Actinium Pharmaceuticals, Inc.
Form 10-Q
August 09, 2018

UNITED STATES

SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 10-Q

(Mark One)

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

For the quarterly period ended **June 30, 2018**

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

(646) 677-3870

(Registrant's Telephone Number, Including Area Code)

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

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 and posted on its corporate Web site, if any, every Interactive Data File required to be submitted and posted 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 and post such files). Yes No

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, smaller reporting company, or an emerging growth company. See the definitions of "large accelerated filer," "accelerated filer," "smaller reporting company," and "emerging growth company" in Rule 12b-2 of the Exchange Act.

Large accelerated filer	Accelerated filer
Non-accelerated filer	Smaller reporting company
(Do not check if a smaller reporting company)	Emerging growth company

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

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

Indicate the number of shares outstanding of each of the issuer's classes of common stock, as of August 9, 2018: 110,463,453.

Actinium Pharmaceuticals, Inc.

FORM 10-Q

For the Six months ended June 30, 2018

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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 June 30, 2018 and December 31, 2017, and the results of operations and cash flows for the three months and six months ended June 30, 2018 and 2017, 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, 2017 in the Company's Annual Report on Form 10-K. The results of operations for the six months ended June 30, 2018 are not necessarily indicative of the operating results for the full year.

Actinium Pharmaceuticals, Inc.

Consolidated Balance Sheets

(Unaudited)

	June 30, 2018	December 31, 2017
Assets		
Current Assets:		
Cash and cash equivalents	$21,474,264	$17,399,636
Restricted cash – current	40,034	-
Prepaid expenses and other current assets	570,034	439,322
Total Current Assets	22,084,332	17,838,958
Property and equipment, net of accumulated depreciation of $240,440 and $215,660, respectively	59,381	57,350
Security deposit	49,859	49,859
Restricted cash	390,940	390,940
Total Assets	$22,584,512	$18,337,107
Liabilities and Stockholders' Equity		
Current Liabilities:		
Accounts payable and accrued expenses	$5,266,219	$4,650,088
Derivative liabilities	-	15,916
Total Current Liabilities	5,266,219	4,666,004
Total Liabilities	5,266,219	4,666,004
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; 400,000,000 shares authorized; 110,458,121 and 80,072,334 shares issued and outstanding, respectively	110,458	80,072
Additional paid-in capital	191,597,237	176,744,068
Accumulated deficit	(174,389,402)	(163,153,037)
Total Stockholders' Equity	17,318,293	13,671,103
Total Liabilities and Stockholders' Equity	$22,584,512	$18,337,107

See accompanying notes to the consolidated financial statements.

Actinium Pharmaceuticals, Inc.

Consolidated Statements of Operations

(Unaudited)

	For the Three Months Ended June 30,		For the Six Months Ended June 30,	
	2018	2017	2018	2017
Revenue	$-	$-	$-	$-
Operating expenses:				
Research and development, net of reimbursements	3,325,228	4,448,198	7,788,197	9,021,700
General and administrative	1,574,776	2,740,767	3,453,522	5,951,933
Depreciation expense	12,816	14,335	24,780	35,255
Total operating expenses	4,912,820	7,203,300	11,266,499	15,008,888
Loss from operations	(4,912,820)	(7,203,300)	(11,266,499)	(15,008,888)
Other income (expense):				
Interest income	50,030	-	80,372	-
Gain (loss) on change in fair value of derivative liabilities	-	149,592	-	(106,403)
Total other income (expense)	50,030	149,592	80,372	(106,403)
Net loss	$(4,862,790)	$(7,053,708)	$(11,186,127)	$(15,115,291)
Net loss per common share – basic and diluted	$(0.04)	$(0.12)	$(0.11)	$(0.26)
Weighted average common shares outstanding – basic and diluted	110,363,370	58,184,534	99,459,614	57,045,036

See accompanying notes to the consolidated financial statements.

Actinium Pharmaceuticals, Inc.

Consolidated Statements of Cash Flows

(Unaudited)

	For the Six Months Ended June 30,	
	2018	2017
Cash Flows From Operating Activities:		
Net loss	$(11,186,127)	$(15,115,291)
Adjustments to reconcile net loss to net cash used in operating activities:		
Stock-based compensation expense	1,005,764	2,172,279
Depreciation expense	24,780	35,255
Loss on change in fair value of derivative liabilities	-	106,403
Changes in operating assets and liabilities:		
(Increase) decrease in:		
Prepaid expenses and other current assets	(130,712)	826,824
Increase (decrease) in:		
Accounts payable and accrued expenses	616,131	(590,295)
Accounts payable and accrued expenses-related party	-	50,000
Net Cash Used In Operating Activities	(9,670,164)	(12,514,825)
Cash Flows From Investing Activities:		
Purchase of property and equipment	(26,811)	(16,710)
Net Cash Used In Investing Activities	(26,811)	(16,710)
Cash Flows From Financing Activities:		
Sales of shares of common stock and warrants, net of offering costs	13,810,737	3,824,605
Proceeds from exercise of warrants	900	-
Net Cash Provided By Financing Activities	13,811,637	3,824,605
Net change in cash, cash equivalents, and restricted cash	4,114,662	(8,706,930)
Cash, cash equivalents, and restricted cash at beginning of period	17,790,576	20,554,027
Cash, cash equivalents, and restricted cash at end of period	$21,905,238	$11,847,097
Supplemental disclosures of cash flow information:		
Cash paid for interest	$-	$-
Cash paid for taxes	$-	$-

See accompanying notes to the consolidated financial statements.

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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 focused on developing and potentially commercializing targeted therapies for improved conditioning of the bone marrow prior to a bone marrow transplant and for the targeting and killing of cancer cells. The Company is currently conducting multiple clinical trials for two Antibody Radio-Conjugate ("ARC") product candidates in the areas of targeted conditioning and CD33 expressing hematologic indications. The Company is also performing research on other potential drug candidates utilizing our proprietary Actinium Warhead Enabling (AWE) technology platform, which utilizes the alpha-emitting particle actinium-225 (Ac-225) in combination with targeting agents.

The Company's most advanced targeted conditioning product candidate, Iomab-B, is comprised of the anti-CD45 monoclonal antibody, apamistamab, labeled with iodine-131 (I-131). The Company is currently conducting a Phase 3 trial, SIERRA (Study of Iomab-B in Relapsed or Refractory Acute Myeloid Leukemia), of Iomab-B for conditioning of the bone marrow prior to a bone marrow transplant, or BMT, for patients with relapsed or refractory acute myeloid leukemia, or AML, age 55 and older. The SIERRA trial reached 25% patient enrollment in June 2018. Upon successful completion of the Phase 3 clinical trial for Iomab-B the Company intends to submit for marketing approval in the U.S. and European Union. The Company has received guidance from the U.S. Food & Drug Administration, or FDA, as part of its Investigational New Drug filing, or IND, that it would be acceptable to file a Biologics License Application submission, or BLA, that includes the single, pivotal Phase 3 SIERRA clinical study if it is successful.

