

UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

FORM 10-Q

(Mark One)

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

For the quarterly period ended **September 30, 2019**

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: **000-52446**

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

Delaware

(State or Other Jurisdiction of
Incorporation or Organization)

**275 Madison Ave, 7th Floor
New York, NY**

(Address of Principal Executive Offices)

74-2963609

(I.R.S. Employer
Identification No.)

10016

(Zip Code)

(646) 677-3870

(Registrant's Telephone Number, Including Area Code)

(Former Name, Former Address and Former Fiscal Year, if Changed Since Last Report)

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	<input type="checkbox"/>	Accelerated filer	<input checked="" type="checkbox"/>
Non-accelerated filer	<input type="checkbox"/>	Smaller reporting company	<input checked="" type="checkbox"/>
		Emerging growth company	<input type="checkbox"/>

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

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

Indicate the number of shares outstanding of each of the issuer's classes of common stock, as of November 12, 2019: 164,701,167.

Actinium Pharmaceuticals, Inc.
FORM 10-Q
For the Nine months ended September 30, 2019

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PART I - FINANCIAL INFORMATION

ITEM 1. FINANCIAL STATEMENTS

The accompanying consolidated financial statements have been prepared by the Company and are unaudited. In the opinion of management, all adjustments (which include only normal recurring adjustments) necessary to present fairly the financial position at September 30, 2019 and December 31, 2018, and the results of operations and cash flows for the three months and nine months ended September 30, 2019 and 2018, 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, 2018 in the Company's Annual Report on Form 10-K. The results of operations for the three months and nine months ended September 30, 2019 are not necessarily indicative of the operating results for the full year.

Actinium Pharmaceuticals, Inc.
Consolidated Balance Sheets
(Unaudited)

	<u>September 30,</u> <u>2019</u>	<u>December 31,</u> <u>2018</u>
Assets		
Current Assets:		
Cash and cash equivalents	\$ 14,312,909	\$ 13,673,308
Restricted cash – current	48,056	40,075
Prepaid expenses and other current assets	189,870	616,222
Total Current Assets	<u>14,550,835</u>	<u>14,329,605</u>
Property and equipment, net of accumulated depreciation of \$225,071 and \$266,381, respectively	121,076	118,799
Operating leases right-of-use assets	963,434	-
Finance leases right-of-use assets	241,397	-
Security deposit	49,859	49,859
Restricted cash	391,180	391,131
Total Assets	<u>\$ 16,317,781</u>	<u>\$ 14,889,394</u>
Liabilities and Stockholders' Equity		
Current Liabilities:		
Accounts payable and accrued expenses	\$ 5,130,710	\$ 5,814,004
Note payable	25,331	249,239
Operating leases current liability	307,684	-
Finance leases current liability	77,178	-
Total Current Liabilities	<u>5,540,903</u>	<u>6,063,243</u>
Long-term operating lease obligations	669,860	-
Long-term finance lease obligations	171,214	13,354
Total Liabilities	<u>6,381,977</u>	<u>6,076,597</u>
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; 600,000,000 shares authorized; 164,701,167 and 115,703,044 shares issued and outstanding, respectively	164,701	115,703
Additional paid-in capital	213,926,229	195,554,332
Accumulated deficit	(204,155,126)	(186,857,238)
Total Stockholders' Equity	<u>9,935,804</u>	<u>8,812,797</u>
Total Liabilities and Stockholders' Equity	<u>\$ 16,317,781</u>	<u>\$ 14,889,394</u>

See accompanying notes to the consolidated financial statements.

Actinium Pharmaceuticals, Inc.
Consolidated Statements of Operations
(Unaudited)

	For the Three Months Ended September 30,		For the Nine Months Ended September 30,	
	2019	2018	2019	2018
Revenue	\$ -	\$ -	\$ -	\$ -
Operating expenses:				
Research and development, net of reimbursements	4,829,874	4,227,036	13,176,033	12,023,109
General and administrative	1,822,506	1,970,230	4,261,939	5,440,656
Total operating expenses	<u>6,652,380</u>	<u>6,197,266</u>	<u>17,437,972</u>	<u>17,463,765</u>
Loss from operations	<u>(6,652,380)</u>	<u>(6,197,266)</u>	<u>(17,437,972)</u>	<u>(17,463,765)</u>
Other income:				
Interest income - net	53,054	49,177	141,353	129,549
Total other income	<u>53,054</u>	<u>49,177</u>	<u>141,353</u>	<u>129,549</u>
Net loss	<u>\$ (6,599,326)</u>	<u>\$ (6,148,089)</u>	<u>\$ (17,296,619)</u>	<u>\$ (17,334,216)</u>
Deemed dividend for warrant down-round protection provision	-	-	(1,269)	-
Net loss applicable to common stockholders	<u>\$ (6,599,326)</u>	<u>\$ (6,148,089)</u>	<u>\$ (17,297,888)</u>	<u>\$ (17,334,216)</u>
Loss per common share – basic and diluted	<u>\$ (0.04)</u>	<u>\$ (0.06)</u>	<u>\$ (0.12)</u>	<u>\$ (0.17)</u>
Weighted average common shares outstanding – basic and diluted	<u>163,338,013</u>	<u>110,463,891</u>	<u>144,071,937</u>	<u>103,168,015</u>

See accompanying notes to the consolidated financial statements.

Actinium Pharmaceuticals, Inc.
Consolidated Statement of Changes in Stockholders' Equity
For the Period from January 1, 2019 to September 30, 2019

	Common Stock		Additional Paid- In Capital	Accumulated Deficit	Stockholders' Equity
	Shares	Amount			
Balance, January 1, 2019	115,703,044	\$ 115,703	\$ 195,554,332	\$ (186,857,238)	\$ 8,812,797
Stock-based compensation	2,221	2	316,387	-	316,389
Issuance of common stock from exercise of warrants	2,506,271	2,506	1,501,256	-	1,503,762
Sale of common stock, net of offering costs	924,500	925	379,184	-	380,109
Net loss	-	-	-	(5,670,375)	(5,670,375)
Balance, March 31, 2019	119,136,036	119,136	197,751,159	(192,527,613)	5,342,682
Stock-based compensation	-	-	276,680	-	276,680
Issuance of common stock from exercise of warrants	37,485	38	(38)	-	-
Sale of common stock and warrants, net of offering costs	42,860,000	42,860	15,065,168	-	15,108,028
Deemed dividend for warrant down-round protection provision	-	-	1,269	(1,269)	-
Net loss	-	-	-	(5,026,918)	(5,026,918)
Balance, June 30, 2019	162,033,521	162,034	213,094,238	(197,555,800)	15,700,472
Stock-based compensation	392,079	392	390,152	-	390,544
Sale of common stock, net of costs	2,275,567	2,275	441,839	-	444,114
Net loss	-	-	-	(6,599,326)	(6,599,326)
Balance, September 30, 2019	164,701,167	\$ 164,701	\$ 213,926,229	\$ (204,155,126)	\$ 9,935,804

See accompanying notes to the consolidated financial statements.

Actinium Pharmaceuticals, Inc.
Consolidated Statement of Changes in Stockholders' Equity
For the Three and Nine Months Ended September 30, 2018

	Common Stock		Additional Paid- In Capital	Accumulated Deficit	Stockholders' Equity
	Shares	Amount			
Balance, January 1, 2018	80,072,334	\$ 80,072	\$ 176,810,222	\$ (163,203,275)	\$ 13,687,019
Stock-based compensation	6,500	7	579,932	-	579,939
Sale of common stock and warrants, net of offering costs	30,237,894	30,238	13,780,499	-	13,810,737
Net loss	-	-	-	(6,323,337)	(6,323,337)
Balance, March 31, 2018	110,316,728	110,317	191,170,653	(169,526,612)	21,754,358
Stock-based compensation	139,893	139	425,686	-	425,825
Issuance of common stock from exercise of warrants	1,500	2	898	-	900
Net loss	-	-	-	(4,862,790)	(4,862,790)
Balance, June 30, 2018	110,458,121	110,458	191,597,237	(174,389,402)	17,318,293
Stock-based compensation	5,000	5	405,934	-	405,939
Issuance of common stock from exercise of warrants	5,832	6	3,943	-	3,949
Net loss	-	-	-	(6,148,089)	(6,148,089)
Balance, September 30, 2018	110,468,953	\$ 110,469	\$ 192,007,114	\$ (180,537,491)	\$ 11,580,092

See accompanying notes to the consolidated financial statements.

