells. Myeloablation is applicable to autologous or allogeneic BMT and to autologous gene-edited or modified therapies that can reconstitute a patient's blood and immune systems. Alternatively, low doses of I-131 can be transiently lymphodepleting and spare a patient's bone marrow stem cells, which we believe is ideal for ACT applications such as CAR-T. We intend to develop our CD45 targeted conditioning program for BMT, ACT and Gene Therapy applications for malignant and non-malignant diseases and believe that multiple radioisotopes beyond I-131 may be utilized including alpha and beta emitters.

Our lead CD45 targeted conditioning product candidate is Iomab-B, which uses high doses of I-131 to achieve myeloablative conditioning prior to a BMT. Iomab-B is currently being studied in the pivotal Phase 3 Study of Iomab-B in Elderly Relapsed or Refractory AML ("SIERRA"), clinical trial for targeted conditioning prior to an allogeneic BMT for patients with active, relapsed or refractory ("r/r") Acute Myeloid Leukemia, ("AML"), who are age 55 or older. Patients with active, r/r AML are not normally considered eligible for BMT and the SIERRA trial is the only randomized Phase 3 trial to offer BMT as a treatment option for this patient population. The SIERRA trial compares outcomes of patients randomized to receive Iomab-B and a BMT (the "study arm") to those patients randomized to receive physician's choice of salvage therapy (the "control arm"). The control arm is also defined as conventional care, as no standard of care exists for this patient population and includes over 20 agents that may be used as single agents or in combination including venetoclax, a targeted Bcl-2 inhibitor, Midostaurin and Sorafenib, targeted FLT3 inhibitors, hypomethylating agents and cytotoxic chemotherapies. Patients who fail to achieve a Complete Remission ("CR") on the control arm are ineligible to proceed to a BMT, but the trial design permits these patients to "cross over" to receive the study arm treatment if they meet the eligibility criteria. The primary endpoint of the SIERRA trial is durable Complete Remission ("dCR") of 180 days and the secondary endpoint is Overall Survival ("OS"). When the crossover patients receive Iomab-B and BMT, they have not achieved remission with their salvage therapy and are considered to be failures for the primary endpoint of the study. The SIERRA trial is currently active at 24 sites in the United States and Canada, which includes many of the leading BMT sites based on volume. We expect to complete enrollment of the SIERRA trial and have topline data that we believe will support the submission of a Biologics License Application ("BLA") with the U.S. Food and Drug Administration ("FDA"). If approved, we expect our initial commercial launch would target the leading 50-100 BMT and medical centers that perform the vast majority of BMT's in the United States. In the European Union ("EU"), we received favorable feedback from the European Medicines Agency ("EMA") via their scientific advice program that the trial design, primary endpoint and planned statistical analysis from the SIERRA trial are acceptable as the basis for a Marketing Authorization Application, or MAA. Additionally, the EMA commented that it does not anticipate the need for further standalone preclinical toxicology or safety studies. Overall, transplant procedures in the EU are approximately fifty percent higher than in the United States with a similar market dynamic, with a majority of BMT volume being conducted in a concentrated number of leading medical centers. Currently we intend to secure a partner for Iomab-B in the EU.

The SIERRA trial is powered to show a two-times difference in the primary endpoint of dCR of at least 180 days at complete enrollment of the planned 150 patients. The SIERRA trial design allowed for up to two interim analyses of the primary endpoint, exercisable at our discretion and triggered by an enrollment range of 70 to 110 patients. In April 2020, we exercised a single ad hoc analysis on a number of patients representing less than two thirds of full trial enrollment of 150 patients, which required a higher success threshold compared to the two-time difference in dCR rate at full trial enrollment. In December 2020, we announced that the independent Data Monitoring Committee ("DMC") completed the single ad hoc interim analysis. Based on the DMC's review of unblinded data, including the study's primary endpoint of dCR of at least 180 days, it was recommended that the study continue as planned to full enrollment of 150 patients. We did not receive the unblinded primary and secondary endpoint efficacy data from SIERRA. By exercising only a single interim analysis, there was a minimal alpha spend resulting in a p-value threshold of 0.046 for the primary endpoint evaluation at full enrollment of 150 patients. The SIERRA trial reached 75% enrollment, representing 113 patients, in the third quarter of 2020.

Data from the first 113 patients enrolled in the SIERRA trial, which represents 75% of the total of 150 patients to be enrolled in the trial, was presented in oral presentations at the American Society of Hematology ("ASH") Annual Meeting in December 2020 and at the Transplantation & Cellular Therapy ("TCT") Meetings of the American Society for Transplantation and Cellular Therapy ("ASTCT") and Center for International Bone & Marrow Transplant Research ("CIBMTR") in February 2021. It was reported that 100% of patients (49/49) on the study arm that received a therapeutic dose of Iomab-B received a BMT, with a median time to BMT of 30 days, and all patients achieved neutrophil and platelet engraftment in a median time of 18 days despite a high median blast count of 29%. On the control arm, only 18% of patients (10/57) achieved remission after salvage therapy, and then received a BMT with a median time to BMT of 67 days and median blast count of 20%. Of the 82% of patients failing to achieve a CR with conventional care (47/57), 30 patients were eligible to cross over to receive Iomab-B followed by transplant. These patients are considered as having failed the primary endpoint of the study. All crossover patients who received the therapeutic dose of Iomab-B (30/30) received a BMT, with a median time to BMT of 24 days and they achieved engraftment in a median time of 19 days despite high median blast count of 22% at time of crossover. It was also reported that 100-day non-relapse transplant-related mortality (100-day TRM) of the study or Iomab-B arm was only 4% (2/45) of patients that received a BMT compared to 20% of patients (2/10) who received a BMT after salvage therapy on the control arm. The universal engraftment rate and low 100-day TRM rate of the Iomab-B arm resulted in 43 patients potentially evaluable for the primary endpoint compared to 8 patients in the control arm, a greater than five times difference.

Our Iomab-ACT program is intended for targeted conditioning prior to ACT or Gene Therapy and uses the same I-131-apamistamab ARC construct as Iomab-B at varying doses. At lower doses of one-eighth to one-sixth of the myeloablative dose, it is applicable for lymphodepletion prior to CAR-T or certain Gene Therapy applications where stem cell myeloablation is not necessary. At higher doses it is applicable for Gene Therapy applications where stem cell myeloablation is necessary.

We believe our Iomab-ACT program is highly differentiated when compared to Fludarabine and Cyclophosphamide ("Flu/Cy") or other chemotherapy-based regimens that are used as the standard of practice today for lymphodepletion prior to CAR-T. CD45 is an antigen expressed on certain immune cell types that are relevant to the mechanism of CAR-T therapies including lymphocytes, regulatory T-cells and macrophages that have been associated with clinical responses that may limit the safety, efficacy and durability of response of these CAR-T therapies including cytokine release syndrome ("CRS") and neurotoxicity. Some of these limitations may be attributable to the chemotherapy-based conditioning agents that are being used prior to CAR-T therapies. Preclinical data supporting the rational for our Iomab-ACT program was presented at multiple medical conferences in 2019. Unlike chemotherapy, Iomab-ACT is targeted in nature and, due to this CD45-directed targeting, we expect we can improve CAR-T cell expansion, potentially resulting in responses that are more durable, but also resulting in reduced CAR-T related toxicities. Importantly, we expect the Iomab-ACT program construct to enable lymphodepletion through a single-dose, outpatient administration versus Flu/Cy or other chemotherapy-based lymphodepletion regimens that can require multiple infusion cycles over several days. Because of this potentially superior profile, the Iomab-ACT construct could result in improved access to CAR-T therapy and better outcomes.

