

Actinium Pharmaceuticals, Inc.  
Form 10-Q  
May 10, 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 **March 31, 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 (I.R.S. Employer  
Incorporation or Organization) Identification No.)

**275 Madison Ave, 7<sup>th</sup> Floor**  
**10016**  
**New York, NY**  
(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

Edgar Filing: Actinium Pharmaceuticals, Inc. - Form 10-Q

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

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act).

Yes      No

Indicate the number of shares outstanding of each of the issuer's classes of common stock, as of May 10, 2018:  
110,317,228.

**Actinium Pharmaceuticals, Inc.**

**FORM 10-Q**

**For the three months ended March 31, 2018**

**INDEX**

**PART I – FINANCIAL INFORMATION**

Item 1. Financial Statements	1
Item 2. Management’s Discussion and Analysis of Financial Condition and Results of Operations	12
Item 3. Quantitative and Qualitative Disclosures About Market Risk	17
Item 4. Controls and Procedures	17

**PART II – OTHER INFORMATION**

Item 1. Legal Proceedings	18
Item 1A. Risk Factors	18
Item 2. Unregistered Sales of Equity Securities and Use of Proceeds	18
Item 3. Defaults Upon Senior Securities	18
Item 4. Mine Safety Disclosures	18
Item 5. Other Information	18
Item 6. Exhibits	18
<b>SIGNATURES</b>	19

**PART I - FINANCIAL INFORMATION**

**ITEM 1. FINANCIAL STATEMENTS**

The accompanying consolidated financial statements have been prepared by the Company and are unaudited. In the opinion of management, all adjustments (which include only normal recurring adjustments) necessary to present fairly the financial position at March 31, 2018 and December 31, 2017, and the results of operations and cash flows for the three months ended March 31, 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 three months ended March 31, 2018 are not necessarily indicative of the operating results for the full year.

**Actinium Pharmaceuticals, Inc.****Consolidated Balance Sheets****(Unaudited)**

	March 31, 2018	December 31, 2017
Assets		
Current Assets:		
Cash and cash equivalents	\$26,763,526	\$17,399,636
Restricted cash – current	40,014	-
Prepaid expenses and other current assets	843,936	439,322
Total Current Assets	27,647,476	17,838,958
Property and equipment, net of accumulated depreciation of \$227,624 at March 31, 2018 and \$215,660 at December 31, 2017	52,377	57,350
Security deposit	49,859	49,859
Restricted cash	390,940	390,940
Total Assets	\$28,140,652	\$18,337,107
Liabilities and Stockholders' Equity		
Current Liabilities:		
Accounts payable and accrued expenses	\$6,386,294	\$4,650,088
Derivative liabilities	6,840	15,916
Total Current Liabilities	6,393,134	4,666,004
Total Liabilities	6,393,134	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; 110,316,728 and 80,072,334 shares issued and outstanding, respectively	110,317	80,072
Additional paid-in capital	191,104,499	176,744,068
Accumulated deficit	(169,467,298)	(163,153,037)
Total Stockholders' Equity	21,747,518	13,671,103
Total Liabilities and Stockholders' Equity	\$28,140,652	\$18,337,107

See accompanying notes to the consolidated financial statements.

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

	For the Three Months Ended March 31,	
	2018	2017
Revenue	\$-	\$-
Operating expenses:		
Research and development	4,462,969	4,573,502
General and administrative	1,878,746	3,211,166
Depreciation expense	11,964	20,920
Total operating expenses	6,353,679	7,805,588
Loss from operations	(6,353,679 )	(7,805,588 )
Other income (expense):		
Interest income	30,342	-
Gain (loss) on change in fair value of derivative liabilities	9,076	(255,995 )
Total other income (expense)	39,418	(255,995 )
Net loss	\$(6,314,261 )	\$(8,061,583 )
Net loss per common share - basic and diluted	\$(0.07 )	\$(0.14 )
Weighted average common shares outstanding - basic and diluted	88,434,704	55,892,878

See accompanying notes to the consolidated financial statements.