The Company's CD33 program ARC drug candidate is the anti-CD33 monoclonal antibody lintuzumab conjugated with the alpha-particle actinium-225 (Ac-225) that is being studied in multiple clinical trials. Actinium-225 is a potent alpha-particle isotope that is able to kill cells through double stranded breaks in a cell's DNA and there is no known resistance mechanism to Ac-225. The energy emitted by Ac-225 travels very short distances in the body and our targeted ARC approach is sparing of non-targeted cells. We believe this activity will result in improved safety and tolerability. This combination of high potency and safety of the lintuzumab-actinium-225 ARC facilitates its exploration in other diseases and indications that may not be feasible with some of the other modalities such as naked or bi-specific antibodies or antibody drug conjugates that are being used to target CD33 in AML. Actinium's CD33 targeting agent is the only one in development for multiple diseases and indications where CD33 is expressed including AML, myelodysplastic syndrome, or MDS and multiple myeloma. The ARC is currently being studied for targeted conditioning in our Actimab-MDS and Actimab-A CLAG-M trials and as a therapeutic in our Actimab-A, Actimab-M and Actimab-A MRD trials.

The most advanced CD33 program trial is the Actimab-A Phase 2 clinical trial for patients over the age of 60 who are newly diagnosed with AML and ineligible for intensive chemotherapy. Two Phase 1 investigator-initiated trials are also studying lintuzumab-Ac-225 in patients with AML. One, the Actimab-A CLAG-M trial is being conducted at the Medical College of Wisconsin in patients with relapsed or refractory ("r/r") AML in combination with CLAG-M, a salvage chemotherapy regimen comprised of cladribine, cytarabine, and filgrastim with mitoxantrone. The second trial, Actimab-A MRD is being conducted at Columbia University Medical Center as a single agent to target minimal residual disease as consolidation for patients who have achieved remission. The Company is also conducting the Phase 1 Actimab-M trial with lintuzumab-Ac-225 for patients with refractory multiple myeloma. The Company is planning a clinical trial as a targeting conditioning agent prior to a BMT for patients with high-risk MDS. The Company met with the FDA in June of 2018 and is engaged in discussions with the FDA on an acceptable pathway toward a BLA filing.

We are also developing our AWE Technology Platform with the goal of generating additional drug candidates that will progress in clinical trials and/or out-license. The Company intends to develop a number of products for numerous types of cancer and derive revenue from partnering relationships worldwide and/or direct sales of products primarily in the United States. In March 2018, Actinium entered into a collaborative research partnership with Astellas Pharma, Inc. ("Astellas"), whereby we will conjugate and label selected Astellas targeting agents with Ac-225 and will be responsible for conducting preclinical validation for these novel ARCs. In addition, we have labeled daratumumab, a CD38 targeting monoclonal antibody that is marketed by Johnson & Johnson as Darzalex™ for patients with multiple myeloma with Ac-225. We have studied Ac-225 labeled daratumumab in *in vitro* and *in vivo* preclinical studies and we intend to continue to progress our studies of this ARC. We are also focused on developing additional intellectual property for its technology platform.

As of August 2018, the Company's patent portfolio includes: 74 issued and pending patent applications, of which 11 are issued in the United States, 10 are pending in the United States, and 55 are issued internationally and pending internationally. Additionally, several non-provisional patent applications have and are expected to be filed in 2018 based on provisional patent applications filed in 2017 and 2018. This is part of an ongoing strategy to continue to strengthen Actinium's intellectual property position. Approximately one quarter of our patents are in-licensed from third parties and the remainder are Actinium-owned. These patents cover key areas of our business, including use of the Ac-225 and other alpha emitting isotopes attached to cancer specific carriers like monoclonal antibodies, methods for manufacturing key components of product candidates including Ac-225, the alpha emitting radioisotope and carrier antibodies, and methods of use and for manufacturing finished product candidates for use in cancer treatment.

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, 2017.

Principles of Consolidation - The consolidated financial statements include the Company's accounts and those of the Company's wholly owned subsidiaries. All significant intercompany accounts and transactions have been eliminated.

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 expenses during the reporting period. Actual results could differ from those estimates.

Cash and Cash Equivalents - 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.

Property and Equipment - Machinery and equipment are recorded at cost and depreciated on a straight-line basis over estimated useful lives of three years. Furniture and fixtures are recorded at cost and depreciated on a straight-line basis over estimated useful lives of three years. When assets are retired or sold, the cost and related accumulated depreciation are removed from the accounts, and any related gain or loss is reflected in operations. Repairs and maintenance expenditures are charged to operations.

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. As required by ASC 820 "*Fair Value Measurements and Disclosures"*, financial assets and liabilities are classified in their entirety based on the lowest level of input that is significant to the fair value measurement. The Company's assessment of the significance of a particular input to the fair value measurement requires judgment and may affect the valuation of fair value assets and liabilities and their placement within the fair value hierarchy levels.

Revenue Recognition - The Company adopted new accounting guidance for revenue recognition, effective January 1, 2018, which had no impact on the Company's financial statements. Beginning January 1, 2018, revenues are recognized when control of the promised goods or services is transferred to our customers in an amount that reflects the consideration we expect to be entitled to in exchange for those goods or services**.**

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

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

Net Loss Per Common Share - Basic loss per common share is computed by dividing the net loss available to common stockholders by the weighted average number of common shares outstanding during the reporting period. For the six months ended June 30, 2018 and 2017, respectively, 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.

	June 30, 2018	June 30, 2017
Options	5,800,742	6,988,886
Warrants	56,015,610	8,945,388
Total	61,816,352	15,934,274

Reclassifications - Certain reclassifications have been made to the prior-year financial statements to conform to the current-year presentation, including the addition of restricted cash to cash and cash equivalents on the consolidated statements of cash flows as a result of the adoption of new accounting guidance.

Accounting Pronouncements Recently Adopted - In November 2016, the Financial Accounting Standards Board ("FASB") issued an Accounting Standards Update ("ASU") amending the presentation of restricted cash within the consolidated statements of cash flows. The new guidance requires that restricted cash be added to cash and cash equivalents on the consolidated statements of cash flows. The Company adopted this ASU on January 1, 2018 on a retrospective basis with the following impacts to our consolidated statements of cash flows for the six months ended June 30, 2017:

	Previously Reported	Adjustment	As Revised
Net cash provided by (used in) investing activities	$(372,802)	$ 356,092	$(16,710)

As of June 30, 2018 and December 31, 2017, the Company had a certified deposit of $390,940 as collateral for a letter of credit issued in connection with a lease agreement and as of June 30, 2018, the Company had restricted cash of $40,034 related to credit card accounts.

Following is a summary of cash and cash equivalent and restricted cash at June 30, 2018 and December 31, 2017:

	June 30, 2018	December 31, 2017
Cash and cash equivalent	$21,474,264	$ 17,399,636
Restricted cash – current	40,034	-
Restricted cash	390,940	390,940
Cash and cash equivalent and restricted cash	$21,905,238	$ 17,790,576

In May 2014, the Financial Accounting Standard Board ("FASB") issued ASU No. 2014-09, Revenue from Contracts with Customers. Under the new standard, revenue is recognized at the time a good or service is transferred to a customer for the amount of consideration for which the entity expects to be entitled for that specific good or service. Entities may use a full retrospective approach or report the cumulative effect as of the date of adoption. We adopted this ASU on January 1, 2018 and the adoption did not have a significant impact to the Company’s financial statements.