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

	For the Nine Months Ended September 30,	
	2019	2018
Cash Flows From Operating Activities:		
Net loss	\$ (17,296,619)	\$ (17,334,216)
Adjustments to reconcile net loss to net cash used in operating activities:		
Stock-based compensation expense	983,613	1,411,703
Depreciation & amortization expenses	315,728	38,064
Changes in operating assets and liabilities:		
Decrease in:		
Prepaid expenses and other current assets	426,352	128,140
Decrease in:		
Accounts payable and accrued expenses	(680,570)	(527,864)
Operating lease liabilities	(199,514)	-
Net Cash Used In Operating Activities	<u>(16,451,010)</u>	<u>(16,284,173)</u>
Cash Flows Used In Investing Activities:		
Purchase of property and equipment	(59,488)	(85,522)
Net Cash Used In Investing Activities	<u>(59,488)</u>	<u>(85,522)</u>
Cash Flows From Financing Activities:		
Payments on note payable	(223,908)	-
Payments on finance leases	(53,976)	-
Sales of shares of common stock and warrants, net of offering costs	15,932,251	13,810,737
Proceeds from exercise of warrants	1,503,762	4,849
Net Cash Provided By Financing Activities	<u>17,158,129</u>	<u>13,815,586</u>
Net change in cash, cash equivalents, and restricted cash	647,631	(2,554,109)
Cash, cash equivalents, and restricted cash at beginning of period	14,104,514	17,790,576
Cash, cash equivalents, and restricted cash at end of period	<u>\$ 14,752,145</u>	<u>\$ 15,236,467</u>
Supplemental disclosure of cash flow information:		
Cash paid for interest on note payable	\$ 4,893	\$ -
Supplemental disclosure of non-cash flow information:		
Deemed dividend for warrant down-round protection provision	\$ 1,269	\$ -

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 developing ARCs or Antibody Radiation-Conjugates, which combine the targeting ability of antibodies with the cell killing ability of radiation. Actinium’s lead application for our ARCs is targeted conditioning, which is intended to selectively kill patient’s cancer cells and certain immune cells prior to a Bone Marrow Transplant (“BMT”), CAR-T and other cell therapies. With our ARC approach, we seek to improve patient outcomes and access to these potentially curative treatments by eliminating or reducing the non-targeted chemotherapy that is used for conditioning in standard practice currently. Our lead product candidate, Iomab-B is being studied in the ongoing pivotal Phase 3 Study of Iomab-B in Elderly Relapsed or Refractory Acute Myeloid Leukemia (“SIERRA”) trial for BMT conditioning, which reached fifty percent of total patient enrollment in July 2019. Beyond Iomab-B, we are developing a multi-disease, multi-target pipeline of clinical-stage ARCs targeting the antigens CD45 and CD33 for targeted conditioning and as a therapeutic either in combination with other therapeutic modalities or as a single agent for patients with a broad range of hematologic malignancies including Acute Myeloid Leukemia (“AML”), Myelodysplastic Syndrome (“MDS”) and Multiple Myeloma (“MM”). Underpinning our clinical programs is our proprietary AWE or Antibody Warhead Enabling technology platform. This is where our intellectual property portfolio of over 100 patents, know-how, collective research and expertise in the field are being leveraged to construct and study novel ARCs and ARC combinations to bolster our pipeline and for strategic purposes. Our AWE technology platform is currently being utilized in a collaborative research partnership with Astellas Pharma, Inc.

Going concern - The Company has never generated revenue. Currently it does not have a recurring source of revenue to cover its operating costs. The Company has incurred net losses and negative operating cash flows since inception. As of September 30, 2019 and December 31, 2018, the Company’s accumulated deficit was \$204.2 million and \$186.9 million, respectively. The Company’s net loss was \$17.3 million for the nine months ended September 30, 2019 and 2018. These conditions raise substantial doubt as to the Company’s ability to continue as a going concern. As of September 30, 2019, the Company had a balance of cash and cash equivalents of \$14.3 million. The Company’s consolidated financial statements are prepared using Generally Accepted Accounting Principles in the United States of America applicable to a going concern, which contemplates the realization of assets and the satisfaction of liabilities in the normal course of business. The accompanying consolidated financial statements do not include any adjustments relating to the recoverability and classification of recorded asset amounts and classification of liabilities should the Company be unable to continue as a going concern. As of the date of filing this report, the Company expects that its existing resources will be sufficient to fund its planned operations into the third quarter of 2020; additional capital resources will be needed to fund operations longer-term. If the Company is unsuccessful in accomplishing its plans, it may have to delay or terminate existing and/or planned clinical trials and other related activity, which could have a material adverse impact on its business. The Company’s plans to continue as a going concern include obtaining capital from the sale of its equity securities, fees from licensing one or more of its product candidates, additional collaborations with its Iomab-ACT program and AWE technology platform, and short-term borrowings from banks, stockholders or other related parties, if needed. However, the Company cannot provide any assurance that it will be successful in accomplishing any of its plans.

The Company’s ability to continue as a going concern is dependent upon its ability to successfully accomplish the plans described above and eventually to secure other sources of financing and attain profitable operations.

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, 2018.

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 accounting principles generally accepted in the United States of America 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.

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.

Following is a summary of cash, cash equivalents and restricted cash at September 30, 2019, December 31, 2018 and September 30, 2018:

	September 30, 2019	December 31, 2018	September 30, 2018
Cash and cash equivalents	\$ 14,312,909	\$ 13,673,308	\$ 14,805,472
Restricted cash – current	48,056	40,075	40,055
Restricted cash – long-term	391,180	391,131	390,940
Cash, cash equivalents and restricted cash	<u>\$ 14,752,145</u>	<u>\$ 14,104,514</u>	<u>\$ 15,236,467</u>

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.

Research and Development Costs - Research and development costs are expensed as incurred. 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.

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 common shares 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 nine months ended September 30, 2019 and 2018, 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.

	September 30, 2019	September 30, 2018
Options	11,931,801	7,668,231
Warrants	86,335,713	56,013,474
Total	<u>98,267,514</u>	<u>63,681,705</u>

Reclassification – To conform to the current-year presentation, certain amounts have been reclassified in the presentation of the prior-year financial statements.

Accounting Standards Recently Adopted -

Historically, the Company accounted for certain instruments, which do not have fixed settlement provisions, as derivative instruments in accordance with FASB ASC 815-40, *Derivative and Hedging – Contracts in Entity’s Own Equity*. This was due to an anti-dilution provision for the warrants that provides for a reduction to the exercise price if the Company issues equity or equity-linked instruments in the future at an effective price per share less than the exercise price then in effect for the warrant (“down round provision”). As such, the warrants were re-measured at each balance sheet date based on estimated fair value. Changes in estimated fair value were recorded as non-cash adjustments within other income (expense), net, in the Company’s Consolidated Statements of Operations.

In July 2017, the Financial Accounting Standards Board, (“FASB”), issued ASU No. 2017-11, *Earnings Per Share (Topic 260); Distinguishing Liabilities from Equity (Topic 480); Derivatives and Hedging (Topic 815): (Part I) Accounting for Certain Financial Instruments with Down Round Features*. These amendments simplify the accounting for certain financial instruments with down-round features. The amendments require companies to disregard the down-round feature when assessing whether the instrument is indexed to its own stock, for purposes of determining liability or equity classification. The guidance was adopted as of April 1, 2018 and did not have a significant impact to the Company’s financial statements.

In February 2016, FASB issued ASU No. 2016-02 *Leases (Topic 842)*, which created new accounting and reporting guidelines for leasing arrangements. The standard requires that a lessee recognize the assets and liabilities that arise from operating leases. A lessee should recognize on its balance sheet a liability to make lease payments (the lease liability) and a right-of-use asset representing its right to use the underlying asset for the lease term. The guidance in ASU 2016-02 is effective for annual and interim reporting periods beginning after December 15, 2018. In July 2018, FASB issued ASU No. 2018-11, *Leases (Topic 842) -Targeted Improvements*, providing an optional transition method that allows entities to initially apply the new leases standard at the adoption date. The Company adopted this Standard effective January 1, 2019, see Note 3.