In October 2020, we announced a clinical collaboration with Memorial Sloan Kettering Cancer Center ("MSKCC") to use our Iomab-ACT for targeted conditioning prior to administration of MSKCC's 19-28z CD19 targeting CAR-T in patients with relapsed or refractory B-cell acute lymphoblastic leukemia ("ALL") or diffuse large B-cell lymphoma ("DLBCL"). We received grant funding from the National Institute of Health ("NIH") to fund this trial with MSKCC being a co-recipient on this grant. This is a first of its kind study to use an ARC-based conditioning regimen with CAR-T therapy. MSKCC received clearance from the FDA to initiate this trial and patient enrollment in this study has commenced. The hypothesized rationale for this study is that Iomab-ACT will exert an anti-tumor effect on the chemotherapy-refractory B-ALL cells that are sensitive to radiation resulting in reduced disease burden and simultaneously deplete CD45 expressing immune cells implicated in CAR-T related toxicities, resulting in an optimal homeostatic environment for the CAR-T cells. Results with MSKCC's 19-28z CD-19 CAR-T in 53 patients with r/r B-ALL published in the New England Journal of Medicine reported complete remissions in 83% (44/53) of patients, which compares favorably to standard chemotherapy regimens that have complete remission rates of 18% - 45% in this patient population. Median event-free survival (EFS) was 6.1 months and median overall survival (OS) was 12.9 months at a median follow up period of 29 months (range 1 – 65 months). There was a 26% (14/53) rate of Grade 3 or greater CRS and a 42% rate of Grade 3 or 4 neurotoxicity reported. The study will evaluate the feasibility of using an ARC-based conditioning regimen with CAR-T therapy and will evaluate safety measures including incidence of CRS and neurotoxicity and efficacy measures including responses and survival outcomes. In March 2021, we announced that patient enrollment was initiated, and the first patient was administered Iomab-ACT followed by their 19-28z CAR-T therapy. We expect proof of concept data from this study in the second half of 2021.

In addition, we are working in collaboration with University of California Davis to utilize Iomab-ACT conditioning in an ongoing Phase 1/2 trial with a novel anti-HIV autologous stem cell gene therapy for patients with HIV-related lymphoma. We believe this would be the first Gene Therapy trial to use an ARC-based conditioning regimen. I-131-Apamistamab has clinical proof of concept as a targeted conditioning regimen for patients with high-risk, relapsed or refractory lymphoma prior to an autologous stem cell transplant from a previous study, where a favorable safety profile with no dose-limiting toxicities and minimal non-hematologic toxicities were observed and promising efficacy with median overall survival not reached (range: 29 months to not reached) and 31% of patients in prolonged remission at a median of 36 months follow up (range: 25 – 41 months). In this study, Iomab-ACT is intended to replace the chemotherapy-based condition regimen known as BEAM (BCNU/carmustine, etoposide, cytarabine, and melphalan) to simultaneously kill the patient's lymphoma cells and deplete the patient's stem cells to make room for the transplant. Upon engraftment, the transplanted gene-modified autologous stem cells containing three anti-HIV genes are intended to equip the patient with a new immune system that is resistant to the HIV virus. We continue to identify additional gene therapies for which Iomab-ACT can be used for targeted conditioning with the goal of collaborating with multiple academic or industry developers to establish Iomab-ACT as a non-chemotherapy universal targeted conditioning solution.

In March 2021, we announced an Ac-225-based CD45 ARC, a next-generation targeted conditioning agent. Dosimetry results with this Ac-225-based alpha emitting ARC showed selective accumulation in immune cell target organs such as bone marrow, spleen, and liver with the potential for lower exposure to non-target tissues from longer path length beta emitter radioisotopes like Iodine-131 and Lutetium-177. Preclinical data demonstrated that conditioning with this Ac-225-based CD45-targeting agent result in depletion of peripheral immune cells and hematopoietic progenitor cells, thereby enabling engraftment of donor cells. A dose dependent response was observed with low doses depleting white blood cells without affecting hematopoietic progenitor cells, representing a lymphodepletive dose that is relevant for adoptive cell therapies such as CAR-T, while higher doses eliminated peripheral immune cells and hematopoietic progenitor cells, which is applicable to ex vivo gene therapies and BMT.

CD33 Program: Targeted Conditioning, Combinations and Therapeutics

Our CD33 program is evaluating the clinical utility of Actimab-A, an ARC comprised of the anti-CD33 mAb lintuzumab linked to the potent alpha-emitting radioisotope Actinium-225 ("Ac-225"). CD33 is expressed in the majority of patients with AML and myelodysplastic syndrome ("MDS") as well as approximately one-third of patients with multiple myeloma. Ac-225 emits four alpha particles and can kill a cell with one alpha-particle hit, making it one of the most powerful cell-killing agents with no know resistance mechanism to the double strand DNA breaks it can cause. We source Ac-225 from the Department of Energy's Oak Ridge National Laboratory through an annual supply agreement, which we expect to renew annually.

Our CD33 development program is driven by data obtained from nearly one hundred fifty treated patients, including results from a Phase 1/2 trial that was conducted in 58 patients with newly diagnosed AML, which was completed in 2018. This clinical data, as well as our experience with Iomab-B, is shaping a two-pronged approach with our CD33 program, where at high doses we are exploring its use for targeted conditioning and at low doses we are exploring its use for therapeutic combinations with other treatment modalities.