In July 2017, the 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. See Note 2 for further discussion.

Recent Accounting Pronouncements – From time to time, new accounting pronouncements are issued by the FASB or other standard setting bodies. Unless otherwise discussed, the Company believes that the impact of recently issued standards that are not yet effective will not have a material impact on its consolidated financial position or results of operations upon adoption.

In February 2016, FASB issued ASU No. 2016-02 *Leases* (Topic 842), which creates new accounting and reporting guidelines for leasing arrangements. The new guidance requires organizations that lease assets to recognize assets and liabilities on the balance sheet related to the rights and obligations created by those leases, regardless of whether they are classified as finance or operating leases. Consistent with current guidance, the recognition, measurement, and presentation of expenses and cash flows arising from a lease primarily will depend on its classification as a finance or operating lease. The guidance also requires new disclosures to help financial statement users better understand the amount, timing, and uncertainty of cash flows arising from leases. The new standard is effective for annual reporting periods beginning after December 15, 2018, including interim periods within that reporting period, with early application permitted. The new standard is to be applied using a modified retrospective approach. The Company is currently evaluating the impact of the new pronouncement on its financial statements.

In June 2018, the 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 pronouncement is effective for fiscal years, and for interim periods within those fiscal years, beginning after December 15, 2018, with early adoption permitted. The Company is currently evaluating the impact of the new pronouncement on its financial statements and related disclosures. This is not expected to have a material impact on the Company’s financial statements.

The Company does not believe that any other recently issued effective pronouncements, or pronouncements issued but not yet effective, if adopted, would have a material effect on the accompanying consolidated financial statements.

Note 2 - Derivative Liabilities

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 accompanying Consolidated Statements of Operations. The Company recorded a gain on the change in the estimated fair value of warrants of $0.1 million for the three months ended June 30, 2017 and a loss on the change in the estimated fair value of warrants of $0.1 million for the six months ended June 30, 2017.

As of April 1, 2018, the Company early adopted ASU 2017-11, which revised the guidance for instruments with down-round provisions. As such, the Company treats outstanding warrants as free-standing equity-linked instruments that are recorded to equity in the Consolidated Balance Sheet as of June 30, 2018.

In accordance with the guidance presented in the ASU 2017-11, the fair value of the derivative liability balance for 57,212 warrants as of December 31, 2017 of $16 thousand was reclassified by means of a cumulative-effect adjustment to equity as of January 1, 2018. These warrants had an original exercise price of $2.34. The exercise price is adjusted based on a formula whenever the Company issues, or is deemed to have issued, any common shares for no consideration or a consideration per share less than the exercise price of warrants.

Prior to the Company's adoption of ASU 2017-11, the exercise price of the warrants was reset to $1.25 as a result of various offerings. The difference of $5 thousand between the fair value of the warrants with the exercise price prior to the price reset and the fair value of the warrants with the exercise price after the price reset was accounted for as a deemed dividend. The impact of the adoption was as follows:

	Amount
Derivative liabilities	$(15,916)
Additional paid-in capital	66,154
Accumulated deficit	(50,238)
Total stockholders' equity	$15,916

The fair value of the derivative warrants was calculated using a binomial valuation model with the following assumptions at December 31, 2017:

Market value of common stock on measurement date (1)	$0.66	
Adjusted exercise price	$1.67	
Risk free interest rate (2)	2.09	%
Warrant lives in years	4.1 years	
Expected volatility (3)	80	%
Expected dividend yield (4)	-	
Probability of stock offering in any period over 5 years (5)	100	%
Offering price estimated as of December 31, 2017 (6)	$0.50	

(1) The market value of common stock at the above measurement dates is based on the Company's closing price quoted on the NYSE AMERICAN.

(2) The risk-free interest rate was determined by the Company's management using the Treasury Bill rate as of the respective measurement date.

(3) The volatility was estimated using the historical volatility of the Company's common stock.

(4) Management does not expect to pay dividends for the foreseeable future.

(5) Management determines the probability of future stock offering at each evaluation date.

(6) Represents the estimated offering price in future offerings as determined by management.

Note 3 - 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. MSKCC - On February 11, 2002, the Company entered into a License, Development and Commercialization Agreement with Sloan-Kettering Institute of Cancer Research ("SKI"), an entity related to Memorial Sloan-Kettering Cancer Institute, Inc. ("MSKCC"). The agreement was amended in August 2006. Pursuant to the agreement, the Company licensed certain intellectual property from SKI, including critical patents with respect to the Company's core technology that also supports ongoing research and clinical development of related drug candidates. MSKCC agreed, subject to certain conditions, to utilize the funds paid for certain clinical and preclinical programs and activities related to the Company's drug development and clinical study programs, including the payment of certain costs and expenses that would otherwise have been borne by the Company.

The Company is obligated to make the following milestone payments:

Milestones	Payments
(1) filing of a New Drug Application ("NDA") or regulatory approval for each licensed product	$750,000
(2) upon the receipt of regulatory approval from the U.S. FDA for each licensed product	1,750,000

Under the agreement, the Company shall pay to MSKCC on a country-by-country basis a royalty of 2% of net sales of all licensed products until the later of: (1) 10 years from the first commercial sale, or (2) when the patents expire.

For the six months ended June 30, 2018 and 2017, respectively, the Company incurred $0.1 million for maintenance fees and research conducted by MSKCC.

b. 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 13, 2017, the Company signed a contract with ORNL to purchase $0.2 million of radioactive material during calendar year 2018. During the six

months ended June 30, 2018 and 2017, the Company purchased material from ORNL of approximately $0.1 million and $0.3 million, respectively.

c. 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. Upon commercial sale of the drug, royalty payments of 2% of net sales will be due to FHCRC. For the six months ended June 30, 2018 and 2017, the Company incurred expenses of $0 and $44,000, respectively, related to this agreement.

d. 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 June 30, 2018, the remaining cost of the service agreement is approximately $1.5 million. For each of the six months ended June 30, 2018 and 2017, the Company paid Goodwin $0.8 million and $0.3 million, respectively.

e. On February 16, 2016, the Company entered into an agreement with Medpace, Inc. ("Medpace"), a Contract Research Organization. Medpace provides project management services for the Iomab-B study. The total project is estimated to cost approximately $7.2 million. Medpace bills the Company when services are rendered and the Company records the related expense to research and development costs. For the six months ended June 30, 2018 and 2017, the Company paid Medpace $1.5 million and $1.4 million, respectively.

f. On August 4, 2016, the Company entered into a CRO agreement with George Clinical Services, ("George"). George provides project management services for the study of Actimab-A used for a Phase 2 clinical trial. The total project is estimated to cost approximately $4.6 million. For the six months ended March 31, 2018 and 2017, the Company paid George $0.7 million and $0.2 million, respectively.

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 Platform Technology. 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 4 - Equity

In March 2018, the Company sold an aggregate of 30,237,894 units consisting of an aggregate of 30,237,894 shares of common stock, 7,559,445 series A warrants and 22,678,393 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 to Actinium 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. In the event all of the warrants from the March 2018 offering were to be exercised, estimated gross proceeds would be $20.4 million before deducting any dealer-manager fees or expenses.