In June 2018, FASB issued ASU 2018-07 to expand the scope of ASC Topic 718, *Compensation - Stock Compensation*, to include share-based payment transactions for acquiring goods and services from nonemployees. The standard is effective for fiscal years, and for interim periods within those fiscal years, beginning after December 15, 2018, with early adoption permitted. The Company adopted this Standard effective January 1, 2019 and did not have a significant impact to the Company’s financial statements.

Recent Accounting Standards –

In August 2018, FASB issued ASU 2018-13, *Fair Value Measurement - Disclosure Framework (Topic 820)*. The updated guidance improves the disclosure requirements on fair value measurements and is effective for fiscal years, and interim periods within those fiscal years, beginning after December 15, 2019. Early adoption is permitted upon issuance of the standard for disclosures modified or removed with a delay of adoption of the additional disclosures until their effective date. The Company is in the process of evaluating the impact the standard will have on its financial statements.

In November 2018, FASB issued ASU 2018-18, *Collaborative Arrangements (Topic 808): Clarifying the Interaction Between Topic 808 and Topic 606*, which, among other things, provides guidance on how to assess whether certain collaborative arrangement transactions should be accounted for under Topic 606. The amendments in this ASU are effective for fiscal years, and interim periods within those fiscal years, beginning after December 15, 2019, with early adoption permitted. The Company is in the process of evaluating the impact the standard will have on its 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. Notable inclusions in this category are:

- a. Oak Ridge National Laboratory (“ORNL”) – The Company is contracted to purchase radioactive material to be used for research and development, with a renewal option at the contract end. On December 19, 2018, the Company signed a contract with ORNL to purchase \$0.2 million of radioactive material during calendar year 2019. During the nine months ended September 30, 2019 and 2018, the Company purchased material from ORNL of approximately \$0.2 million in each period.
- b. 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 currently 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.
- c. On February 27, 2014, the Company entered into a manufacturing agreement with Goodwin Biotechnology Inc. (“Goodwin”). Goodwin oversees the current Good Manufacturing Practices (“cGMP”) production of a monoclonal antibody used in the Phase 3 clinical trial of Iomab-B. As of September 30, 2019, the remaining cost of the service agreement is \$0.3 million. For the nine months ended September 30, 2019 and 2018, the Company paid Goodwin \$1.5 million and \$1.0 million, respectively.
- d. On February 16, 2016, the Company entered into an agreement with Medpace, Inc. (“Medpace”), a Contract Research Organization, (“CRO”). Medpace provides project management services for the Iomab-B study. The total project is currently estimated to cost approximately \$10.2 million. As of September 30, 2019, the remaining cost of the agreement is approximately \$0.9 million. Medpace bills the Company when services are rendered and the Company records the related expense to research and development costs. During the nine months ended September 30, 2019 and 2018, the Company paid Medpace \$2.0 million and \$2.6 million, respectively. These payments are for Medpace project management services and pass-through expenses incurred by investigators and clinical sites.

Collaborative Agreement

In March 2018, the Company entered into a research and option agreement with Astellas Pharma Inc. (“Astellas”) to develop ARCs using the Company’s AWE Technology Platform. Under this collaboration, the Company will utilize its AWE Platform to conjugate and label selected Astellas targeting agents with an Actinium-225 payload. The Company will also be responsible for conducting preclinical validation studies on any ARCs generated. Payments from Astellas under this agreement are accounted for as a reduction to research and development expense.

Note 3 - Leases

The Company adopted ASC 842 as of January 1, 2019, using a modified retrospective approach and applying the standard’s transition provisions at January 1, 2019, the effective date. The Company made an accounting policy election to exclude from balance sheet reporting those leases with initial terms of 12 months or less. At September 30, 2019, 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. Upon adoption of ASC 842, the Company recognized \$1.2 million of right-to-use assets as operating leases and \$0.3 million of right-to-use assets as finance leases. The Company also recognized \$0.9 million of long-term operating lease obligations, net of the current portion of \$0.3 million and \$0.2 million of long-term finance lease obligations, net of the current portion of \$0.1 million.

The components of lease expense are as follows:

	Three months ended September 30, 2019	Nine months ended September 30, 2019
Operating lease expense	\$ 93,044	\$ 279,132
Finance lease cost		
Amortization of right-to-use assets	\$ 20,324	\$ 60,971
Interest on lease liabilities	\$ 5,213	\$ 16,719
Total finance lease cost	\$ 25,537	\$ 77,690

Supplemental cash flow information related to leases are as follows:

	Nine months ended September 30, 2019
Cash flow information:	
Cash paid for amounts included in the measurement of lease liabilities:	
Operating cash flows from operating leases	\$ 265,024
Operating cash flows from finance leases	\$ 16,719
Financing cash flows from finance leases	\$ 53,976
Non-cash activity:	
Right-of-use assets obtained in exchange for lease obligations at September 30, 2019:	
Operating leases	\$ 963,434
Finance Leases	\$ 241,397

Non-cash activity:

Right-of-use assets obtained in exchange for lease obligations at September 30, 2019:

Operating leases	\$ 963,434
Finance Leases	\$ 241,397

Weighted average remaining lease terms are as follows at September 30, 2019:

Weighted average remaining lease term:	
Operating leases	2.9 years
Finance Leases	3.0 years

As the Company's leases do not provide an implicit rate, the Company used its incremental borrowing rate based on the information available at adoption date in determining the present value of lease payments. Below is information on the weighted average discount rates used:

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

Maturities of lease liabilities are as follows:

Year ending December 31,	Operating Leases	Finance Leases
2019 (excluding nine months ended September 30, 2019)	\$ 93,646	\$ 23,565
2020	375,352	94,260
2021	377,715	94,260
2022	252,907	64,144
2023	-	3,912
Total lease payments	\$ 1,099,620	\$ 280,141
Less imputed interest	(122,076)	(31,749)
Present value of lease liabilities	\$ 977,544	\$ 248,392

Note 4 - Equity

In April 2019, the Company sold 42.9 million shares of common stock at an offering price of \$0.385 per share and warrants to purchase up to 42.9 million shares of common stock at an exercise price of \$0.50 per share and with a term of 5 years, resulting in gross proceeds of \$16.5 million and net proceeds of \$15.1 million after deducting underwriting and other offering expenses.

During the nine months ended September 30, 2019, the Company sold 2.8 million common shares through its at-the-market program, resulting in net proceeds of \$0.8 million.

During the nine months ended September 30, 2019, the Company issued 0.4 million shares of restricted common stock for consulting services, which all vested and issued during 2019. The shares had a total value of \$0.1 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 nine months ended September 30, 2019, the Company elected to sell to Lincoln Park 0.4 million shares and received \$0.1 million.

In March 2018, the Company sold an aggregate of 30.2 million units consisting of an aggregate of 30.2 million shares of common stock, 7.6 million series A warrants and 22.7 million series B warrants, with each series A warrant exercisable for one share of Common Stock at an exercise price of \$0.60 per share and each series B warrant exercisable for one share of Common Stock at an exercise price of \$0.70 per share, resulting in gross proceeds of approximately \$15.1 million (each unit was sold at \$0.50 per unit), and net proceeds of approximately \$13.8 million after deducting expenses relating to dealer-manager fees and other offering expenses.

From January through March 2019, holders of March 2018 series A warrants exercised 2.5 million shares, resulting in the Company receiving \$1.5 million. The remaining March 2018 series A warrants expired in March 2019.