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

	For the Three Months Ended March 31,	
	2018	2017
<b>Cash Flows From Operating Activities:</b>		
Net loss	\$(6,314,261 )	\$(8,061,583 )
Adjustments to reconcile net loss to net cash used in operating activities:		
Stock-based compensation expense	579,939	1,030,609
Depreciation expense	11,964	20,920
(Gain) loss on change in fair value of derivative liabilities	(9,076 )	255,995
Changes in operating assets and liabilities:		
(Increase) decrease in:		
Prepaid expenses and other current assets	(348,330 )	805,193
Increase in:		
Accounts payable and accrued expenses	620,520	573,934
<b>Net Cash Used In Operating Activities</b>	<b>(5,459,244 )</b>	<b>(5,374,932 )</b>
<b>Cash Flows From Investing Activities:</b>		
Purchase of property and equipment	(6,991 )	(8,313 )
<b>Net Cash Used In Investing Activities</b>	<b>(6,991 )</b>	<b>(8,313 )</b>
<b>Cash Flows From Financing Activities:</b>		
Sales of shares of common stock and warrants, net of offering costs	14,870,139	1,917,048
<b>Net Cash Provided By Financing Activities</b>	<b>14,870,139</b>	<b>1,917,048</b>
Net change in cash, cash equivalents, and restricted cash	9,403,904	(3,466,197 )
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	\$27,194,480	\$17,087,830
<b>Supplemental disclosures of cash flow information:</b>		
Cash paid for interest	\$-	\$-
Cash paid for taxes	\$-	\$-
<b>Supplemental disclosure of non-cash investing and financing activities:</b>		
Stock issuance costs included in accounts payable and accrued expenses	\$1,115,686	\$-
Subscription receivable received subsequent to balance sheet date	\$56,284	\$-

See accompanying notes to the consolidated financial statements.



**Actinium Pharmaceuticals, Inc.**

**Notes to Consolidated Financial Statements**

**(Unaudited)**

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

**Nature of Business** - Actinium Pharmaceuticals, Inc. (the “Company”, “Actinium”, or “We”) is a clinical-stage biopharmaceutical company focused on developing and potentially commercializing targeted therapies for improved myeloablation and conditioning of the bone marrow prior to a bone marrow transplant and for the targeting and killing of cancer cells. We are currently conducting clinical trials for two antibody radio-conjugate (“ARC”) product candidates in the areas of myeloablation and CD33 expressing hematologic indications as well as performing research on other potential drug candidates utilizing our proprietary Actinium Warhead Enabling (AWE) technology platform, which utilizes the alpha-emitting particle actinium-225 ( $^{225}\text{Ac}$ ) in combination with targeting agents.

The Company’s most advanced myeloablation product candidate, Iomab-B, is comprised of the anti-CD45 monoclonal antibody, apamistamab, labeled with iodine-131 ( $^{131}\text{I}$ ). The Company is currently conducting a pivotal Phase 3 trial of Iomab-B for myeloablation and conditioning of the bone marrow prior to a bone marrow transplant for patients with relapsed or refractory acute myeloid leukemia (“AML”) age 55 and older. 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 FDA as part of its IND filing that it would be acceptable to file a BLA submission that includes the single, pivotal Phase 3 SIERRA clinical study if it is successful.

Our CD33 program drug candidate is the anti-CD33 monoclonal antibody lintuzumab conjugated with the alpha-particle actinium-225 ( $^{225}\text{Ac}$ ). 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. The Company is also conducting the Phase 1 Actimab-M trial for lintuzumab- $^{225}\text{Ac}$  for patients with refractory multiple myeloma. The Company is planning a Phase 2 clinical trial for patients with high-risk MDS and a Phase 1 trial for patients with relapsed or refractory (“r/r”) AML in combination CLAG-M, a salvage chemotherapy regimen comprised of cladribine, cytarabine, and filgrastim with mitoxantrone, that is expected to begin patient enrollment in 2018.

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  $^{225}\text{Ac}$  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 <sup>225</sup>Ac. We have studied <sup>225</sup>Ac labeled daratumumab in *in vitro* and *in vivo* preclinical studies and we intend to continue to progress our studies of this ARC. We are focused on developing additional intellectual property for its technology platform.

As of May 2018, the Company's patent portfolio includes: 68 issued and pending patent applications, of which 11 are issued in the United States, 4 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 <sup>225</sup>Ac and other alpha emitting isotopes attached to cancer specific carriers like monoclonal antibodies, methods for manufacturing key components of product candidates including <sup>225</sup>Ac, 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 of revenue and 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.