Stock Options

During the six months ended June 30, 2018, the Company granted its employees 1,267,500 options to purchase the Company’s common stock with an exercise price ranging from $0.34 to $0.72 per share, a term of 10 years, and a vesting period of 4 years. The options have an aggregated fair value of approximately $0.5 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 2.34% to 2.94% (2) expected life of 6 years, (3) expected volatility range from 79.1% to 80.4%, and (4) no expected dividends. During the six months ended June 30, 2018, options to purchase 641,350 common 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 June 30, 2018 was approximately $2.5 million. During the six months ended June 30, 2018 and 2017, the Company recorded compensation expense related to stock options of approximately $0.9 million and $1.9 million, respectively.

Warrants

Following is a summary of warrant activities for the six months ended June 30, 2018:

	Number of Shares	Weighted Average Exercise	Weighted Average Remaining	Aggregate Intrinsic Value

		Price	Contractual Term (in years)	
Outstanding, December 31, 2017	25,662,340	1.89	3.62	995,373
Granted	30,354,770	0.67	2.14	
Exercised	(1,500)	0.60		
Expired	-			
Outstanding, June 30, 2018	56,015,610	1.23	2.47	1,280,523
Exercisable, June 30, 2018	55,722,173	1.21	2.46	1,254,273

In March 2018, the Company sold an aggregate of 30,237,894 units consisting of 30,237,894 shares of common stock, 7,559,445 series A warrants and 22,678,393 series B warrants. The series A warrants are exercisable for a period of 1 year at an exercise price of $0.60 per share. The transaction date relative fair value of the series A warrants of $0.5 million was determined utilizing the Black-Scholes option pricing model. Variables used in the Black-Scholes option-pricing model include (1) discount rate of 2.06%, (2) expected term of 1 years, (3) expected volatility of 72%, and (4) no expected dividends. The series B warrants are exercisable for a period of 2.5 years at an exercise price of $0.70 per share. The transaction date relative fair value of the series B warrants of $2.5 million was determined utilizing the Black-Scholes option pricing model. Variables used in the Black-Scholes option-pricing model include (1) discount rate of 2.33%, (2) expected term of 2.5 years, (3) expected volatility of 71%, and (4) no expected dividends.

In addition, during the six months ended June 30, 2018, the Company issued 116,930 warrants to consultants, having an aggregate value of approximately $25 thousand and an exercise price range from $0.36 to $0.65.

Note 5 - Subsequent Event

Subsequent to June 30, 2018, the Company granted stock options to its employees and directors to purchase a total of 2,145,658 common shares at a price range from $0.61 to $0.78 per share related to new hires or 2017 compensation.

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. (the "Company", "Actinium", or "We") is a clinical-stage biopharmaceutical company focused on developing and potentially commercializing targeted therapies for improved conditioning of the bone marrow prior to a bone marrow transplant and for the targeting and killing of cancer cells. We are currently conducting multiple clinical trials for two Antibody Radio-Conjugate, or ARC product candidates, in the areas of targeted conditioning and CD33 expressing hematologic indications. We are also performing research on other potential drug candidates utilizing our proprietary Actinium Warhead Enabling (AWE) technology platform, which utilizes the alpha-emitting particle actinium-225 (Ac-225) in combination with targeting agents.

Our most advanced targeted conditioning product candidate, Iomab-B, is comprised of the anti-CD45 monoclonal antibody, apamistamab, labeled with iodine-131 (I-131). We are currently conducting a Phase 3 trial, SIERRA (Study of Iomab-B in Relapsed or Refractory Acute Myeloid Leukemia), of Iomab-B for conditioning of the bone marrow prior to a bone marrow transplant, or BMT, for patients with relapsed or refractory acute myeloid leukemia, or AML, age 55 and older. The SIERRA trial reached 25% patient enrollment in June 2018. Upon successful completion of the Phase 3 clinical trial for Iomab-B we intend to submit for marketing approval in the U.S. and European Union. We have received guidance from the U.S. Food & Drug Administration, or FDA, as part of our Investigational New Drug filing, or IND, that it would be acceptable to file a Biologics License Application submission, or BLA, that includes the single, pivotal Phase 3 SIERRA clinical study, if it is successful.

Our CD33 program ARC drug candidate is the anti-CD33 monoclonal antibody lintuzumab conjugated with the alpha-particle actinium-225 (Ac-225) that is being studied in multiple clinical trials. Actinium-225 is a potent alpha-particle isotope that is able to kill cells through double stranded breaks in a cell's DNA and there is no known resistance mechanism to Ac-225. The energy emitted by Ac-225 travels very short distances in the body and our targeted ARC approach is sparing of non-targeted cells. We believe this activity will result in improved safety and tolerability. This combination of high potency and safety of the lintuzumab-actinium-225 ARC facilitates its exploration in other diseases and indications that may not be feasible with some of the other modalities such as naked or bi-specific antibodies or antibody drug conjugates that are being used to target CD33 in AML. Our CD33 targeting agent is the only one in development for multiple diseases and indications where CD33 is expressed including AML, myelodysplastic syndrome, or MDS and multiple myeloma. The ARC is currently being studied for targeted conditioning in our Actimab-MDS and Actimab-A CLAG-M trials and as a therapeutic in our Actimab-A, Actimab-M and Actimab-A MRD trials.

The most advanced CD33 program trial is the Actimab-A Phase 2 clinical trial for patients over the age of 60 who are newly diagnosed with AML and ineligible for intensive chemotherapy. Two Phase 1 investigator-initiated trials are also studying lintuzumab-Ac-225 in patients with AML. One, the Actimab-A CLAG-M trial is being conducted at the Medical College of Wisconsin in patients with relapsed or refractory ("r/r") AML in combination with CLAG-M, a salvage chemotherapy regimen comprised of cladribine, cytarabine, and filgrastim with mitoxantrone. The second trial, Actimab-A MRD is being conducted at Columbia University Medical Center as a single agent to target minimal residual disease as consolidation for patients who have achieved remission. We are also conducting the Phase 1 Actimab-M trial with lintuzumab-Ac-225 for patients with refractory multiple myeloma. We are planning a clinical trial as a targeting conditioning agent prior to a BMT for patients with high-risk MDS. We met with the FDA in June of 2018 and are engaged in discussions with the FDA on an acceptable pathway toward a BLA filing.

We are also developing our AWE Technology Platform with the goal of generating additional drug candidates that will progress in clinical trials and/or out-license. We intend to develop a number of products for numerous types of cancer and derive revenue from partnering relationships worldwide and/or direct sales of products primarily in the United States. In March 2018, we entered into a collaborative research partnership with Astellas Pharma, Inc. or Astellas, whereby we will conjugate and label selected Astellas targeting agents with Ac-225 and will be responsible for conducting preclinical validation for these novel ARCs. In addition, we have labeled daratumumab, a CD38 targeting monoclonal antibody that is marketed by Johnson & Johnson as Darzalex™ for patients with multiple myeloma with Ac-225. We have studied Ac-225 labeled daratumumab in *in vitro* and *in vivo* preclinical studies and we intend to continue to progress our studies of this ARC. We are also focused on developing additional intellectual property for its technology platform.