Stock Options

The following is a summary of stock option activity for the nine months ended September 30, 2019:

	Number of Shares	Weighted Average Exercise Price	Weighted Average Remaining Contractual Term (in years)	Aggregate Intrinsic Value
Outstanding, December 31, 2018	7,236,101	\$ 1.74	7.97	\$ 6,400
Granted	5,738,500	0.27		
Cancelled	(1,042,800)	0.54		
Outstanding, September 30, 2019	11,931,801	1.14	8.33	525
Exercisable, September 30, 2019	4,347,257	2.28	6.74	-

During the nine months ended September 30, 2019, the Company granted its employees 5.7 million options to purchase the Company's common stock with an exercise price ranging from \$0.223 to \$0.58 per share, a term of 10 years, and a vesting period of 4 years. The options have an aggregated fair value of \$1.1 million that was calculated using the Black-Scholes option-pricing model. Variables used in the Black-Scholes option-pricing model include: (1) discount rate range from 1.38% to 2.60% (2) expected life of 6 years, (3) expected volatility range from 78.5% to 80.6%, and (4) no expected dividends. During the nine months ended September 30, 2019, options to purchase 1.0 million shares were cancelled upon the termination of employment for several employees.

The fair values of all options issued and outstanding are being amortized over their respective vesting periods. The unrecognized compensation expense at September 30, 2019 was approximately \$2.5 million related to unvested options, which is expected to be expensed over a weighted average of 3.4 years. During the nine months ended September 30, 2019 and 2018, the Company recorded compensation expense related to stock options of approximately \$0.9 million and \$1.3 million, respectively.

Warrants

Following is a summary of warrant activity for the nine months ended September 30, 2019:

	Number of Shares	Weighted Average Exercise Price	Weighted Average Remaining Contractual Term (in years)	Aggregate Intrinsic Value
Outstanding, December 31, 2018	55,820,876	\$ 1.20	2.04	\$ 569,038
Granted	42,900,000	0.50	5.00	
Exercised	(2,543,826)	0.59		
Cancelled/Expired	(9,841,337)	2.80		
Outstanding, September 30, 2019	<u>86,335,713</u>	\$ 0.69	3.19	\$ 322,227
Exercisable, September 30, 2019	<u>86,106,964</u>	\$ 0.68	3.19	\$ 322,227

In April 2019, the Company sold 42.9 million shares of common stock at an offering price of \$0.385 per share and warrants to purchase up to 42.9 million shares of common stock at an exercise price of \$0.50 per share and with a term of 5 years. The transaction date relative fair value of the April 2019 warrants of \$5.3 million was determined utilizing the Black-Scholes option pricing model and variables of (1) a discount rate of 2.35%, (2) expected term of 5 years, (3) expected volatility of 78% and (4) zero expected dividends.

The Company has outstanding warrants to purchase 57,212 shares that include down-round protection. For warrants with down-round protection, a deemed dividend is recorded for the change in fair value of the warrants when the down-round provision is triggered. As result of the April 2019 offering, the exercise price of the warrant was reset from \$1.25 per share to \$0.88 per share. The down-round protection provision in the above warrants created a deemed dividend to common stockholders of \$1,269, which is reflected in the accompanying consolidated statement of operations and consolidated statement of changes in stockholders' equity.

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 within the meaning of the Private Securities Litigation Reform Act of 1995. 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 developing ARCs or Antibody Radiation-Conjugates, which combine the targeting ability of antibodies with the cell killing ability of radiation. Actinium's lead application for our ARCs is targeted conditioning, which is intended to selectively kill patient's cancer cells and certain immune cells prior to a Bone Marrow Transplant, or BMT, CAR-T and other cell therapies. With our ARC approach, we seek to improve patient outcomes and access to these potentially curative treatments by eliminating or reducing the non-targeted chemotherapy that is used for conditioning in standard practice currently. Our lead product candidate, Iomab-B is being studied in the ongoing pivotal Phase 3 Study of Iomab-B in Elderly Relapsed or Refractory Acute Myeloid Leukemia ("SIERRA") trial for BMT conditioning. The SIERRA trial achieved fifty percent patient enrollment in July 2019 and is our leading clinical priority. Beyond Iomab-B, we are developing a multi-disease, multi-target pipeline of clinical-stage ARCs targeting the antigens CD45 and CD33 for targeted conditioning and as a therapeutic either in combination with other therapeutic modalities or as a single agent for patients with a broad range of hematologic malignancies including AML or Acute Myeloid Leukemia, MDS or Myelodysplastic Syndrome MM or Multiple Myeloma. Underpinning our clinical programs is our proprietary AWE or Antibody Warhead Enabling technology platform. This is where our intellectual property portfolio of over 100 patents, know-how, collective research and expertise in the field are being leveraged to construct and study novel ARCs and ARC combinations to bolster our pipeline and for strategic purposes. Our AWE technology platform is currently being utilized in a collaborative research partnership with Astellas Pharma, Inc.

Our lead product candidate, Iomab-B, is an ARC comprised of the anti-CD45 monoclonal antibody apamistamab and the radioisotope I-131 or Iodine-131. Iomab-B is intended for targeted conditioning or preparation of patients prior to their BMT and is being studied in the SIERRA trial for patients age 55 and above with active, relapsed or refractory AML. BMT is the only curative treatment option for this patient population and currently no standard of care exists. Excluding the SIERRA trial, Iomab-B has been studied in over three hundred patients in twelve clinical trials in six blood-related cancers. Iomab-B has generated consistently high engraftment rates and improved overall survival outcomes compared to standard of care including in patients with AML. In the proof of concept trial for Iomab-B, 36 patients age fifty and above with relapsed or refractory AML, all patients achieved engraftment of their BMT, and the 1-year overall survival rate was 30% compared to 10% reported with standard chemotherapy-based conditioning. This extensive body of clinical data for Iomab-B informed the design of our ongoing pivotal Phase 3 SIERRA trial. The SIERRA trial is a 150-patient, multi-center trial with patients randomized 1:1 to receive either Iomab-B and a BMT or physician's choice of salvage chemotherapy. The primary endpoint of the SIERRA trial is dCR or durable Complete Remission of 6 months and the secondary endpoint is 1-year Overall Survival (OS).

In July 2019, we announced that the SIERRA trial has reached fifty percent patient enrollment. Completion of the SIERRA trial is our highest corporate priority and in the second quarter of 2019, we restructured our clinical development and clinical operations teams to prioritize the execution of the SIERRA trial. Currently, a majority of our clinical development and clinical operations staff are allocated to our Iomab-B program and the SIERRA trial. Activities being undertaken by our clinical teams include coordinating with active sites and our CRO or clinical research organization to facilitate patient enrollment, providing training and education to active sites, meeting with potential referring physicians to create awareness for the SIERRA trial and working with top BMT centers to expand the number of active centers participating in the trial. Completion of the SIERRA trial will remain our highest priority and we will allocate capital and staff as necessary to complete enrollment of the study as efficiently as possible.

In October 2019, we presented safety and feasibility data from the first 75 patients enrolled on the SIERRA trial, which represents fifty percent of the total of 150 patients to be enrolled in the trial. It was observed that all patients initially randomized to the study arm that received a therapeutic dose of Iomab-B (31/31) received a BMT, with a median time to BMT of 30 days, and all patients achieved neutrophil and platelet engraftment in a median time of 18 days despite a high median blast count of 30%. On the control arm, 18% of patients (7/38) patients received a BMT after receiving conventional care with a median time to BMT of 67 days and had a median blast count of 26%. All patients failing to achieve a Complete Remission or CR with conventional care 82% (31/38) are considered as having failed the primary endpoint of the study. The high failure rate of the control arm at the fifty percent interim analysis is consistent with the observations from the first interim analysis at twenty-five percent of enrollment. This result is important, as the recently approved targeted agents such as BCL-2, FLT3 and IDH inhibitors are now available to patients randomized to the control arm where 32% of these patients (12/38) have received a targeted agent. Of those patients receiving a targeted agent, 92% of these patients (11/12) received the Bcl-2 inhibitor venetoclax with either a hypomethylating agent or low-dose cytarabine. The remission rate for patients receiving venetoclax combination was 27% (3/11) and its inclusion did not materially improve the 18% remission rate (7/38) for the control arm at the fifty percent when compared to the 21% (4/19) remission rate observed at the twenty-five percent interim analysis. Of the patients who failed the primary endpoint in the control arm (31/28), 20 were eligible to cross over to the study arm and will be excluded from the primary endpoint analysis. All cross over patients (20/20) received a BMT after receiving Iomab-B, with a median time to BMT of 64 days and all patients achieved neutrophil and platelet engraftment in a median time of 17 days despite high median blast count of 35% at time of cross over.