**Income Taxes** - The Company uses the asset and liability method to calculate deferred taxes. Deferred taxes are recognized based on the differences between the financial reporting and income tax bases of assets and liabilities using the enacted tax rates and laws that will be in effect when the differences are expected to reverse. The Company reviews deferred tax assets for a valuation allowance based upon whether it is more likely than not that the deferred tax asset will be fully realized. A valuation allowance, if necessary, is provided against deferred tax assets, based upon management's assessment as to their realization.

**Revenue Recognition** - Prior to January 1, 2018, revenue was recognized when the four basic criteria for recognition were met: (1) persuasive evidence of an arrangement exists; (2) delivery has occurred or services have been rendered; (3) consideration is fixed or determinable; and (4) collectability is reasonably assured. The Company adopted new accounting guidance for revenue recognition effective January 1, 2018 which did not have a material 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 three months ended March 31, 2018 and 2017, 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.

	<b>March 31, 2018</b>	<b>March 31, 2017</b>
Options	5,812,042	7,644,386
Warrants	55,903,878	8,955,388
Total	61,715,920	16,599,774

**Subsequent Events** - The Company's management reviewed all material events through the date the consolidated financial statements were issued for subsequent event disclosure consideration.

**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 three months ended March 31, 2017:

### **Adjustment**

	<b>Previously Reported</b>	<b>As Revised</b>
Net cash provided by (used in) investing activities	\$ 26,420	\$ (34,733 ) \$ (8,313 )

As of March 31, 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. As of March 31, 2018, the Company also had restricted cash of \$40,014 related to credit card accounts.

In May 2014, the FASB issued an ASU amending revenue recognition guidance and requiring more detailed disclosures to enable users of financial statements to understand the nature, amount, timing, and uncertainty of revenue and cash flows arising from contracts with customers. We adopted this ASU on January 1, 2018 and the adoption did not have a significant impact to the Company's financial statements.

**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.

Management does not believe that any recently issued, but not yet effective accounting pronouncements, when adopted, will have a material effect on the consolidated financial statements.



**Note 2 - Related Party Transactions**

***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:

<b>Milestones</b>	<b>Payments</b>
(1) filing of an 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 three months ended March 31, 2018 and 2017, the Company incurred \$0.1 million and \$0, respectively, for maintenance fees and research conducted by MSKCC.

**Note 3 - Commitments and Contingencies**

**License and Research Agreements**

The Company has entered into license and research and development agreements with third parties under which the Company was obligated to make upfront payments as well as milestone and royalty payments. Notable inclusions in this category are:

AbbVie Biotherapeutics Corp. - The Company entered into a Product Development and Patent License Agreement with AbbVie Biotherapeutics Corp. in 2003 to secure exclusive rights to a specific antibody when conjugated with alpha emitting radioisotopes. Upon execution of the agreement, the Company made a license fee payment of \$3,000,000.

The Company agreed to make milestone payments totaling \$7,750,000 for the achievement of certain contracted milestones.

Under the agreement, the Company shall pay to AbbVie Biotherapeutics Corp. on a country-by-country basis a royalty of 12% of net sales of all licensed products until the later of: (1) 12.5 years after the first commercial sale, or (2) when the patents expire.

The Company met its first milestone in 2012 and upon reaching the milestone the Company paid AbbVie Biotherapeutics Corp. a milestone payment of \$750,000. The milestone payment for the Phase 1 Clinical Trial was recorded as research and development expense. In September 2016, the Company met its second milestone and as of March 31, 2018, \$750,000 was included in accounts payable and accrued expenses on the balance sheet.

b. MSKCC - see Note 2 - Related Party Transactions.

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 three months ended March 31, 2018 and 2017, the Company purchased material from ORNL of approximately \$0.1 million.

d. 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 three months ended March 31, 2018 and 2017, the Company incurred expenses of \$0 and \$27,000, respectively, related to this agreement.

e. 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 to be used in the Phase 3 clinical trial of Iomab-B. As of March 31, 2018, the remaining cost of the service agreement is approximately \$1.8 million. For each of the three months ended March 31, 2018 and 2017, the Company paid Goodwin \$0.4 million and \$0.1 million, respectively.

f. 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 three months ended March 31, 2018 and 2017, the Company paid Medpace \$0.6 million and \$0.4 million, respectively.

g. 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 three 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 will be 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 \$13.9 million after deducting expenses relating to dealer-manager fees and other offering expenses. The Company received \$56,284 of the subscription in April 2018. This amount was included in prepaid expense and other current assets on the balance sheet as of March 31, 2018.