As of August 2018, our patent portfolio includes: 74 issued and pending patent applications, of which 11 are issued in the United States, 10 are pending in the United States, and 55 are issued internationally and pending internationally. Additionally, several non-provisional patent applications have and are expected to be filed in 2018 based on provisional patent applications filed in 2017 and 2018. This is part of an ongoing strategy to continue to strengthen our intellectual property position. Approximately one quarter of our patents are in-licensed from third parties and the remainder are Actinium-owned. These patents cover key areas of our business, including use of the Ac-225 and other alpha emitting isotopes attached to cancer specific carriers like monoclonal antibodies, methods for manufacturing key components of product candidates including Ac-225, the alpha emitting radioisotope and carrier antibodies, and methods of use and for manufacturing finished product candidates for use in cancer treatment.

We have also developed proprietary know-how related to the development, manufacturing and supply chain required for our product candidates. We supply our product candidates to clinical trial sites on a just in time basis through the management of the manufacturing our drug product components, final drug product and the distribution of our final drug product to medical centers where our trials are conducted. In the case of Iomab-B, we calculate, produce and supply personalized doses of drug for our clinical trial. We have secured access to I-131 produced by two premier commercial global suppliers that provide reliable and redundant supplies of I-131 and we have the additional security of an ensured supply as this radioisotope has been commoditized. We continually evaluate additional I-131 suppliers on a global basis and may add additional suppliers if we determine it would be beneficial to our clinical or commercial needs. The current supply of I-131 is able to meet our commercial needs for the Iomab-B program. We have a secure and reliable supply of Ac-225 with sufficient quantities of the radioisotope produced to address multiples of our current Ac-225 needs, facilitating unhindered pre-commercial and early commercial development. Our current source of Ac-225 is derived from the natural decay of thorium-229 (Th-229), so-called ‘thorium cows’ and supplied by the United States Department of Energy, or DOE with whom we have had a long-standing relationship. To further support the expansion of the thorium cows the DOE is engaged in a project to generate new thorium cows from its stockpile of uranium-233. An alternative accelerator-produced source of Ac-225 is available now and is currently being evaluated by Actinium. 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 have development programs. Actinium has intellectual property and developed know-how for Ac-225 production in a cyclotron which represents an additional and captive route towards high-quality and proprietary Ac-225 supply. In addition, we are evaluating eight potential suppliers of Ac-225 in Canada, the European Union, Russia and Japan who currently supply, or in the future will be able to supply, Ac-225. Some of the technologies either completed, underway or planned by these sources would have production capacity that is significantly higher than even the DOE’s projected supply from the accelerator route.

Plan of Operation

Our current operations are primarily focused on furthering the development of our clinical drug candidates including Iomab-B and our CD33 program candidates for targeted conditioning and therapeutic indications, supporting investigator-initiated clinical trials that use our product candidates and leveraging our AWE platform to create new clinical programs and to enable collaborations.

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Operations related to Iomab-B include progressing the ongoing multi-center Phase 3 pivotal trial (a trial that could lead to registration trial marketing approved by the FDA), that includes investigator engagement, site activation and supporting patient enrollment. In addition, we are focused on commercial-scale manufacturing of apamistamab suitable for a registration trial and preparation of appropriate regulatory submissions. We are also focused on producing final Iomab-B drug product material that consists of apamistamab labelled with the isotope I-131. Operations related to our planned Actimab-MDS trial include preparation for appropriate regulatory submissions, protocol development and investigator engagement.

In the case of our CD33 program, key ongoing activities include progressing the multi-center Phase 2 Actimab-A trial, the Phase 1 Actimab-M trial, the Phase 1 Actimab-A CLAG-M combination trial and planned Phase 1 Actimab-A MRD trial, managing isotope and other materials, supply chain and managing the manufacturing of the finished drug candidate product.

We have primarily management position employees and consultants who direct, organize and monitor the activities described above through contractors. We also make clinical trial arrangements with other well-known cancer centers. Our Iomab-B and CD33 ARCs and their components are contract-manufactured and maintained under our supervision by specialized contract manufacturers and suppliers in the United States.

We have never generated revenue. Currently we do not have a recurring source of revenue to cover our operating costs. For the six months ended June 30, 2018 and 2017, we incurred a net loss of $11.2 million and $15.1 million, respectively.

Opportunities, Challenges and Risks

The market for drugs for cancer treatment is a large market in need of novel products, in which successful products can command multibillion dollars in annual sales. A number of large pharmaceutical and biotechnology companies regularly acquire products in development, with preference given to products in Phase 2 or later clinical trials. These transactions are typically structured to include an upfront payment that ranges from several million dollars to tens of million dollars or more and additional milestone payments tied to regulatory submissions and approvals and sales milestones. Our goal is to develop our product candidates through Phase 2 clinical trials and enter into partnership agreements with one or more large pharmaceutical and/or biotechnology companies.

We believe our future success will be heavily dependent upon our ability to successfully conduct clinical trials and preclinical development of our drug candidates. In addition, we plan to continue and expand other research and clinical trial collaborations. Moreover, we will have to maintain sufficient supply of Ac-225 and successfully maintain

and if and when needed replenish or obtain our reserves of monoclonal antibodies. We will have to maintain and improve manufacturing procedures we have developed for production of our drug candidates from the components that include the I-131 and Ac-225 isotopes, monoclonal antibodies and other materials. It is possible that despite our best efforts our clinical trials results may not meet regulatory requirements for approval. If our efforts are successful, we may be able to partner our development stage products on commercially favorable terms if they enjoy appropriate patent coverage and/or considerable know-how and other protection that ensures market exclusivity. For these reasons, we intend to continue our efforts to maintain existing and generate new intellectual property. Intellectual property is a key factor in the success of our business as well as market exclusivity.

To achieve our goal, we intend to continue to invest in research and development at high rates, thus incurring further losses until one or more of our products are sufficiently developed to partner them with a large pharmaceutical and/or biotechnology company.

Results of Operations – Three Months Ended June 30, 2018 Compared to Three Months Ended June 30, 2017

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

	For the Three Months Ended June 30,	
	2018	2017
Revenue	$-	$-
Operating expenses:		
Research and development, net of reimbursements	3,325,228	4,448,198
General and administrative	1,574,776	2,740,767
Depreciation expense	12,816	14,335
Total operating expenses	4,912,820	7,203,300
Other income (expense):		
Interest income	50,030	-
Gain on change in fair value of derivative liabilities	-	149,592
Total other income (expense)	50,030	149,592
Net loss	$(4,862,790)	$(7,053,708)

Revenue

We recorded no commercial revenue for the three months ended June 30, 2018 and 2017.

Research and Development Expense

Research and development expenses declined approximately $1.1 million to $3.3 million for the three months ended June 30, 2018 compared to $4.4 million for the three months ended June 30, 2017. The decrease was primarily attributable to lower expenses related to Actimab-A, as well as the recognition of payments received from Astellas. Such payments are accounted for as a reduction in research and development expenses.

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.

General and Administrative Expenses

General and administrative expenses declined approximately $1.1 million to $1.6 million for the three months ended June 30, 2018 compared to $2.7 million for the three months ended June 30, 2017, primarily attributable to lower compensation expense as a result of lower stock option expense.