In addition to the universal engraftment rate in patients receiving a therapeutic dose of Iomab-B, there was a very low incidence of non-relapse transplant related mortality at day-100 with one patient reported from the 31 patients receiving a therapeutic dose in the Iomab-B arm. By comparison, the number of evaluable patients in the control arm for the primary endpoint was 5 after accounting for two patients that experienced non-relapse transplant related mortality by day-100.

A poster reporting the single-agent activity of Iomab-B in the first twenty five percent of patients in the SIERRA trial was presented at ASCO or the American Society of Clinical Oncology annual Meeting in June 2019. A strong anti-leukemic effect was observed from single agent Iomab-B in the 16 patients for whom data was available with a median reduction in peripheral blasts by day 3 following Iomab-B administration of 98% and 100% by day 8, prior to any other pre-BMT conditioning. Clearance of peripheral blasts is necessary for BMT to be successful and has been reported as being an independent prognostic marker that is predictive of both Complete Response and Relapse-Free Survival.

Our targeted conditioning portfolio also includes the Actimab-MDS program for BMT conditioning for patients with high-risk MDS or myelodysplastic syndrome and the Iomab-ACT program for lymphodepletion prior to CAR-T or other adoptive cell therapies. Actimab-MDS is an ARC comprised of the anti-CD33 monoclonal antibody lintuzumab linked to the radioisotope Ac-225 or actinium-225. We have reached agreement with the FDA or U.S. Food and Drug Administration that Actimab-MDS be a pivotal program that will include a Phase 1 clinical trial that will be followed by a randomized pivotal trial that can be the basis for a BLA or Biologics License Application. We are currently working to finalize the protocol for these studies with the FDA. Upon finalization of the protocols, we intend to begin the Phase 1 clinical trial at up to four clinical trials sites with an estimated enrollment of eighteen patients. Our Iomab-ACT program will utilize a lower dose of Iomab-B (apamistamab – I-131) that we intend to be a universal lymphodepletion regimen for CAR-T and other adoptive cell therapies. We have completed preclinical *in vitro* and *in vivo* studies to evaluate the Iomab-ACT program's ability to target and deplete CD45 positive immune cells. These studies, which were presented at the TCT Annual Meeting in February 2019 and at the SNMMI or Society of Nuclear Medicine and Molecular Imaging Annual Meeting in June 2019, supported the advancement of the Iomab-ACT into human clinical studies. We are currently evaluating CAR-T constructs and conducting negotiations with potential collaborators that will study our Iomab-ACT program in combination with a select CAR-T. We intend to conduct a Phase 1 clinical trial designed to demonstrate the safety of Iomab-ACT based lymphodepletion and evaluate the depletion of the patient's cancer cells and lymphocytes as well as response rates and survival outcomes of patients. The Actimab-MDS and Iomab-ACT targeting conditioning programs leverage our experiences and knowledge gained from developing Iomab-B and execution of the SIERRA trial at many of the leading BMT centers in the U.S. and Canada.

Our CD33 program is studying the ARC comprised of the monoclonal antibody lintuzumab and the radioisotope Ac-225 as a single agent or in combination with other therapeutic modalities such as chemotherapy, targeted agents or immunotherapy. We intend to advance selected CD33 ARC trials with the goal of generating clinical proof of concept data as efficiently as possible. The Phase 1 combination trial Actimab-A plus CLAG-M is studying our CD33 ARC with the salvage chemotherapy regimen CLAG-M (cladribine, cytarabine, filgrastim and mitoxantrone) for patients with relapsed or refractory AML. This is an investigator-initiated trial at the Medical College of Wisconsin where we are responsible for providing drug product and ancillary support. Interim results from the Actimab-A CLAG-M have been accepted for presentation at the 2019 ASH or American Society of Hematology Annual Meeting in December 2019. Interim results presented in the accepted ASH abstract observed a complete remission rate of 83% of patients (5/6) receiving 0.50 uCi/kg of Actimab-A and CLAG-M in the second dosing cohort. The Medical College of Wisconsin reported a remission rate of 53% in relapsed or refractory patients treated at their institution with CLAG-M alone. It was also reported that 33% of patients (3/9) enrolled in the trial subsequently received a BMT. All patients completed the planned cycle of Actimab-A and CLAG-M with no mortalities observed on study. The study investigators reported that combining lower doses of Actimab-A and CLAG-M appear to have a clinically acceptable safety profile. We are also exploring the combination with our CD33 ARC and venetoclax, a BCL-2 inhibitor, for patients with relapsed or refractory AML. We believe our CD33 ARC can be potentiating when used with venetoclax. We have generated preclinical research that observed improved tumor regression and survival benefit with Actimab-A and venetoclax over venetoclax alone in animal studies, which we believe is attributed to a reduction in McI-1 and double-stranded DNA breaks caused by the targeted radiation from our CD33 ARC. The Actimab-M trial is studying our CD33 ARC as a single agent for patients with penta-refractory multiple myeloma. This Phase 1 trial is currently active at three clinical trial sites and we plan to add a fourth clinical trial site in the near future. We have elected to not advance a previously announced Phase 1 clinical trial with our CD33 ARC for patients with post-remission MRD or minimal residual disease positive AML at this time to better focus our energy and resources on the SIERRA trial. We will revisit this decision periodically and potentially reinitiate the trial at an appropriate time.

Our research and development efforts include the advancement of our AWE technology platform. Ongoing activities with our AWE technology platform include the completion of preclinical *in vitro* and *in vivo* studies of novel ARCs and ARC combinations, prosecution of patents and other intellectual property, evaluating novel radioisotope supply and supporting our ongoing collaboration with Astellas. Actinium's clinical programs and AWE technology platform are covered by a portfolio of over 100 patents with a useful life extending as far out as 2039 that cover composition of matter, formulations, methods of use, the DOTA linker technology for actinium-225 applications and methods of manufacturing the actinium-225 radioisotope in a cyclotron.

We have never generated revenue. Currently we do not have a recurring source of revenues to cover our operating costs. We have incurred net losses and negative operating cash flows since inception. As of September 30, 2019 and December 31, 2018, our accumulated deficit was \$204.2 million and \$186.9 million, respectively. Our net loss was \$17.3 million for the nine months ended September 30, 2019 and 2018. These conditions raise substantial doubt as to our ability to continue as a going concern. As of September 30, 2019, we had a balance of cash and cash equivalents of \$14.3 million. Our consolidated financial statements are prepared using Generally Accepted Accounting Principles in the United States of America applicable to a going concern, which contemplates the realization of assets and the satisfaction of liabilities in the normal course of business. The accompanying consolidated financial statements do not include any adjustments relating to the recoverability and classification of recorded asset amounts and classification of liabilities should we be unable to continue as a going concern. As of the date of filing this report, we expect that our existing resources will be sufficient to fund our planned operations into the third quarter of 2020; additional capital resources will be needed to fund operations longer-term. If we are unsuccessful in accomplishing our plans, we may have to delay or terminate existing and/or planned clinical trials and other related activity, which could have a material adverse impact on our business. Our plan to continue as a going concern includes obtaining capital from the sale of our equity securities, fees from licensing one or more of our product candidates, additional collaborations with our Iomab-ACT program and AWE technology platform, and short-term borrowings from banks, stockholders or other related parties, if needed. However, we cannot provide any assurance that we will be successful in accomplishing any of our plans. Our ability to continue as a going concern is dependent upon our ability to successfully accomplish the plans described above and eventually to secure other sources of financing and attain profitable operations.

Results of Operations – Three Months Ended September 30, 2019 Compared to Three Months Ended September 30, 2018

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

	For the Three Months Ended September 30,	
	2019	2018
Revenue	\$ -	\$ -
Operating expenses:		
Research and development, net of reimbursements	4,829,874	4,227,036
General and administrative	1,822,506	1,970,230
Total operating expenses	<u>6,652,380</u>	<u>6,197,266</u>
Other income:		
Interest income – net	53,054	49,177
Total other income	<u>53,054</u>	<u>49,177</u>
Net loss	<u>\$ (6,599,326)</u>	<u>\$ (6,148,089)</u>

Revenue

We recorded no commercial revenue for the three months ended September 30, 2019 and 2018.