We believe that radiation via an ARC can be synergistic when used in combination with chemotherapy, targeted agents and immunotherapy based on mechanistic rationales supported by our own clinical data, preclinical research and scientific and clinical evidence in the literature. We have prioritized our efforts and resources in favor of combination trials for our CD33 program development strategy rather than single agent trials at this time. Our CD33 ARC development program encompasses the following ongoing trials:

Combination Trials:

- Phase 1 investigator initiated Actimab-A + CLAG-M combination trial with the salvage chemotherapy regimen CLAG-M (cladribine, cytarabine, filgrastim and mitoxantrone) for fit patients age 18 and above with relapsed or refractory AML at the Medical College of Wisconsin ("MCW"). The combination of Actimab-A + CLAG-M is supported by mechanistic rationale for combining inhibitors of DNA replication and/or repair processes such as mitoxantrone, a topoisomerase-II inhibitor, and radiation, as imparted by tumor-targeting of Ac-225 with Actimab-A. In September 2020, we completed the third and planned final dose cohort of 0.75 µCi/kg of Actimab-A. At the 2020 American Society of Hematology Annual Meeting, it was reported that 100% of patients (3/3) receiving 0.75 µCi/kg of Actimab-A, and CLAG-M achieved a complete remission, which is nearly 85% greater than the 55% remission rate observed in a study of CLAG-M alone conducted at MCW in the same r/r AML patient population. Complete Remission or Complete Remission with Incomplete blood count recovery ("CRi") were observed in all dose cohorts (0.25, 0.50 and 0.75 µCi/kg) with 67% of patients (10/15) achieving CR or CRi. The 0.25 and 0.50 µCi/kg doses of Actimab-A have been shown to be subtherapeutic as a single agent. Of the 10 patients achieving CR or Cri, 70% achieved negative minimal residual disease ("MRD) status with no detectable disease via flow cytometry, indicating that these are deep remissions. No dose-limiting toxicities ("DLTs") were reported in the third dose cohort of 0.75 µCi/kg and therefore maximum tolerable dose (MTD) was not reached. As a result, MCW amended the study protocol to allow for continued dose escalation and the trial is now enrolling patients at a dose of 1.0 µCi/kg. Upon completion of this Phase 1 trial, we will work to develop a regulatory and development pathway that can potentially support a registration for the Actimab-A + CLAG-M combination. In addition, the Actimab-A + CLAG-M combination study has provided proof of principle that the addition of subtherapeutic doses of Actimab-A to other AML therapies can lead to well-tolerated regimens with improved responses.

- Phase 1/2 Actimab-A + Ven combination trial with the BCL-2 inhibitor Venetoclax ("ven") for fit and unfit patients age 18 and above with relapsed or refractory AML. This multi-center trial is being led by UCLA Medical Center. This combination is supported by mechanistic evidence in preclinical studies using ven-resistant AML tumor cell lines. In these models, we have demonstrated that Actimab-A can deplete Mcl-1 and Bcl-XL, two proteins implicated in mediating resistance to venetoclax, in addition to causing potentially lethal double-stranded DNA breaks in these CD33 expressing cells. Furthermore, in vivo studies in animal models of ven-resistant AML demonstrated robust tumor regression and improved survival in cohorts receiving the Actimab-A ven combination compared to ven alone. The rationale for this clinical study is that the addition of Actimab-A will; 1) have a direct anti-tumor effect via double-stranded DNA breaks and 2) deplete Mcl-1 and BCL-XL making the AML cells more susceptible to ven. At the 2020 ASH annual meeting, data from the first dose cohort of 0.50 µCi/kg Actimab-A in combination with ven were presented. There was a 67% overall response rate (2/3 patients), including one CR and one partial response ("PR") with blast count reduction of 50%. All 3 patients were poor risk with adverse cytogenetics and each patient had an additional high-risk marker (FLT3-ITD+, antecedent JAK2+ myelofibrosis, or TP53 mutation). The patient achieving a CR was in second relapse and a TP53 mutation as well as multiple other high-risk markers. The trial is now active and recruiting at 4 trial sites in dose escalation cohorts. We expect to have Phase 1 safety and preliminary proof of concept clinical data from this combination study in 2021.

In addition to these active trials, we are working to identify additional modalities and agents that can be the basis for Actimab-A therapeutic combinations.

Antibody Warhead Enabling Technology Platform

Our proprietary AWE technology platform is supported by intellectual property, know-how and trade secrets that cover the generation, development, methods of use and manufacture of ARCs and certain of their components. Our AWE technology patent portfolio includes 34 patent families comprised of over 140 issued and pending patent applications, of which 9 are issued and 29 are pending in the United States, and 104 are issued or pending internationally. The effective life of the patents in our portfolio range from expirations between 2021 and 2040. Our technology enables the direct labeling, or conjugation and labeling, of a biomolecular targeting agent to a radionuclide warhead and its development and use as a therapeutic regimen for the treatment of diseases such as cancer. Our AWE intellectual property covers various methods of use for ARCs in multiple diseases, including indication, dose and scheduling, radionuclide warhead, and therapeutic combinations. We have particular expertise in the area of ARCs utilizing the alpha emitting isotope Ac-225 including clinical experience in treating approximately 150 patients with our alpha-emitter ARCs, “gold standard” linker technology and 5 issued patents in the United States and 49 patents internationally related to the manufacturing or Ac-225 in a cyclotron, which we believe has the potential to produce higher quantities of Ac-225 then currently utilized methods.

We have enhanced our research and development capabilities around AWE by securing and staffing research facilities. Our research laboratories are focused on applying our AWE technology platform to the development of radiation conjugates and to execute on research collaborations. Our R&D efforts employ a multidisciplinary approach leveraging our team’s knowledge and experience in cancer cell biology, radiochemistry, radiation sciences, immunology and oncology drug development. We intend to focus on generating ARCs using our existing intellectual property, evaluating assets for in-licensing to complement our existing clinical pipeline and securing collaborations and partnerships with biopharmaceutical companies. By adding research and development capabilities to our clinical development and clinical supply chain capabilities, we seek to enable the rapid translation of radiotherapies. We have formed a wholly owned research subsidiary for the purposes of advancing certain of our R&D objectives.

In January 2021, we announced a collaborative research agreement with Astellas and began work on this project that will utilize our AWE technology platform with select targeting agents owned by Astellas in the development of theranostics for solid tumor indications, which combine the ability of radioisotopes to be used for both diagnostic and therapeutic purposes.

Recent Developments

Impact of COVID–19 Pandemic

In December 2019, a novel strain of COVID-19 was reported in China. Since then, COVID-19 has spread globally. The spread of COVID-19 from China to other countries has resulted in the World Health Organization (WHO) declaring the outbreak of COVID-19 as a "pandemic," or a worldwide spread of a new disease, on March 11, 2020. Many countries around the world have imposed quarantines and restrictions on travel and mass gatherings to slow the spread of the virus and have closed non-essential businesses, and as of the date of this report, many local jurisdictions continue to have such restrictions in place.

As many local jurisdictions continue to have such restrictions in place, our ability to continue to operate our business may also be limited. Such events may result in a period of business, supply and drug product manufacturing disruption, and in reduced operations, any of which could materially affect our business, financial condition and results of operations. In response to COVID-19, we implemented remote working and thus far have not experienced a significant disruption or delay in our operations as it relates to the clinical development of our drug candidates. Such government-imposed precautionary measures may have been relaxed in certain countries or states, but there is no assurance that more strict measures will be put in place again due to a resurgence in COVID-19 cases, including those involving new variants of the coronavirus, which may be more contagious and deadly than prior strains. Therefore, the COVID-19 pandemic may continue to affect our operation, may further divert the attention and efforts of the medical community to coping with COVID-19 and disrupt the marketplace in which we operate and may have a material adverse effect on our operations.