Other Income (Expense)

Other income of $50 thousand for the three months ended June 30, 2018 was attributable to interest income.

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 certain warrants that provide for a reduction to the exercise price if we issued equity or equity-linked instruments at an effective price per share less than the exercise price then in effect for the warrant, or a "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 accompanying Consolidated Statements of Operations. We recorded a gain on the change in the estimated fair value of warrants of $150 thousand for the three months ended June 30, 2017.

As of April 1, 2018, we early adopted ASU 2017-11, which revised the guidance for instruments with down-round provisions. As such, we treat outstanding warrants as free-standing equity-linked instruments that are recorded to equity in the Consolidated Balance Sheet as of June 30, 2018. As a result, there was no gain or loss from the valuation of the derivative liability recorded for the three months ended June 30, 2018.

Results of Operations – Six Months Ended June 30, 2018 Compared to Six Months Ended June 30, 2017

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

	For the Six Months Ended June 30,	
	2018	2017

Revenues	$-	$-
Operating expenses:		
Research and development, net of reimbursements	7,788,197	9,021,700
General and administrative	3,453,522	5,951,933
Depreciation expense	24,780	35,255
Total operating expenses	11,266,499	15,008,888
Other income (expense):		
Interest income	80,372	-
Gain on change in fair value of derivative liabilities	-	(106,403)
Total other income (expense)	80,372	(106,403)
Net loss	$(11,186,127)	$(15,115,291)

Revenues

We recorded no commercial revenues for the six months ended June 30, 2018 and 2017.

Research and Development Expense

Research and development expenses declined approximately $1.2 million to $7.8 million for the six months ended June 30, 2018 compared to $9.0 million for the six months ended June 30, 2017. The decrease was primarily attributable to lower expenses related to Actimab-A, as well as the recognition of payments received from Astellas. Such payments are accounted for as a reduction in research and development expenses.

General and Administrative Expenses

General and administrative expenses declined approximately $2.5 million to $3.5 million for the six months ended June 30, 2018 compared to $6.0 million for the three months ended June 30, 2017, primarily attributable to lower compensation expense as a result of lower stock option expense and the payment of severance and bonuses in the prior-year period.

Other Income (Expense)

Other income of $80 thousand for the six months ended June 30, 2018 was attributable to interest income. Other expense of $106 thousand in the prior-year period is due to the change in valuation of our warrant derivative liability. Upon the adoption of ASC 2017-11 as of April 1, 2018, the warrants previously accounted for as derivative liability were reclassified to equity. As a result, there was no gain or loss from the valuation of the derivative liability recorded for the six months ended June 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 Six Months Ended June 30,	
	2018	2017
Cash used in operating activities	$(9,670,164)	$(12,514,825)
Cash used in investing activities	(26,811)	(16,710)
Cash provided by financing activities	13,811,637	3,824,605
Net change in cash	$4,114,662	$(8,706,930)

Net cash used in operating activities was approximately $9.7 million and $12.5 million for the six months ended June 30, 2018 and 2017, respectively. Net cash used in operating activities for the six months ended June 30, 2018 primarily reflects our net loss for the period of approximately $11.2 million adjusted for various non-cash charges and income, including $1.0 million of stock-based compensation. Net cash used in operating activities for the six months ended June 30, 2017 primarily reflects our net loss for the period of $15.1 million adjusted for various non-cash charges and income, including $2.2 million of non-cash stock-based compensation.

Net cash provided by financing activities was $13.8 million for the six months ended June 31, 2018, reflecting our March 2018 sale of units, see below. During the six months ended June 31, 2017, we received net proceeds of $3.8 million from the sale of our common stock.

As of June 30, 2018, our cash balance was $21.5 million. We believe that we have sufficient cash to fund our operations through the next 12 months.

Recent Equity Offerings

In March 2018, we sold 30,237,894 units consisting of 30,237,894 shares of common stock, 7,559,445 series A warrants and 22,678,393 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.

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, 2017.

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.

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.

Accounting Pronouncements Recently Adopted

In November 2016, the Financial Accounting Standards Board (“FASB”) issued an Accounting Standards Update (“ASU”) amending the presentation of restricted cash within the consolidated statements of cash flows. The new guidance requires that restricted cash be added to cash and cash equivalents on the consolidated statements of cash flows. The Company adopted this ASU on January 1, 2018 on a retrospective basis with the following impacts to our consolidated statements of cash flows for the six months ended June 30, 2017:

	Previously Reported	Adjustment	As Revised
Net cash provided by (used in) investing activities	$(372,802)	$ 356,092	$(16,710)

As of June 30, 2018 and December 31, 2017, the Company had a certified deposit of $390,940 as collateral for a letter of credit issued in connection with a lease agreement and as of June 30, 2018, the Company had restricted cash of $40,034 related to credit card accounts.

In May 2014, the Financial Accounting Standard Board ("FASB") issued ASU No. 2014-09, Revenue from Contracts with Customers. Under the new standard, revenue is recognized at the time a good or service is transferred to a customer for the amount of consideration for which the entity expects to be entitled for that specific good or service. Entities may use a full retrospective approach or report the cumulative effect as of the date of adoption. We adopted this ASU on January 1, 2018 and the adoption did not have a significant impact to the Company’s financial statements.

In July 2017, the 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. See Note 2 to the consolidated financial statements for more details.

Recent Accounting Pronouncements

In February 2016, FASB issued ASU No. 2016-02 *Leases* (Topic 842), which creates new accounting and reporting guidelines for leasing arrangements. The new guidance requires organizations that lease assets to recognize assets and liabilities on the balance sheet related to the rights and obligations created by those leases, regardless of whether they are classified as finance or operating leases. Consistent with current guidance, the recognition, measurement, and presentation of expenses and cash flows arising from a lease primarily will depend on its classification as a finance or operating lease. The guidance also requires new disclosures to help financial statement users better understand the amount, timing, and uncertainty of cash flows arising from leases. The new standard is effective for annual reporting periods beginning after December 15, 2018, including interim periods within that reporting period, with early application permitted. The new standard is to be applied using a modified retrospective approach. The Company is currently evaluating the impact of the new pronouncement on its financial statements.

In June 2018, the 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 pronouncement is effective for fiscal years, and for interim periods within those fiscal years, beginning after December 15, 2018, with early adoption permitted. The Company is currently evaluating the impact of the new pronouncement on its financial statements and related disclosures. This is not expected to have an impact on the Company’s 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 June 30, 2018, 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 three and six months ended June 30, 2018 and 2017.

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 June 30, 2018, 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 June 30, 2018, 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 elsewhere throughout this Annual Report on Form 10-K. 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

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

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

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

We are not profitable and have incurred losses in each period since our inception. As of June 30, 2018, we had an accumulated deficit of $174.4 million. For the six months ended June 30, 2018, we reported a net loss of $11.2 million. For the years ended December 31, 2017 and 2016, we reported a net loss of $26.6 million and $24.3 million, respectively. We expect to continue to operate at a net loss as we continue our research and development efforts, continue to conduct clinical trials and develop manufacturing, sales, marketing and distribution capabilities. There can be no assurance that the products under development by us will be approved for sale in the United States or elsewhere. Furthermore, there can be no assurance that if such products are approved they will be successfully commercialized, which would have an adverse effect on our business prospects, financial condition and results of operation.