Research and Development Expense

In March 2018, we entered into a research and option agreement with Astellas to develop Actinium-225 Radio-Conjugates, or ARCs, using our Actinium Warhead Enabling, or AWE, Platform Technology. Under this collaboration, we will utilize our AWE Platform to conjugate and label selected Astellas targeting agents with an Actinium-225 payload. We will also be responsible for conducting preclinical validation studies on any ARCs generated.

Research and development expenses increased \$0.6 million to \$4.8 million for the three months ended September 30, 2019 compared to \$4.2 million for the three months ended September 30, 2018. The increase was due to higher expenses on our CD45 program and higher compensation expense.

General and Administrative Expenses

General and administrative expenses of \$1.8 million for the three months ended September 30, 2019 decreased \$0.2 million compared to \$2.0 million for the three months ended September 30, 2018, primarily attributable to lower professional fees and lower compensation expense relating to stock option compensation.

Other Income

Other income is comprised of net interest income in both reporting periods. The amount for the three months ended September 30, 2019 of \$53 thousand was virtually unchanged compared to \$49 thousand for the three months ended September 30, 2018.

Results of Operations – Nine Months Ended September 30, 2019 Compared to Nine Months Ended September 30, 2018

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

	For the Nine Months Ended September 30,	
	2019	2018
Revenue	\$ -	\$ -
Operating expenses:		
Research and development, net of reimbursements	13,176,033	12,023,109
General and administrative	4,261,939	5,440,656
Total operating expenses	<u>17,437,972</u>	<u>17,463,765</u>
Other income:		
Interest income – net	141,353	129,549
Total other income	<u>141,353</u>	<u>129,549</u>
Net loss	<u>\$ (17,296,619)</u>	<u>\$ (17,344,216)</u>

Revenue

We recorded no commercial revenue for the nine months ended September 30, 2019 and 2018.

Research and Development Expense

Research and development expenses increased \$1.2 million to \$13.2 million for the nine months ended September 30, 2019 compared to \$12.0 million for the nine months ended September 30, 2018, primarily attributable to higher expenses on our CD45 program and higher compensation expense, partially offset by lower expenses on our CD33 program.

General and Administrative Expenses

General and administrative expenses of \$4.3 million for the nine months ended September 30, 2019 decreased \$1.1 million compared to \$5.4 million for the nine months ended September 30, 2018, primarily attributable to lower professional fees.

Other Income

Other income, resulting from net interest income, for the nine months ended September 30, 2019 was \$141 thousand, compared to \$130 thousand recorded for the nine months ended September 30, 2018.

Liquidity and Capital Resources

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

	For the Nine Months Ended September 30	
	2019	2018
Cash used in operating activities	\$ (16,451,010)	\$ (16,284,173)
Cash used in investing activities	(59,488)	(85,522)
Cash provided by financing activities	17,158,129	13,815,586
Net change in cash, cash equivalents and restricted cash	\$ 647,631	\$ (2,554,109)

Net cash used in operating activities for the nine months ended September 30, 2019 of \$16.5 million increased by \$0.2 million from \$16.3 million in the prior-year period, primarily due to the timing of payments to vendors.

Net cash provided by financing activities was \$17.2 million for the nine months ended September 30, 2019, reflecting \$15.9 million from the sale of common stock and warrants and \$1.5 million in proceeds from the exercise of warrants, partially offset by payments on our note payable and finance leases. During the nine months ended September 30, 2018, we received net proceeds of \$13.8 million from the sale of our common stock and warrants.

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, or 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, 2018.

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.

Research and Development Costs

Research and development costs are expensed as incurred. 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 -

Historically, we accounted for certain instruments, which do not have fixed settlement provisions, as derivative instruments in accordance with FASB ASC 815-40, *Derivative and Hedging – Contracts in Entity's Own Equity*. This was due to an anti-dilution provision for the warrants that provides for a reduction to the exercise price if we issue equity or equity-linked instruments in the future at an effective price per share less than the exercise price then in effect for the warrant ("down round provision"). As such, the warrants were re-measured at each balance sheet date based on estimated fair value. Changes in estimated fair value were recorded as non-cash adjustments within other income (expense), net, in our Consolidated Statements of Operations.

In July 2017, the Financial Accounting Standards Board, or FASB, issued ASU No. 2017-11, *Earnings Per Share (Topic 260); Distinguishing Liabilities from Equity (Topic 480); Derivatives and Hedging (Topic 815): (Part I) Accounting for Certain Financial Instruments with Down Round Features*. These amendments simplify the accounting for certain financial instruments with down-round features. The amendments require companies to disregard the down-round feature when assessing whether the instrument is indexed to its own stock, for purposes of determining liability or equity classification. The guidance was adopted as of April 1, 2018 and did not have a significant impact to our financial statements.

In February 2016, FASB issued ASU No. 2016-02 *Leases (Topic 842)*, which created new accounting and reporting guidelines for leasing arrangements. The standard requires that a lessee recognize the assets and liabilities that arise from operating leases. A lessee should recognize on its balance sheet a liability to make lease payments (the lease liability) and a right-of-use asset representing its right to use the underlying asset for the lease term. The guidance in ASU 2016-02 is effective for annual and interim reporting periods beginning after December 15, 2018. In July 2018, FASB issued ASU No. 2018-11, *Leases (Topic 842) -Targeted Improvements*, providing an optional transition method that allows entities to initially apply the new leases standard at the adoption date and we adopted this Standard effective January 1, 2019, see footnote 3.

In June 2018, FASB issued ASU 2018-07 to expand the scope of ASC Topic 718, *Compensation - Stock Compensation*, to include share-based payment transactions for acquiring goods and services from nonemployees. The standard is effective for fiscal years, and for interim periods within those fiscal years, beginning after December 15, 2018, with early adoption permitted. We adopted this Standard effective January 1, 2019. There was no material impact on our financial statements.

Recent Accounting Standards –

In August 2018, FASB issued ASU 2018-13, *Fair Value Measurement - Disclosure Framework (Topic 820)*. The updated guidance improves the disclosure requirements on fair value measurements and is effective for fiscal years, and interim periods within those fiscal years, beginning after December 15, 2019. Early adoption is permitted upon issuance of the standard for disclosures modified or removed with a delay of adoption of the additional disclosures until their effective date. We are in the process of evaluating the impact the standard will have on our financial statements.

In November 2018, FASB issued ASU 2018-18, *Collaborative Arrangements (Topic 808): Clarifying the Interaction Between Topic 808 and Topic 606*, which, among other things, provides guidance on how to assess whether certain collaborative arrangement transactions should be accounted for under Topic 606. The amendments in this ASU are effective for fiscal years, and interim periods within those fiscal years, beginning after December 15, 2019, with early adoption permitted. We are in the process of evaluating the impact the standard will have on our financial statements.

ITEM 3. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK.

We are not currently exposed to significant market risk related to changes in interest rates. As of September 30, 2019, our cash equivalents consisted of primarily of short-term money market funds. Our primary exposure to market risk is interest rate sensitivity, which is affected by changes in the general level of U.S. interest rates. Due to the short-term nature of the cash equivalents in our portfolio and the low risk profile of our cash equivalents, an immediate 10% change in interest rates would not have a material effect on the fair market value of our financial position or results of operations.

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

Inflation generally affects us by increasing our cost of labor and clinical trial costs. We do not believe that inflation had a material effect on our business, financial condition or results of operations during the nine months ended September 30, 2019 and 2018.

ITEM 4. CONTROLS AND PROCEDURES.

Evaluation of Disclosure Controls and Procedures. Under the supervision and with the participation of our management, including our chief executive officer and principal financial and accounting officer, we conducted an evaluation of the effectiveness, as of September 30, 2019, 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 chief executive officer and principal financial and accounting officer have concluded that, as of September 30, 2019, 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 chief 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, 2018. 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.

Risks Related to Our Business

Recurring losses and negative cash flows from operations raise substantial doubt about our ability to continue as a going concern and we may not be able to continue as a going concern.

Our recurring losses from operations and negative cash flows from operations raise substantial doubt about our ability to continue as a going concern. Substantial doubt about our ability to continue as a going concern may create negative reactions to the price of the common shares of our stock and we may have a more difficult time obtaining financing.