The spread of COVID-19, which has caused a broad impact globally, may materially affect us economically. While the ultimate economic impact brought by, and the duration of, the COVID-19 pandemic may be difficult to assess or predict, including new information which may emerge concerning the severity of COVID-19 and the actions to contain COVID-19 or treat its impact, among others, the pandemic has resulted in significant disruptions in the general commercial activity and the global economy and caused financial market volatility and uncertainty in significant and unforeseen ways in the recent months. A continuation or worsening of the levels of market disruption and volatility seen in the recent past could have an adverse effect on our ability to access capital, which could in the future negatively affect our liquidity. In addition, a recession or market correction resulting from the spread of COVID-19 could materially affect our business and the value of our common stock.

Currently, the Phase 3 SIERRA trial for our lead program, Iomab-B, remains active at a majority of our clinical trial sites, with investigators providing feedback that recruitment and enrollment will remain active because of the acute nature of the disease, the high unmet needs of patients with relapsed or refractory AML, the potentially curative nature of BMT and the differentiated profile of Iomab-B. Certain sites that had not been actively enrolling due to COVID-19 at the initial outbreak of the pandemic resumed recruitment and enrollment in mid-2020, and we currently do not have any sites that are not recruiting and enrolling patients due to COVID-19. We also believe our earlier stage CD33 clinical trials will continue to recruit and enroll patients given the acute nature of relapsed or refractory AML. The continuation of the pandemic could adversely affect our planned clinical trial operations, including our ability to conduct the trials on the expected timelines and recruit and retain patients and principal investigators and site staff who, as healthcare providers, may have heightened exposure to COVID-19 if their geography is impacted by the pandemic. Further, the continuation and/or resurgence of the COVID-19 pandemic could result in delays in our clinical trials due to prioritization of hospital resources toward the pandemic, restrictions in travel, potential unwillingness of patients to enroll in trials at this time, or the inability of patients to comply with clinical trial protocols if quarantines or travel restrictions impede patient movement or interrupt healthcare services. In addition, we rely on independent clinical investigators, contract research organizations and other third-party service providers to assist us in managing, monitoring and otherwise carrying out our preclinical studies and clinical trials, and the pandemic may affect their ability to devote sufficient time and resources to our programs or to travel to sites to perform work for us.

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

To date, COVID-19 has not had a financial impact on our company. However, COVID-19 has caused severe disruptions in transportation and limited access to our facility, resulting in limited support from our staff and professional advisors.

We continue to monitor the impacts of COVID-19 on the global economy and on our business operations. Although we expect that vaccinations for COVID-19 will continue to improve conditions, the ultimate impact from COVID-19 on our business operations and financial results during 2021 will depend on, among other things, the ultimate severity and scope of the pandemic, the pace at which governmental and private travel restrictions and public concerns about public gatherings will ease, the rate at which historically large increases in unemployment rates will decrease, if at all, and whether, and the speed with which the economy recovers. We are not able to fully quantify the impact that these factors will have on our financial results during 2021 and beyond, but developments related to COVID-19 may materially affect us in 2021.

Results of Operations – Three Months Ended March 31, 2021 Compared to Three Months Ended March 31, 2020

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

	For the Three Months Ended March 31,	
(in thousands)	**2021**	**2020**
Revenue:		
Revenue	$ -	$ -
Other revenue	622	-
Total revenue	622	-
Operating expenses:		
Research and development, net of reimbursements	4,276	4,151
General and administrative	1,718	1,532
Total operating expenses	5,994	5,683
Other income:		
Interest income – net	52	13
Total other income	52	13
Net loss	$ (5,320)	$ (5,670)

Revenue

We recorded no commercial revenue for the three months ended March 31, 2021 and March 31, 2020.

Other revenue

We determined that certain collaborations with a third-party are within the scope of ASC 606. The collaboration agreement is made up of multiple modules related to various research activities. While we identified a single performance obligation to provide research services within each module for which we receive monetary consideration, as the promises included in each module are similar in nature, the third-party can choose to proceed with each module or can terminate the agreement at any time. The consideration is recognized to revenue over each module and revenue recognized during the three months ended March 31, 2021 of $0.6 million was due to the recognition of revenue from nonrefundable payments received from the third-party.

Research and development expense

Research and development expenses increased $0.1 million to $4.3 million for the three months ended March 31, 2021 compared to $4.2 million for the three months ended March 31, 2020. The increase was primarily due to higher compensation expense resulting from the hiring of additional employees, mostly offset by lower expenses on our CD45 program.

General and administrative expense

General and administrative expenses of $1.7 million for the three months ended March 31, 2021 increased $0.2 million compared to $1.5 million for the three months ended March 31, 2020, primarily attributable to higher professional fees.

Other income

Other income is comprised of net interest income in both reporting periods. The amount for the three months ended March 31, 2021 of $52 thousand increased from $13 thousand for the three months ended March 31, 2020, as a higher average balance of cash and cash equivalents offset a lower average interest rate.

Net loss

Net loss of $5.3 million for the three months ended March 31, 2021 decreased by $0.4 million from $5.7 million for the three months ended March 31, 2020 primarily due to revenue recognized during this period, partially offset by higher research and development expenses and higher general and administrative expenses.

Liquidity and Capital Resources

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

(in thousands)	For the Three Months Ended March 31, 2021	2020
Cash used in operating activities	$ (5,642)	$ (5,854)
Cash used in investing activities	(4)	-
Cash provided by financing activities	14,340	2,542
Net change in cash, cash equivalents and restricted cash	$ 8,694	$ (3,312)

Net cash used in operating activities for the three months ended March 31, 2021 of $5.6 million decreased by $0.3 million from $5.9 million in the prior-year period, primarily due to the earned revenue.

Net cash provided by financing activities for the three months ended March 31, 2021 was $14.3 million, primarily from the sale of shares of our common stock. During the three months ended March 31, 2020, net cash provided by financing activities was $2.5 million, including $2.7 million from the sale of shares of our 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 may sell, from time to time, through or to JonesTrading, up to an aggregate of $200 million of our common stock. Shares of common stock are offered pursuant to our shelf registration statement on Form S-3 filed with the SEC on August 7, 2020. As of December 31, 2020, we had sold 2.1 million shares of common stock, resulting in gross proceeds of $22.6 million and net proceeds of $21.7 million. For the three months ended March 31, 2021, we sold 1.7 million shares of common stock, resulting in gross proceeds of $14.8 million and net proceeds of $14.4 million.

Off-Balance Sheet Arrangements

We do not have any off-balance sheet arrangements that have, or are reasonably likely to have a current or future effect on our financial condition, changes in financial condition, revenue or expenses, results of operations, liquidity, capital expenditures or capital resources that is material to investors.

Critical Accounting Policies and Use of Estimates

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

Our significant accounting policies are described in detail in the notes to our consolidated financial statements appearing in our Annual Report filed on Form 10-K for the year ended December 31, 2020.