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

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 2019 and any partnering revenues that it may generate may not be sufficient to fund our ongoing operations. Our cash balance as of June 30, 2018 was $21.5 million. During the year ended December 31, 2017, we raised total net proceeds of approximately $3.8 million from the sale of our common stock through our ATM. In March 2018, we raised $13.8 million through the sale of units comprised of shares of common stock and two warrant tranches.

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.

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.

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 radio-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 radio-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 lintuzuamab-Ac-225 drug candidate under our own sponsorship including a Phase 2 clinical trial 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 500 patients in need of HSCT. 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 have ongoing a Phase 2 portion of our multi-center Phase 1/2 Actimab-A clinical trial for our product candidate consisting of the anti-CD33 antibody lintuzumab linked with the isotope Ac-225 in AML. Our lintuzumab-Ac-225 product candidate is also being studied in several 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 clinical trial designed to test the initial safety and efficacy of Actimab-A in newly diagnosed AML patients over the age of 60. Subsequent to the completion of the Phase 1 portion of the Phase 1/2 clinical trial we submitted protocol amendments to the FDA in August of 2016, which were agreed upon in September of 2016. The Phase 2 portion of the trial is now underway with the purpose of examining the use of Actimab-A in AML patients who are not eligible for approved forms of treatment with curative intent. The trial is not designed to support marketing approval for the product candidate, and one or more additional trials will have to be conducted in the future before we file a BLA. 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, lintzumab-Ac-225, or any other product candidate for which we might seek approval, have failed to demonstrate safety and effectiveness, we would not receive FDA approval to market that product candidate in the United States for the indications sought. In addition, such an outcome could cause us to abandon the product candidate and might delay development of others. Any delay or termination of our clinical trials will delay or preclude the filing of any submissions with the FDA and, ultimately, our ability to commercialize our product candidates and generate revenues. It is also possible that patients enrolled in clinical trials will experience adverse side effects that are not currently part of a product candidate’s profile.

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

The humanized antibody, lintuzumab, which we use in our CD33 program product candidates was licensed from Facet Biotech Corporation, a wholly-owned subsidiary of AbbVie Laboratories. The key patents related to this antibody have expired. It is generally possible that others may be eventually able to use an antibody with the same sequence, and we will then need to rely on additional patent protection covering alpha particle drug products comprising Ac-225. Our final drug construct consists of the lintuzumab antibody labeled with the isotope Ac-225. We have licensed issued patents that relate to the linker technology we use to conjugate the isotope to the antibody and own issued and pending patents related to isotope production methods and drug preparation methods. In addition, we possess trade secrets and know how related to the manufacturing and use of isotopes. Any competing product based on the lintuzumab antibody is likely to require several years of development before achieving our product candidate's current status and may be subject to significant regulatory hurdles but is nevertheless a possibility that could negatively impact our business in the future. Neither the antibody portion nor the composition of matter as a whole for the conjugated Iomab-B product candidate is covered by the claims of any issued patent. Accordingly, there are no patents that would prevent others from using an antibody with the same antibody sequence in any drug product. We have dedicated research and development activities towards improving the product'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. 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.

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 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 would make it 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 trial including our Phase 2 Actimab-A trial in AML and several investigator initiated trials 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 Ac-225 labeled lintuzumab.

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

Iodine-131 is a key component of our Iomab-B drug candidate. We source medical grade I-131 produced by two premier 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 at a minimum of three 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 a third I-131 supplier or obtain on it terms that are acceptable to us.

Actinium-225 is a key component of Actimab-A, Actimab-M, our 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. 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 have development. 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.

Our contract for supply of this isotope from the DOE must be renewed yearly, and the current contract extends through the end of 2018. 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 Actimab-A, Actimab-M and any other Ac-225 based drug candidates that we may develop and would materially harm our business. We are also aware of and have ongoing discussions with seven to eight other entities in Canada, the EU, Japan and Russia that have several Ac-225 production programs ongoing or planned that could represent additional sources of Ac-225 within the next two to five years, a commercially relevant timeframe.

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. We do not have experience in manufacturing medical grade Ac-225 and may not obtain the resources necessary to establish our own manufacturing capabilities. 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 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, trial site staff'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.

Our product candidates for which we intend to seek approval as biologic products may face competition sooner than anticipated.

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. While it is uncertain when such processes intended to implement BPCIA may be fully adopted by the FDA, any such processes could have a material adverse effect on the future commercial prospects for our biologic products.

Our product candidates may never achieve market acceptance.

Iomab-B, CD33 program candidates and future product candidates that we may develop may never gain market acceptance among physicians, patients and the medical community. The degree of market acceptance of any of our products will depend on a number of factors, including the actual and perceived effectiveness and reliability of the product; the results of any long-term clinical trials relating to use of the product; the availability, relative cost and perceived advantages and disadvantages of alternative technologies; the degree to which treatments using the product

are approved for reimbursement by public and private insurers; the strength of our marketing abilities, distribution infrastructure; and the level of education and awareness among physicians and hospitals concerning the product.

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

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

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 our product candidates, and plan to continue to do so for the foreseeable future. Any performance failure on the part of our existing or future manufacturers could delay clinical development or regulatory approval of our product candidates or commercialization of any approved products. We are currently manufacturing the antibody lintuzumab, which is a component of several of our drug candidates that are currently in clinical trials. At this time, we are undertaking release testing of a new batch of lintuzumab antibody. If we are unable to successfully release the manufactured batch of the lintuzumab antibody in a timely fashion, we may encounter delays in our clinical trials. Inability to secure continued clinical supply of lintuzumab antibody may impact our competitive position with these drug candidates as manufacturing another batch would require additional resources and time.

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.

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 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 adverse to our best interests. Any such disagreement could result in one or more of the following, each of which could delay or prevent the development or commercialization of our product candidates, and in turn prevent us from generating revenues: unwillingness on the part of a partner to pay us milestone payments or royalties we believe are due under a collaboration; uncertainty regarding ownership of intellectual property rights arising from our collaborative activities, which could prevent us from entering into additional collaborations; unwillingness by the partner to cooperate in the development or manufacture of the product, including providing us with product data or materials; unwillingness on the part of a partner to keep us informed regarding the progress of its development and commercialization activities or to permit public disclosure of the results of those activities; initiating litigation or alternative dispute resolution options by either party to resolve the dispute; or attempts by either party to terminate the agreement.

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 has been considered a Penny Stock.

For 2017, 2016 and most of 2015, the price of our common stock has traded below $5.00 per share, and therefore has been 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.

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.

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, 2017 and 2016 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.

The following includes information required to be disclosed on Form 8-K but included in this Form 10-Q:

Item 4.01 Changes in Registrant's Certifying Accountant

On August 9, 2018, Actinium Pharmaceuticals, Inc. (the “Company”) engaged Marcum LLP (“Marcum”) as its independent registered public accountants. This engagement occurred in connection with the Company’s prior independent public accountants, GBH CPAs, PC ("GBH") resigning as a result of combining its practice with Marcum effective July 1, 2018. The engagement of Marcum has been approved by the Audit Committee of the Company's Board of Directors.