We have prepared our financial statements on a going concern basis, which contemplates the realization of assets and the satisfaction of liabilities and commitments in the normal course of business. The financial statements do not include any adjustments relating to the recoverability and classification of recorded asset amounts or amounts of liabilities that might be necessary should we be unable to continue in existence.

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

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

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

We are not profitable and have incurred losses in each period since our inception. As of September 30, 2019 and December 31, 2018, we had an accumulated deficit of \$204.2 million and \$186.9 million, respectively. We reported a net loss of \$17.3 million for the nine months ended September 30, 2019 and 2018. 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.

We do not currently have sufficient funding for the completion of development nor commercialization of our product candidates and we will need to continue to seek capital from time to time to continue development of our product candidates and to acquire and develop other product candidates. Our first product candidate is not expected to be commercialized, if approved, until at least 2021 and any partnering revenues that it may generate may not be sufficient to fund our ongoing operations. Any partnering revenues generated by licensing activities may not be sufficient to fund ongoing operations. Further, our other product candidates are not expected to be approved for several years and may not generate sufficient revenues from our licensing and commercialization efforts to fund operations.

Presently, with no further source of capital either via a financing or a collaboration, we project that we may run out of funds in 2020. We currently do not have any additional source of capital secured. If we are unable to raise additional funds, we could be required to reduce our spending plans, reduce our workforce, license one or more of our products or technologies that we would otherwise seek to commercialize ourselves, sell all or some of our assets, cease operations or even declare bankruptcy. We will require additional cash in order to maximize the commercial opportunity and continue clinical development of our product candidates. Alternatives available to us to sustain our operations include collaborative agreements, equity financing, debt and other financing arrangements with potential corporate partners and other sources. However, there can be no assurance that any such collaborative agreements or other sources of funding will be available to us on favorable terms, if at all.

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

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

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

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

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

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

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

Iomab-B, which we licensed from the Fred Hutchinson Cancer Research Center, 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 trial's DMC or Data Monitoring Committee 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.

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 Biologics License Application (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, manufacturing 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.

We currently have two product candidates in clinical development. In December 2015, the FDA cleared our IND filing for Iomab-B, and we are currently enrolling patients in a randomized, controlled, pivotal, Phase 3 clinical trial. Assuming the trial meets its endpoints, it will form the basis for a BLA. Additionally, there are physician IND trials at the FHCRC that have been conducted or are currently ongoing at FHCRC with Iomab-B and the BC8 antibody we licensed. We have multiple clinical trials ongoing for our drug candidates under our own sponsorship and multiple investigator-initiated trials ongoing.

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 institutional review boards (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 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. 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. In addition, 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, these data may not be predictive of the results of any future clinical trials.

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, lintuzumab-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

We have dedicated research and development activities towards improving Iomab-B's stability to enhance commercial usefulness of the product and now have a proprietary formulation for which IP is pending. 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 Iomab-B and Actimab-A. 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.

For our CD33 program, lintuzumab-Ac225, we have pursued a broad strategy of key patent filings and anticipated regulatory protections in the US and abroad to protect this asset and its use. Our final drug construct consists of the lintuzumab antibody labeled with the alpha radioisotope Ac225. We have licensed issued patents that relate to the linker technology we use to conjugate the isotope to the antibody. We also own issued and pending patents related to Ac225 isotope production methods and drug preparation methods. Furthermore, we have pending patent applications covering methods of use in the treatment of disease, including therapeutic combinations, and for targeted conditioning in preparation for cell therapy such as bone marrow transplant, which may provide protection to 2039. This approach, we believe, provides important intellectual property protection given that key patents related to the humanized antibody, lintuzumab, which we use in our CD33 program product candidates have expired. While it is possible that others may eventually use an antibody with the same sequence, we believe that our pending patent portfolio will provide protection within critical areas of clinical focus. In addition, we possess trade secrets and know-how related to the manufacturing and use of antibody radio-conjugates including lintuzumab-Ac225. Any potentially competing product based on the lintuzumab antibody is also likely to require several years of development before achieving our product candidate's current status and may be subject to significant regulatory hurdles. Nevertheless, the development of such a molecule remains a possibility and could negatively impact our business in the future.

The indications for which we are developing our product candidates for are orphan drug designations, which are disease indications that affect fewer than 200,000 patients in the United States and less than 5 in 10,000 patients in the European Union ("EU"). We have received orphan drug designation for Iomab-B and our lintuzumab-CD33 ARC for patients with AML in both the United States and the EU. As a result, if our products are to be approved, they may receive 7 years and 10 years of market exclusivity in the US and EU, respectively. In addition, our product candidates are biologics combined with radioisotopes. The Hatch-Waxman Act requires that a manufacturer of generic drugs, which for a biologic drug is called a biosimilar, requires that the manufacturer demonstrate bioequivalence. We believe that due to the nature of radioisotopes having half-lives combined with the complexities of biologic drugs it would be difficult for a manufacturer to demonstrate bioequivalence of our product candidates.

Our CD33 program clinical trials are testing the same drug construct

Our CD33 program is comprised of several clinical trials including several investigator-initiated trials including AML, MDS and Multiple Myeloma 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 lintuzumab-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, or 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 Department of Energy, 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 2019. 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 Actimab-A clinical trials would adversely affect our business and prospects and could cause us to cease operations.

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 pre-clinical and 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.

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 risk evaluation and mitigation strategy 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 cGCPs 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.

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 depend on third-party manufacturers to produce our pre-clinical and clinical trial drug supplies.

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. 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 contract manufacturer 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 they 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. 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 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.

We may be subject, directly or indirectly, to federal and state healthcare fraud and abuse laws, false claims laws, and health information privacy and security laws. If we are unable to comply, or have not fully complied, with such laws, we could face substantial penalties.

If we obtain FDA approval for any of our product candidates and begin commercializing those products in the United States, our operations may be directly, or indirectly through our customers, subject to various federal and state fraud and abuse laws, including, without limitation, the federal Anti-Kickback Statute, the federal False Claims Act, and physician sunshine laws and regulations. These laws may impact, among other things, our proposed sales, marketing, and education programs. In addition, we may be subject to patient privacy regulation by both the federal government and the states in which we conduct our business. The laws that may affect our ability to operate include:

- the federal Anti-Kickback Statute, which prohibits, among other things, persons from knowingly and willfully soliciting, receiving, offering or paying remuneration, directly or indirectly, to induce, or in return for, the purchase or recommendation of an item or service reimbursable under a federal healthcare program, such as the Medicare and Medicaid programs;
- federal civil and criminal false claims laws and civil monetary penalty laws, which prohibit, among other things, individuals or entities from knowingly presenting, or causing to be presented, claims for payment from Medicare, Medicaid, or other third-party payors that are false or fraudulent;
- the federal Health Insurance Portability and Accountability Act of 1996, or HIPAA, which created federal criminal statutes that prohibit executing a scheme to defraud any healthcare benefit program and making false statements relating to healthcare matters;
- HIPAA, as amended by the Health Information Technology and Clinical Health Act, or HITECH, and its implementing regulations, which imposes certain requirements relating to the privacy, security, and transmission of individually identifiable health information;
- the federal physician sunshine requirements under PPACA, which require certain manufacturers of drugs, devices, biologics, and medical supplies to report annually to the U.S. Department of Health and Human Services information related to payments and other transfers of value to physicians, other healthcare providers, and teaching hospitals, and ownership and investment interests held by physicians and other healthcare providers and their immediate family members and applicable group purchasing organizations;
- state law equivalents of each of the above federal laws, such as anti-kickback and false claims laws that may apply to items or services reimbursed by any third-party payor, including commercial insurers; state laws that require pharmaceutical companies to comply with the industry's voluntary compliance guidelines and the relevant compliance guidance promulgated by the federal government, or otherwise restrict payments that may be made to healthcare providers and other potential referral sources; state laws that require drug manufacturers to report information related to payments and other transfers of value to physicians and other healthcare providers or marketing expenditures; and state laws governing the privacy and security of health information in certain circumstances, many of which differ from each other in significant ways, thus complicating compliance efforts.