Fair Value of Financial Instruments

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

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

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

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

Collaborative Arrangements

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

Research and Development Costs

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

Share-Based Payments

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

Accounting Standards Recently Adopted

In August 2020, FASB issued ASU 2020-06, *Debt—Debt with Conversion and Other Options (Subtopic 470-20) and Derivatives and Hedging—Contracts in Entity's Own Equity (Subtopic 815-40): Accounting for Convertible Instruments and Contracts in an Entity's Own Equity*, which, among other things, provides guidance on how to account for contracts on an entity's own equity. This ASU simplifies the accounting for certain financial instruments with characteristics of liabilities and equity. Specifically, the ASU eliminated the need for us to assess whether a contract on our own equity (1) permits settlement in unregistered shares, (2) whether counterparty rights rank higher than shareholder's rights, and (3) whether collateral is required. In addition, the ASU requires incremental disclosure related to contracts on our own equity and clarifies the treatment of certain financial instruments accounted for under this ASU on earnings per share. This ASU may be applied on a full retrospective of modified retrospective basis. This ASU is effective January 1, 2022 and interim periods presented, although early adoption of this ASU was permitted effective January 1, 2021. We early adopted this standard effective January 1, 2021 and the standard did not have a significant impact on our financial statements.

Subsequent Event

Since March 31, 2021, we have sold 0.9 million shares of common stock under our Capital on Demand™ Sales Agreement with JonesTrading, resulting in net proceeds of $7.2 million.

ITEM 3. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK.

We are not currently exposed to significant market risk related to changes in interest rates. As of March 31, 2021, our cash equivalents consisted primarily of short-term money market funds. Our primary exposure to market risk is interest rate sensitivity, which is affected by changes in the general level of U.S. interest rates. Due to the short-term nature of the cash equivalents in our portfolio and the low risk profile of our cash equivalents, an immediate 10% change in interest rates would not have a material effect on the fair market value of our financial position or results of operations.

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

Inflation generally affects us by increasing our cost of labor and clinical trial costs. We do not believe that inflation had a material effect on our business, financial condition or results of operations during the three months ended March 31, 2021 and 2020.

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 March 31, 2021, 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 March 31, 2021, our disclosure controls and procedures were effective to provide reasonable assurance that the information we are required to disclose in our filings with the Securities and Exchange Commission, or SEC, under the Exchange Act (i) is recorded, processed, summarized and reported within the time periods specified in the SEC's rules and forms and (ii) accumulated and communicated to our management, including our principal executive officer and principal financial and accounting officer, as appropriate to allow timely decisions regarding required disclosure.

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

PART II – OTHER INFORMATION

ITEM 1. LEGAL PROCEEDINGS

None.

ITEM 1A. RISK FACTORS

In analyzing our company, you should consider carefully the following risk factors, together with all of the other information included in this Quarterly Report on Form 10-Q. Factors that could cause or contribute to differences in our actual results include those discussed in the following subsection, as well as those discussed above in "Management's Discussion and Analysis of Financial Condition and Results of Operations" and in our Annual Report filed on Form 10-K for the year ended December 31, 2020. 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 our Annual Report on Form 10-K for the year ended December 31, 2020 in their entirety for additional information regarding the material factors that make an investment in our securities speculative or risky. These risks and uncertainties include, but are not limited to, the following:

- We are a clinical-stage company and have generated no revenue from commercial sales to date;
- We have incurred net losses in every year since our inception and anticipate that we will continue to incur net losses in the future;
- If we fail to obtain additional financing, we will be unable to continue or complete our product development and you will likely lose your entire investment;
- We are highly dependent on the success of Iomab-B and the SIERRA trial and we many not able to complete the necessary clinical development or our development efforts may not result in the data necessary to receive regulatory approval;
- Our business could be adversely affected by the effects of health epidemics, including the global COVID-19 pandemic;
- We have not demonstrated that any of our products are safe and effective for any indication and will continue to expend substantial time and resources on clinical development before any of our current or future product candidates will be eligible for FDA approval, if ever;
- Our clinical trials may fail to demonstrate adequately the efficacy and safety of our product candidates, which would prevent or delay regulatory approval and commercialization;
- Healthcare legislative reform measures intended to increase pressure to reduce prices of pharmaceutical products paid for by Medicare or, otherwise, affect the federal regulation of the U.S. healthcare system could have a material adverse effect our business, future revenue, if any, and results of operations;
- We rely on third parties to conduct our clinical trials. If these third parties do not successfully carry out their contractual duties or meet expected deadlines or comply with regulatory requirements, we may not be able to obtain regulatory approval for or commercialize our product candidates;

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

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

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

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

- We are highly dependent on our key personnel, and if we are not successful in attracting and retaining highly qualified personnel, we may not be able to successfully implement 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 March 31, 2021 and December 31, 2020, we had an accumulated deficit of $236.3 million and $231.0 million, respectively. We reported a net loss of $5.3 million and $5.7 million for the three months ended March 31, 2021 and March 31, 2020, 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.

In August 2020, we entered into the Capital on Demand™ Sales Agreement with JonesTrading, pursuant to which we may sell, from time to time, through or to JonesTrading, up to an aggregate of $200 million of our common stock. Shares of common stock are offered pursuant to our shelf registration statement filed with the United States Securities and Exchange Commission ("SEC") on August 7, 2020. For the three months ended March 31, 2021, we sold 1.7 million shares of common stock, resulting in net proceeds of $14.4 million. As of the date of filing this report, we expect that our existing resources will be more than sufficient to fund our planned operations for more than 12 months following the date of this report.

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

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

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

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

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

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

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

Iomab-B, which we licensed from the Fred Hutchinson Cancer Research Center ("FHCRC") in June 2012 is our lead program to which we allocate a significant portion of our resources. We are currently enrolling patients in the pivotal Phase 3 SIERRA trial (Study of Iomab-B in Elderly Relapsed or Refractory AML), a 150-patient multi-center randomized trial that will compare outcomes of patients who receive Iomab-B and a BMT to those patients receiving physician's choice of salvage chemotherapy, defined as conventional care, as no standard of care exists for this patient population. The SIERRA trial may be unsuccessful and fail to demonstrate a safety and efficacy profile that is necessary to receive favorable regulatory approval. The trials DMC may recommend that the trial be stopped early for safety or efficacy concerns, which could prevent us from completing the SIERRA trial. Even if Iomab-B receives favorable regulatory approval, we may not be successful in securing adequate reimbursement or establishing successful commercial operations. Any or all of these factors could have a material adverse impact on our business and ability to continue operations.

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

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

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

In December 2019, a novel strain of coronavirus was reported in China. Since then, COVID-19 has spread globally. The spread of COVID-19 from China to other countries resulted in the World Health Organization (WHO) declaring the outbreak of COVID-19 as a "pandemic," or a worldwide spread of a new disease, on March 11, 2020. Many countries around the world have imposed quarantines and restrictions on travel and mass gatherings to slow the spread of the virus and have closed non-essential businesses, and many domestic jurisdictions continue to have such restrictions in place.