Pursuant to applicable rules, the Company makes the following additional disclosures:

(a) GBH’s reports on the consolidated financial statements of the Company as at and for the fiscal years ended December 31, 2017 and 2016 did not contain any adverse opinion or disclaimer of opinion and were not qualified or modified as to uncertainty, audit scope or accounting principles.

(b) During the fiscal years ended December 31, 2017 and 2016 and through August 9, 2018, there were no disagreements with GBH on any matter of accounting principles or practices, financial statement disclosure, or auditing scope or procedure, which if not resolved to GBH's satisfaction would have caused it to make reference thereto in connection with its reports on the financial statements for such years. During the fiscal years ended December 31, 2017 and 2016 and through August 9, 2018, there were no events of the type described in Item 304(a)(1)(v) of Regulation S-K.

(c) During the fiscal years ended December 31, 2017 and 2016 and through August 9, 2018, the Company did not consult with Marcum with respect to any matter whatsoever including without limitation with respect to any of (i) the application of accounting principles to a specified transaction, either completed or proposed; (ii) the type of audit opinion that might be rendered on the Company's financial statements; or (iii) any matter that was either the subject of a disagreement (as defined in Item 304(a)(1)(iv) of Regulation S-K) or an event of the type described in Item 304(a)(1)(v) of Regulation S-K.

The Company has provided GBH with a copy of the foregoing disclosure and requested that it furnish the Company with a letter addressed to the Securities and Exchange Commission stating whether it agrees with the statements made therein. A copy of such letter, dated August 9, 2018, is filed as Exhibit 16.1 to this Report.

Item 1.01 entry into a Material Definitive Agreement.

Item 5.02 Departure of Directors or Certain Officers; Election of Directors; Appointment of Certain Officers; Compensatory Arrangements of Certain Officers.

Compensatory Plan with Mr. Seth (Chief Executive Officer and Chairman of the Board)

On August 8, 2018, we amended and restated Mr. Seth's, our Chief Executive Officer, August 6, 2015 Executive Chairman Agreement (the "Prior Agreement"), as amended. This new agreement (the "Agreement") sets forth the terms related to his position as Chief Executive Officer and Chairman of the Board of the Company while retaining and adapting material provisions of the Prior Agreement to that of his role of Chief Executive Officer. Pursuant to the Agreement, Mr. Seth is entitled to the following compensation and benefits that were not contemplated in the Prior Agreement:

Base Salary and Bonus

The Board reviews the amount of his base salary and performance bonus, and determines the appropriate

adjustments to each component of his compensation each calendar year, and he may be entitled to a cash bonus in an amount to be determined by the board with a target of 50% of the base salary.

Options

From time to time the Board may grant Mr. Seth options or restricted stock to purchase common shares of the Company.

Benefits

Mr. Seth is eligible to receive all standard benefits that Company employees are eligible to receive, including 20 vacation days and 5 sick days each year. The Company will provide Mr. Seth with standard business reimbursements (including mileage, supplies, long distance calls), subject to Company policies and procedures and with appropriate receipts. In addition, he will receive any other statutory benefits required by law.

A copy of the Agreement is filed herewith as Exhibit 10.1 and is incorporated herein by reference. The above description is only a summary of the terms of the Agreement and does not purport to be complete description of such document, and are qualified in their entirety by reference to the Agreement, a copy of which is attached as an exhibit hereto and which are incorporated by reference in this Item 1.01 and Item 5.02.

Compensatory Plan with Mr. O'Loughlin (Principal Financial Officer)

On August 8, 2018, we amended and restated Mr. O'Loughlin's, our Principal Financial Officer, September 17, 2015 Employment Agreement (the "Prior Agreement"), as amended. This new agreement (the "Employment Agreement") sets forth the terms related to his position as Principal Financial Officer of the Company while retaining and adapting material provisions of the Prior Agreement to that of his role of Principal Financial Officer.

Mr. O'Loughlin's employment with the Company is on an "at will" basis, meaning that either Mr. O'Loughlin or the Company may terminate his employment at any time for any reason or no reason, without further obligation or liability, except as provided in his Employment Agreement. Pursuant to the employment Agreement, Mr. O'Loughlin is entitled to the following compensation and benefits that were not contemplated in the Prior Agreement:

Base Salary and Bonus

The Board shall review the amount of his base salary and performance bonus, and shall determine the appropriate adjustments to each component of his compensation each calendar year. Mr. O'Loughlin's is entitled to participate in an executive bonus program pursuant to which the Board may award him bonuses, based upon the achievement of written individual and corporate objectives such as the Board shall determine. Upon the attainment of such performance objectives, in addition to base salary, he shall be entitled to a cash bonus in an amount to be determined by the board with a target of 30% of the base salary.

Options

From time to time the Board may grant him options or restricted stock to purchase common shares of the Company.

Benefits

Mr. O'Loughlin is eligible to receive all standard benefits that Company employees are eligible to receive, including 20 vacation days and 5 sick days each year.

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A copy of the Employment Agreement is filed herewith as Exhibit 10.2 and is incorporated herein by reference. The above description is only a summary of the terms of Employment Agreement and does not purport to be complete description of such document, and are qualified in their entirety by reference to the Employment Agreement, a copy of which is attached as an exhibit hereto and which are incorporated by reference in this Item 1.01 and Item 5.02.

Item 5.03 Amendments to Articles of Incorporation or Bylaws; Change in Fiscal Year.

Effective as of August 8, 2018, the Board amended and restated the Company's Bylaws (the "Amended and Restated Bylaws"). Among other things, the Amended and Restated Bylaws of the Company (i) provides certain cleanup and conforming changes throughout the document, (ii) updates the advance notice requirements for nominations for election to the Company's board of directors and for proposals of business to be acted upon at stockholder meetings, to require among other things, additional information from the stockholder making the request, (iii) specifies that special meetings of the stockholders may only be called by the chairman, chief executive officer and board, (iv) specifies rules for conducting business at a stockholder meeting, (v) specifies procedures for taking action by written consent of the stockholders; (vi) updates the indemnification of officers and directors section, and (vii) specifies that in order for the stockholders to alter, amend, repeal or replace the bylaws at least 66 2/3 in voting power of the stock entitled to vote must approve such action.

A copy of the Amended and Restated Bylaws is attached hereto as Exhibit 3.1 and is incorporated herein by reference. The above description of the Amended and Restated Bylaws is only a summary of the terms of such document, does not purport to be a complete description of such document, and is qualified in its entirety by reference to the Amended and Restated Bylaws, a copy of which is attached as an exhibit hereto and which is incorporated by reference into this Item 5.03.

ITEM 6. EXHIBITS

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

Exhibit No.	Title of Document	Location
3.1	Amended and Restated Bylaws of Actinium Pharmaceuticals, Inc., dated August 8, 2018.	Attached
10.1	Employment Agreement, dated August 8, 2018, between Sandesh Seth and Actinium Pharmaceuticals, Inc.	Attached
10.2	Employment Agreement, dated August 8, 2018, between Steve O'Loughlin and Actinium Pharmaceuticals, Inc.	Attached
16.1	Letter of GBH CPAs, PC to the Securities and Exchange Commission dated August 9, 2018.	Attached
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.

ACTINIUM PHARMACEUTICALS, INC.

Date: August 9, 2018 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)