## Stock Options

During the three months ended March 31, 2018, the Company granted its employees 840,000 options to purchase the Company's common stock with an exercise price ranging from \$0.39 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 \$377,000 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 2.35% to 2.72% (2) expected life of 6 years, (3) expected volatility range from 80.09% to 80.46%, and (4) zero expected dividends. The estimated option life was determined based on the "simplified method," giving consideration to the overall vesting period and the contractual terms of the award.

The fair values of all options issued and outstanding are being amortized over their respective vesting periods. The unrecognized compensation expense at March 31, 2018 was approximately \$3.1 million. During the three months ended March 31, 2018 and 2017, the Company recorded total option expense of approximately \$0.6 million and \$0.9 million, respectively.

**Warrants**

Following is a summary of warrant activities for the three months ended March 31, 2018:

	<b>Number of Units</b>	<b>Weighted Average Exercise Price</b>	<b>Weighted Average Remaining Contractual Term (in years)</b>	<b>Aggregate Intrinsic Value</b>
Outstanding, December 31, 2017	25,662,340	1.89	3.62	995,373
Granted	30,241,538	1.23	2.13	
Exercised	-			
Cancelled	-			
Outstanding, March 31, 2018	55,903,878	1.23	2.66	546,959
Exercisable, March 31, 2018	55,708,878	1.21	2.66	546,959

As discussed above, 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. 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 71%, and (4) zero 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 1.33%, (2) expected term of 2.5 years, (3) expected volatility of 71%, and (4) zero expected dividends.

**Note 5 – Subsequent Event**

Subsequent to March 31, 2018, the Company granted its employees and consultants options and warrants to purchase a total of 387,230 common shares at a price range from \$0.35 to \$0.39 per share.

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

### FORWARD-LOOKING STATEMENT NOTICE

This Form 10-Q contains certain forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995. For this purpose, any statements contained in this Form 10-Q that are not statements of historical fact may be deemed to be forward-looking statements. Without limiting the foregoing, words such as “may,” “will,” “expect,” “believe,” “anticipate,” “estimate” or “continue” or comparable terminology are intended to identify forward-looking statements. These statements by their nature involve substantial risks and uncertainties, and actual results may differ materially depending on a variety of factors, many of which are not within our control. These factors include but are not limited to economic conditions generally and in the industries in which we may participate; competition within our chosen industry, including competition from much larger competitors; technological advances and failure to successfully develop business relationships.

### Description of Business

Actinium Pharmaceuticals Inc. is a clinical-stage biopharmaceutical company focused on developing and potentially commercializing targeted therapies for improved myeloablation and conditioning of the bone marrow prior to a bone marrow transplant and for the targeting and killing of cancer cells. Our targeted therapies are Antibody Radio-Conjugates, or ARC, that combine the targeting ability of monoclonal antibodies (“mAb”) with the cell-killing ability of radioisotopes. Our ARC’s have demonstrated the ability to improve access to bone marrow transplants with the potential for better outcomes, namely increased marrow engraftment and survival. Our product pipeline consists of two ARC product candidates that are currently being studied in three clinical trials with two additional clinical trials expected to begin patient enrollment in 2018. In each of the indications, we believe our product candidates are either first in class or have best in class potential. Our lead myeloablation product candidate, Iomab-B, is currently being studied in a pivotal Phase 3 trial as a conditioning agent in older patients with relapsed or refractory (“r/r”) Acute Myeloid Leukemia AML (“AML”) who are ineligible for a bone marrow transplant as they cannot withstand chemotherapy-based conditioning. Iomab-B is an ARC that is comprised of the anti-CD45 mAb apamistamab and the radioisotope iodine-131 (<sup>131</sup>I). Our CD33 program trials include; the ongoing Phase 2 Actimab-A trial for patients newly diagnosed with AML over the age of 60, the Phase 1 Actimab-M trial for patients with refractory multiple myeloma, the planned Phase 2 Actimab-MDS trial for patients with high-risk myelodysplastic syndrome (“MDS”) with a p53 genetic mutation and the Phase 1 Actimab-A & CLAG-M trial for patients with r/r AML. These trials are studying our ARC drug candidate comprised of the anti-CD33 mAb lintuzumab and the radioisotope actinium-225 (<sup>225</sup>Ac”). In addition, we are developing our Actinium Warhead Enabling, or AWE, Technology Platform to leverage our intellectual property and know-how to create additional ARC drug candidates by labeling <sup>225</sup>Ac to targeting moieties that we will either progress in clinical trials ourselves or out-license. 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 <sup>225</sup>Ac and we 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<sup>TM</sup> for patients with multiple myeloma with <sup>225</sup>Ac. We have studied <sup>225</sup>Ac labeled daratumumab in *in vitro* and *in vivo* preclinical studies and we intended to continue to progress our studies of this ARC. We are focused on developing additional intellectual property for its technology platform.