As many domestic jurisdictions continue to maintain such restrictions in place, our ability to continue to operate our business may also be limited. These restrictions may result in a period of business, supply and drug product manufacturing disruption, and in reduced operations, any of which could materially affect our business, financial condition and results of operations. In response to COVID-19, we implemented remote working and thus far have not experienced a significant disruption or delay in our operations as it relates to the clinical development of our drug candidates. Such government-imposed precautionary measures may have been relaxed in certain countries or states, but there is no assurance that more strict measures will be put in place again due to a resurgence in COVID-19 cases, including those involving new variants of the coronavirus, which may be more contagious and deadly than prior strains. Therefore, the COVID-19 pandemic may continue to affect our operation, may further divert the attention and efforts of the medical community to coping with COVID-19 and disrupt the marketplace in which we operate and may have a material adverse effect on our operations.

The spread of COVID-19, which has caused a broad impact globally, may materially affect us economically. While the ultimate economic impact brought by, and the duration of, the COVID-19 pandemic may be difficult to assess or predict, including new information which may emerge concerning the severity of COVID-19 and the actions to contain COVID-19 or treat its impact, among others, the pandemic has resulted in significant disruptions in the general commercial activity and the global economy and caused financial market volatility and uncertainty in significant and unforeseen ways in the recent months. A continuation or worsening of the levels of market disruption and volatility seen in the recent past could have an adverse effect on our ability to access capital, which could in the future negatively affect our liquidity. In addition, a recession or market correction resulting from the spread of COVID-19 could materially affect our business and the value of our common stock.

Currently, the Phase 3 SIERRA trial for our lead program, Iomab-B, remains active at a majority of our clinical trial sites, with investigators providing feedback that recruitment and enrollment will remain active because of the acute nature of the disease, the high unmet needs of patients with relapsed or refractory AML, the potentially curative nature of BMT and the differentiated profile of Iomab-B. Certain sites that had not been actively enrolling due to COVID-19 at the initial outbreak of the pandemic resumed recruitment and enrollment in mid-2020, and we currently do not have any sites that are not recruiting and enrolling due to COVID-19. We also believe our earlier stage CD33 clinical trials will continue to recruit and enroll patients given the acute nature of relapsed or refractory AML. The continuation of the pandemic globally could adversely affect our planned clinical trial operations, including our ability to conduct the trials on the expected timelines and recruit and retain patients and principal investigators and site staff who, as healthcare providers, may have heightened exposure to COVID-19 if their geography is impacted by the pandemic. Further, the continuation and/or resurgence of the COVID-19 pandemic could result in delays in our clinical trials due to prioritization of hospital resources toward the pandemic, restrictions in travel, potential unwillingness of patients to enroll in trials at this time, or the inability of patients to comply with clinical trial protocols if quarantines or travel restrictions impede patient movement or interrupt healthcare services. In addition, we rely on independent clinical investigators, contract research organizations and other third-party service providers to assist us in managing, monitoring and otherwise carrying out our preclinical studies and clinical trials, and the pandemic may affect their ability to devote sufficient time and resources to our programs or to travel to sites to perform work for us.

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

COVID-19 has caused severe disruptions in transportation and limited access to our facility, resulting in limited support from our staff and professional advisors.

We continue to monitor the impacts of COVID-19 on the global economy and on our business operations. However, the ultimate impact from COVID-19 on our business operations and financial results during 2021 will depend on, among other things, the ultimate severity and scope of the pandemic, the pace at which governmental and private travel restrictions and public concerns about public gatherings will ease, the rate at which historically large increases in unemployment rates will decrease, if at all, and whether, and the speed with which the economy recovers. We are not able to fully quantify the impact that these factors will have on our financial results during 2021 and beyond, but developments related to COVID-19 may materially affect us in 2021.

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;
- 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 recently secured cybersecurity insurance coverage to protect against cybersecurity risks. However, we cannot ensure that it will be sufficient to cover any particular losses we may experience as a result of such cyberattacks. Any cyber incident could have a material adverse effect on our business, financial condition and results of operations.

Risks Related to Regulation

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

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

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

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

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

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

- completion of preclinical laboratory tests and animal studies in accordance with FDA's good laboratory practices ("GLPs") and applicable requirements for the humane use of laboratory animals or other applicable regulations;
- submission to the FDA of an Investigational New Drug ("IND"), which must become effective before human clinical trials in the United States may begin;
- performance of adequate and well-controlled human clinical trials in accordance with FDA's IND regulations, GCPs, and any additional requirements for the protection of human research subjects and their health information, to establish the safety and efficacy of the proposed biological product for its intended use;
- submission to the FDA of a BLA for marketing approval that meets applicable requirements to ensure the continued safety, purity, and potency of the product that is the subject of the BLA based on results of preclinical testing and clinical trials;
- satisfactory completion of an FDA inspection of the manufacturing facility or facilities where the biological product is produced, to assess compliance with cGMPs and assure that the facilities, methods and controls are adequate to preserve the biological product's identity, strength, quality and purity;
- potential FDA audit of the nonclinical study and clinical trial sites that generated the data in support of the BLA; and
- FDA review and approval, or denial, of the BLA.

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

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

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

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

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

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

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

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

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

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

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

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

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

In June 2012, we acquired rights to BC8 (Iomab), a clinical stage monoclonal antibody with safety and efficacy data in more than 300 patients in need of a BMT. Iomab-B is our product candidate that links I-131 to the BC8 antibody that is being studied in an ongoing Phase 3 pivotal trial. Product candidates utilizing this antibody would require BLA approval before they can be marketed in the United States. We are also evaluating a lower dose of the BC8 antibody and I-131 for lymphodepletion prior to CAR-T or adoptive cell therapy. We are currently evaluating clinical trials that would use our construct for lymphodepletion. Our lintuzumab-Ac-225 product candidate is also being studied in several Phase 1 trials under our sponsorship and investigator-initiated trials in patients with AML, myelodysplastic syndrome and multiple myeloma. 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.

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

Initiating and completing clinical trials necessary to support FDA approval of a BLA for Iomab-B, CD33 program candidates, and other product candidates, is a time-consuming and expensive process, and the outcome is inherently uncertain. Moreover, the results of early clinical trials are not necessarily predictive of future results, and any product candidate we advance into clinical trials may not have favorable results in later clinical trials. We have worked with the FDA to develop a clinical trial designed to test the safety and efficacy of Iomab-B in patients with relapsed or refractory AML who are age 55 and above prior to a BMT. This trial is designed to support a BLA filing for marketing approval by the FDA, pending results from the trial. In addition to clinical data, a BLA filing encompasses preclinical, CMC, labeling and other information. Even if the clinical data from the SIERRA trial is positive, there can be no assurances that the BLA filing we produce will meet all of the FDA's requirements or that they will not request additional information or studies, which may delay the FDA's review or we may not be able to produce. We have also worked with the FDA to develop a regulatory pathway for our Actimab-MDS trial that consists of a dose-confirming Phase 1 trial that can be followed by a randomized, controlled pivotal trial that could support a BLA filing. There can be no assurance that the data generated during the trial will meet our chosen safety and effectiveness endpoints or otherwise produce results that will eventually support the filing or approval of a BLA. Even if the data from this trial are favorable, the data may not be predictive of the results of any future clinical trials.