Because of the breadth of these laws and the narrowness of the statutory exceptions and safe harbors available, it is possible that some of our business activities could be subject to challenge under one or more of such laws. In addition, recent health care reform legislation has strengthened these laws. For example, the PPACA, among other things, amends the intent requirement of the federal anti-kickback and criminal healthcare fraud statutes. A person or entity no longer needs to have actual knowledge of this statute or specific intent to violate it to have committed a violation. Moreover, the PPACA provides that the government may assert that a claim including items or services resulting from a violation of the federal Anti-Kickback Statute constitutes a false or fraudulent claim for purposes of the False Claims Act.

If our operations are found to be in violation of any of the laws described above or any other governmental regulations that apply to us, we may be subject to penalties, including civil and criminal penalties, damages, fines, exclusion from participation in government health care programs, such as Medicare and Medicaid, imprisonment, and the curtailment or restructuring of our operations, any of which could adversely affect our ability to operate our business and our results of operations.

Recent federal legislation will increase pressure to reduce prices of pharmaceutical products paid for by Medicare, which could materially adversely affect our revenue, if any, and our results of operations.

In the United States, the Medicare Prescription Drug, Improvement, and Modernization Act of 2003, also called the MMA, changed the way Medicare covers and pays for pharmaceutical products. The legislation expanded Medicare coverage for drug purchases by the elderly and introduced a new reimbursement methodology based on average sales prices for physician-administered drugs. In addition, this legislation provided authority for limiting the number of drugs that will be covered in any therapeutic class. As a result of this legislation and the expansion of federal coverage of drug products, we expect that there will be additional pressure to reduce costs. These cost reduction initiatives and other provisions of this legislation could decrease the scope of coverage and the price that we receive for any approved products and could harm our business. While the MMA applies only to drug benefits for Medicare beneficiaries, private payors often follow Medicare coverage policies and payment limitations in setting their own reimbursement rates, and any reduction in reimbursement that results from the MMA may cause a similar reduction in payments from private payors. This legislation may pose an even greater risk to our drug candidates as a significant portion of the target patient population for our drug candidates would likely be over 65 years of age and, therefore, many such patients will be covered by Medicare.

In March 2010, the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Affordability Reconciliation Act, or collectively, the PPACA, became law in the United States. The goal of the PPACA is to reduce the cost of healthcare and substantially change the way healthcare is financed by both governmental and private insurers. While we cannot predict what impact on federal reimbursement policies this legislation will have in general or on our business specifically, the PPACA may result in downward pressure on pharmaceutical reimbursement, which could negatively affect market acceptance of our drug candidates, if approved, or any of our future products. In 2012, members of the U.S. Congress and some state legislatures sought to overturn certain provisions of the PPACA including those concerning the mandatory purchase of insurance. However, on June 28, 2012, the United States Supreme Court upheld the constitutionality of these provisions. Members of the U.S. Congress have since proposed a number of legislative initiatives, including possible repeal of the PPACA. We cannot predict the outcome or impact of current proposals or whether new proposals will be made or adopted, when they may be adopted or what impact they may have on us if they are adopted. These challenges add to the uncertainty of the legislative changes as part of ACA. Changes that may affect our business include those governing enrollment in federal healthcare programs, reimbursement changes, fraud and abuse and enforcement. These changes will impact existing government healthcare programs and will result in the development of new programs, including Medicare payment for performance initiatives and improvements to the physician quality reporting system and feedback program.

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 considered a Penny Stock.

During the first nine months of 2019, and for the years of 2018, 2017 and 2016, the price of our common stock has traded below \$5.00 per share, and therefore is treated as a penny stock. Penny stocks generally are equity securities with a price of less than \$5.00. Penny stock rules require a broker-dealer, prior to a transaction in a penny stock not otherwise exempt from the rules, to deliver a standardized risk disclosure document that provides information about penny stocks and the risks in the penny stock market. The broker-dealer also must provide the customer with current bid and offer quotations for the penny stock, the compensation of the broker-dealer and its salesperson in the transaction, and monthly account statements showing the market value of each penny stock held in the customer's account. The broker-dealer must also make a special written determination that the penny stock is a suitable investment for the purchaser and receive the purchaser's written agreement to the transaction. These requirements may have the effect of reducing the level of trading activity, if any, in the secondary market for a security that becomes subject to the penny stock rules. The additional burdens imposed upon broker-dealers by such requirements may discourage broker-dealers from effecting transactions in our securities, which could severely limit their market price and liquidity of our securities. These requirements may restrict the ability of broker-dealers to sell our common stock and may affect your ability to resell our common stock.

We may be required to effectuate a reverse stock split to be able to maintain compliance with applicable listing requirements or standards of the NYSE AMERICAN exchange or our common stock could get delisted.

If our stock trades at a depressed valuation for an extended period of time, we may be required to effectuate a reverse stock split to maintain compliance with NYSE American listing requirements, or we could be delisted from the exchange. In addition, we may elect to seek approval for and if authorized, effectuate a reverse stock split to increase the price of our common stock so that our stock is no longer considered a penny stock and to make our stock more marketable to institutional investors that cannot buy stocks below certain prices.

In order to effectuate a reverse split, we would be required to obtain shareholder approval at a meeting of shareholders. We would also need the approval of the Financial Regulatory Authority (FINRA) to effectuate a stock split. There is no guarantee that we would be successful in obtaining the necessary approval from FINRA or the votes required to reach a quorum to hold a meeting or to authorize our Board of Directors to approve a reverse stock split. To conduct a meeting of shareholders we would have to file and issue the required proxy information and materials, which could take a significant amount of time. It is possible that during the proxy solicitation process our stock would be delisted before we could obtain the necessary authorization for our Board of Directors to approve a reverse split to regain compliance with NYSE AMERICAN listing requirement.

If we fail to maintain compliance with NYSE American listing requirements and our stock is delisted, the market price and liquidity of our common stock could be adversely impacted. This may also reduce our ability to raise additional capital. Even if we are successful in obtaining authorization and our Board of Directors approves a reverse stock split, there can be no assurance that institutional investors will buy shares of our common stock. There can be no assurance that our common stock can maintain its post-reverse split price and it may be treated as a penny stock. In the event, that our common stock is delisted from the NYSE AMERICAN or another national securities exchange, trading of our common stock could occur in the over-the-counter market or on an electronic bulletin board established for unlisted securities such as the OTC Bulletin Board or Pink Sheets. This could result in adverse impact on the market price and liquidity of our common stock, a reduction in coverage by security analysts and impair our ability to raise additional capital, all of which could cause the price of our common stock to decline.

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. 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, 2018 and 2017 and while our testing did not reveal any material weaknesses in our internal controls, subsequent testing by our independent registered public accounting firm may reveal material weaknesses in our internal controls that we would be required to remediate in a timely manner so as to be able to comply with the requirements of Section 404 of the Sarbanes-Oxley Act each year. If we are not able to comply with the requirements of Section 404 of the Sarbanes-Oxley Act 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.

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
31.1	Certification of the Principal 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 Principal 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.

Date: November 12, 2019

ACTINIUM PHARMACEUTICALS, INC.

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
Principal Financial Officer
(Duly Authorized Officer and
Principal Financial and Accounting Officer)

**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. The Registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(c) 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. The Registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):
 - a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
 - b) Any fraud, whether or not material, that involved management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: November 12, 2019

By: /s/ Sandesh Seth
Sandesh Seth
Chairman & CEO
(Duly Authorized Officer and
Principal Executive Officer)

**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. The Registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 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. The Registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):
 - a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
 - b) Any fraud, whether or not material, that involved management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: November 12, 2019

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

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

In connection with the Quarterly Report of Actinium Pharmaceuticals, Inc. (the "Company") on Form 10-Q for the period ended September 30, 2019 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: November 12, 2019

By: /s/ Sandesh Seth
Sandesh Seth
Chairman & CEO
(Duly Authorized Officer and
Principal Executive Officer)

**CERTIFICATION OF PRINCIPAL FINANCIAL AND ACCOUNTING OFFICER
PURSUANT TO
18 U.S.C. SECTION 1350,
AS ADOPTED PURSUANT TO
SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002**

In connection with the Quarterly Report of Actinium Pharmaceuticals, Inc. (the "Company") on Form 10-Q for the period ended September 30, 2019 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, Steve O'Loughlin, Principal 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: November 12, 2019

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