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

From time to time, we may publicly disclose preliminary, interim, and top-line data from our clinical trials, which is based on a preliminary analysis of then-available data, and the results and related findings and conclusions are subject to change as more patient data become available or following a more comprehensive review of the data related to the particular study or trial. For example, on February 10, 2021, interim safety, and feasibility data from 75% patient enrollment was presented at the TCT Annual Meeting. We also make assumptions, estimations, calculations and conclusions as part of our analyses of data, and we may not have received or had the opportunity to fully and carefully evaluate all data. Interim or preliminary results that we report may differ from future results of the same studies, or different conclusions or considerations may qualify such results once additional data have been received and fully evaluated. Preliminary, interim or top-line data also remain subject to audit and verification procedures that may result in the final data being materially different from the top-line, interim or preliminary data we previously published. As a result, top-line, interim and preliminary data should be viewed with caution until the final data are available.

From time to time, we may also disclose interim data from our preclinical studies and clinical trials. Interim data from clinical trials that we may complete are subject to the risk that one or more of the clinical outcomes may materially change as patient enrollment continues and more patient data become available. Adverse differences between interim data and final data could significantly harm our business prospects. Further, disclosure of interim data by us or by our competitors could result in volatility in the price of our common stock.

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

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

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

Even if our clinical trials are completed as planned, we cannot be certain that their results will support our product candidate claims or that the FDA or foreign authorities will agree with our conclusions regarding them. Success in pre-clinical studies and early clinical trials does not ensure that later clinical trials will be successful, and we cannot be sure that the later trials will replicate the results of prior trials and pre-clinical studies. The clinical trial process may fail to demonstrate that our product candidates are safe and effective for the proposed indicated uses. If FDA concludes that the clinical trials for Iomab-B, lintzumab-Ac-225, or any other product candidate for which we might seek approval, have failed to demonstrate safety and effectiveness, we would not receive FDA approval to market that product candidate in the United States for the indications sought. In addition, such an outcome could cause us to abandon the product candidate and might delay development of others. Any delay or termination of our clinical trials will delay or preclude the filing of any submissions with the FDA and, ultimately, our ability to commercialize our product candidates and generate revenues. It is also possible that patients enrolled in clinical trials will experience adverse side effects that are not currently part of a product candidate's profile.

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

The key patents related to the humanized antibody, lintuzumab, which we use in our CD33 program product candidates have expired. It is generally possible that others may be eventually able to use an antibody with the same sequence, and we will then need to rely on additional patent protection covering alpha particle drug products comprising Ac-225. Our final drug construct consists of the lintuzumab antibody labeled with the isotope Ac-225. We have licensed issued patents that relate to the linker technology we use to conjugate the isotope to the antibody. Further, we own issued and pending patents related to methods for drug conjugation and isotope labeling and for methods of isotope production. 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 is nevertheless a possibility that could negatively impact our business in the future. We own 2 issued patents in the US and 1 in Europe relating to composition of the Iomab-B product candidate. Five related patents are also pending in the US 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 BC8 antibody or the construct. We have pending patents related to radioimmunoconjugate composition, formulation administration, and methods of use in solid or liquid cancers. This matter includes composition, administration, and methods of treatment for our products Actimab-A and Iomab-B. Any competing product based on the antibody used in Iomab-B is likely to require several years of development before achieving our product candidate's current status and may be subject to significant regulatory hurdles but is nevertheless a possibility that could negatively impact our business in the future.

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

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

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

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

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

Our contract for supply of this isotope from the DOE must be renewed yearly, and the current contract extends through the end of 2021. While we expect this contract will 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. 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 ARC 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 isotope could result in delays in our clinical trials, which could have a negative impact on our business. We have developed intellectual property, know-how and trade secrets related to the manufacturing process of Ac-225. While we have manufactured medical grade Ac-225 of a purity compared to the cyclotron sourced material in the past, this activity was terminated due to operating cost reasons and we currently do not have experience in manufacturing medical grade Ac-225 and may not obtain the resources necessary to establish our own manufacturing capabilities in future. Our inability to build out and establish our own manufacturing facilities would require us to continue to rely on third party suppliers as we currently do. However, based on our current third-party suppliers and potential future suppliers of Ac-225 we expect to have adequate isotope supply to support our current ongoing clinical trials, current AWE program activities and commercialization should our drug candidates receive approval.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

- restrictions on the marketing or manufacturing of our product candidates, withdrawal of the product from the market, or voluntary or mandatory product recalls;
- fines, warning letters or holds on clinical trials;
- refusal by the FDA to approve pending applications or supplements to approved applications filed by us or suspension or revocation of license approvals;
- product seizure or detention, or refusal to permit the import or export of our product candidates; and
- injunctions or the imposition of civil or criminal penalties.

The FDA's and other regulatory authorities' policies may change, and additional government regulations may be enacted that could prevent, limit or delay regulatory approval of our product candidates. We cannot predict the likelihood, nature or extent of government regulation that may arise from future legislation or administrative action, either in the United States or abroad. If we are slow or unable to adapt to changes in existing requirements or the adoption of new requirements or policies, or if we are not able to maintain regulatory compliance, we may lose any marketing approval that we may have obtained, and we may not achieve or sustain profitability.

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

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

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

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

There have been significant ongoing judicial, administrative, executive, and legislative initiatives to modify, limit, replace, or repeal the Affordable Care Act. For example, former President Trump issued several Executive Orders and other directives designed to delay the implementation of certain provisions of the Affordable Care Act or otherwise circumvent some of the requirements for health insurance mandated by the Affordable Care Act. Concurrently, Congress considered legislation that would repeal or replace all or part of the Affordable Care Act. While Congress has not passed comprehensive repeal legislation, several bills affecting the implementation the Affordable Care Act have been passed. For example, the Tax Cuts and Jobs Act of 2017 eliminated the Affordable Care Act provision requiring individuals to purchase and maintain health coverage, or the "individual mandate," by reducing the associated penalty to zero, beginning in 2019. In December 2018, a district court in Texas held that the individual mandate is unconstitutional and that the rest of the Affordable Care Act is, therefore, invalid. On appeal, the Fifth Circuit Court of Appeals affirmed the holding on the individual mandate but remanded the case back to the lower court to reassess whether and how such holding affects the validity of the rest of the Affordable Care Act. The U.S. Supreme Court is currently reviewing the case. Substantial uncertainty remains as to the future of the Affordable Care Act. There is no way to predict whether, and to what extent, if any, the Affordable Care Act will remain in-effect in the future, and it is unclear how these decisions, subsequent appeals, or other efforts to repeal and replace the Affordable Care Act will impact the United States healthcare industry or our business.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

Risks Related to Third Parties

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

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

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

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

The antibodies we use in our antibody radiation-conjugate product candidates may be subject to generic competition.

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

Our product candidates may never achieve market acceptance.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

We face significant competition from other biotechnology and pharmaceutical companies.

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

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

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

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

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

Risks Related to Our Intellectual Property

We depend upon securing and protecting critical intellectual property.

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

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

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

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

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

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

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

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

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

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

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

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

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

We rely on trade secrets that we seek to protect through 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. We may not have any remedies against our competitors and 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.

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 cooperating of a commercialization partner, conducting drug development in foreign countries involves inherent risks, including, but not limited to difficulties in staffing, funding and managing foreign operations; unexpected changes in regulatory requirements; export restrictions; tariffs and other trade barriers; difficulties in protecting, acquiring, enforcing and litigating intellectual property rights; fluctuations in currency exchange rates; and potentially adverse tax consequences.

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

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

Our future operations and successes depend in large part upon the continued service of key members of our senior management team whom we are highly dependent upon to manage our business. If any member of our current senior management terminates his employment with us and we are unable to find a suitable replacement quickly, the departure could have a material adverse effect on our business.

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. 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, which will place a significant strain on our financial, managerial and operational resources. In order to achieve and manage growth effectively, we must continue to improve and expand our operational and financial management capabilities. Moreover, we will need to increase staffing and to train, motivate and manage our employees. All of these activities will increase our expenses and may require us to raise additional capital sooner than expected. Failure to manage growth effectively could materially harm our business, financial condition or results of operations.

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

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

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

Risks Related to Ownership of Our Common Stock

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

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

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

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

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

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

- actual or anticipated variations in our operating results;
- announcements of developments by us or our competitors;
- the timing of IND and/or BLA approval, the completion and/or results of our clinical trials;
- regulatory actions regarding our products;
- announcements by us or our competitors of significant acquisitions, strategic partnerships, joint ventures or capital commitments;
- adoption of new accounting standards affecting our industry;

- additions or departures of key personnel;
- introduction of new products by us or our competitors;
- sales of our common stock or other securities in the open market; and
- other events or factors, many of which are beyond our control.

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

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

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

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

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

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

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

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

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

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, 2020 and 2019 and while our testing did not reveal any material weaknesses in our internal controls, any material weaknesses in our internal controls in the future would be required us to remediate in a timely manner so as to be able to comply with the requirements of Section 404 each year. If we are not able to comply with the requirements of Section 404 in a timely manner each year, we could be subject to sanctions or investigations by the SEC, NYSE American or other regulatory authorities which would require additional financial and management resources and could adversely affect the market price of our common stock. Furthermore, if we cannot provide reliable financial reports or prevent fraud, our business and results of operations could be harmed, and investors could lose confidence in our reported financial information.

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

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

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

Our amended and restated bylaws, as amended, provide that, unless we consent in writing to the selection of an alternative forum, the federal district courts of the United States of America will be the exclusive forum for resolving any complaint asserting a cause of action arising under the Securities Act of 1933, as amended. In addition, our amended and restated bylaws, as amended, state that any person purchasing or otherwise acquiring any interest in our security shall be deemed to have notice of and to have consented to such provision. Such choice of forum provision may limit a stockholder's ability to bring a claim in a judicial forum that it finds favorable for disputes with us or our directors, officers or other employees, which may discourage such lawsuits, if successful, might benefit our stockholders. Stockholders who do bring a claim in the federal district courts of the United States of America could face additional litigation costs in pursuing any such claim.

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

None.

ITEM 3. DEFAULTS UPON SENIOR SECURITIES.

None.

ITEM 4. MINE SAFETY DISCLOSURES.

None.

ITEM 5. OTHER INFORMATION.

None.

ITEM 6. EXHIBITS

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

Exhibit No.	Title of Document	Location
3.1	Certificate of Incorporation of Actinium Pharmaceuticals, Inc. (incorporated by reference to Exhibit 3.1 of the Company's Form 8-K filed with the SEC on April 17, 2013).	
3.2	Certificate of Amendment to Certificate of Incorporation, as amended, filed January 7, 2014 (incorporated by reference to Exhibit 3.5 to Form S-1 filed on January 31, 2014).	
3.3	Certificate of Amendment to Certificate of Incorporation, as amended, filed February 3, 2014. (incorporated by reference to Exhibit 3.1 to Form 8-K filed on February 7, 2014).	
3.4	Certificate of Amendment to Certificate of Incorporation, as amended, filed on February 26, 2015 (incorporated by reference to Exhibit 3.1 to Form 8-K filed on March 4, 2015).	
3.5	Certificate of Amendment to Certificate of Incorporation, as amended, filed on February 26, 2018 (incorporated by reference to Exhibit 3.1 to Form 8-K filed on February 26, 2018).	
3.6	Certificate of Amendment to Certificate of Incorporation, as amended, filed on March 6, 2019 (incorporated by reference to Exhibit 3.7 to Form 10-K filed on March 15, 2019).	
3.7	Certificate of Amendment to Certificate of Incorporation, as amended, filed on June 16, 2020 (incorporated by reference to Exhibit 3.1 to Form 8-K filed on June 16, 2020).	
3.8	Certificate of Amendment to Certificate of Incorporation, as amended, filed on August 10, 2020 (incorporated by reference to Exhibit 3.1 to Form 8-K filed on August 14, 2020).	
3.9	Amended and Restated Bylaws, dated August 8, 2018 (incorporated by reference to Exhibit 3.1 to Form 10-Q filed on August 9, 2018).	
3.10	Amendment to Amended and Restated Bylaws, dated May 7, 2020 (incorporated by reference to Exhibit 3.1 to Form 8-K filed on May 5, 2020).	
31.1*	Certification of the Chief Executive Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.	Attached
31.2*	Certification of the Principal Financial and Accounting Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.	Attached
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*	Attached
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*	Attached
101.INS	XBRL Instance Document	Attached
101.SCH	XBRL Taxonomy Extension Schema Document	Attached
101.CAL	XBRL Taxonomy Calculation Linkbase Document	Attached
101.DEF	XBRL Taxonomy Extension Definition Linkbase Document	Attached
101.LAB	XBRL Taxonomy Label Linkbase Document	Attached
101.PRE	XBRL Taxonomy Presentation Linkbase Document	Attached

* The Exhibit attached to this Form 10-Q shall not be deemed "filed" for purposes of Section 18 of the Securities Exchange Act of 1934 (the "Exchange Act") or otherwise subject to liability under that section, nor shall it be deemed incorporated by reference in any filing under the Securities Act of 1933, as amended, or the Exchange Act, except as expressly set forth by specific reference in such filing.

SIGNATURES

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

ACTINIUM PHARMACEUTICALS, INC.

Date: May 14, 2021

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 present 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 financing 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 involved management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: May 14, 2021

By: /s/ Sandesh Seth
Sandesh Seth
Chairman & CEO
(Duly Authorized Officer and
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 present 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 financing 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 involved management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: May 14, 2021

By: /s/ Steve O'Loughlin
Steve O'Loughlin
Chief Financial Officer
(Duly Authorized Officer and 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 March 31, 2021 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: May 14, 2021

By: /s/ Sandesh Seth
Sandesh Seth
Chairman & CEO
(Duly Authorized Officer and 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 March 31, 2021 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: May 14, 2021

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