Bone marrow is semi-solid tissue found within the spongy section of bones that produces new blood cells in a process called hematopoiesis. Bone marrow contains hematopoietic stem cells which give rise to the three classes of blood cells that are found in circulation: red blood cells and platelets that are responsible for blood function and white blood cells that are responsible for immune system function. A bone marrow transplant may be the only potentially curative treatment option, or the best treatment option, for patients with blood cancers such as leukemias, lymphomas and multiple myeloma, or benign blood, or marrow disorders such as inherited immune system disorders, sickle cell disease and severe aplastic anemia.

In order to receive a bone marrow transplant, (“BMT”), patients are administered treatment to ablate or destroy their bone marrow in a process referred to as myeloablation. Myeloablative treatments typically consist of chemotherapy and external radiation, which is also called total body irradiation. As an alternative to myeloablation, the bone marrow may also be conditioned or prepared for a transplant via lower intensity treatment known as reduced intensity conditioning, which uses lower doses of external radiation and less toxic types of chemotherapy. Patients with blood cancers must ideally be disease-free, or at least in remission, before receiving myeloablative or conditioning therapy. Myeloablative treatments are associated with greater and more severe toxicities, including higher treatment related mortality rates, and may be too intense for patients, particularly those of advanced age, to tolerate as compared to reduced intensity conditioning. Reduced intensity conditioning is generally better tolerated by patients but is associated with higher rates of relapse, which can reduce overall survival. Our ARC based approach is designed to target blood cancer and bone marrow cells via a mAb and deliver potent radioisotope payloads directly to those cells to achieve myeloablation without systemic toxicities. In doing so, we hope to improve access to BMT for a greater number of patients while improving outcomes through improved myeloablation via our ARC technologies.

We have licensed our product candidates and ARC technologies from the Fred Hutchinson Cancer Research Center and the Memorial Sloan Kettering Cancer Center. These licenses include rights to certain patents and we own outright patents pertaining to our product candidates and AWE technology platform. Our intellectual property portfolio consists of 68 issued and pending patent applications that we have licensed or fully own. We have compiled scientific and medical advisory boards of thought-leading physicians in their respective fields to advise and guide us through the development process of our pipeline product candidates.

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  $^{131}\text{I}$  produced by two premier commercial global suppliers. We project that these two suppliers have sufficient  $^{131}\text{I}$  production capacity to meet our commercial needs for the Iomab-B program. We have secured access to  $^{225}\text{Ac}$  through a renewable contractual arrangement with the United States Department of Energy, or DOE. We project that these quantities are sufficient to support early stages of commercialization of actinium isotope-based products and that the DOE's accelerator route of production of  $^{225}\text{Ac}$  has the potential to provide commercial quantities of  $^{225}\text{Ac}$ . We have also developed our own proprietary process for industrial-scale  $^{225}\text{Ac}$  production in a cyclotron in quantities adequate to support full product commercialization.

## **Plan of Operation**

Our current operations are primarily focused on furthering the development of our clinical drug candidates for myeloablation, our CD33 program drug candidates, supporting investigator initiated clinical trials that use our product candidates and leveraging our AWE platform to create new clinical programs and contribute to collaborations.

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  $^{131}\text{I}$ . Operations related to our planned Phase 2 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 and planned Phase 1 Actimab-A and CLAG-M combination 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 made 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 had never generated revenue. Currently we do not have a recurring source of revenue to cover our operating costs. For the three months ended March 31, 2018 and 2017, we incurred a net loss of \$6.3 million and \$8.1 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 <sup>225</sup>Ac 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 <sup>131</sup>I and <sup>225</sup>Ac 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 will be able to partner our development stage products on commercially favorable terms only if they enjoy appropriate patent coverage and/or considerable know-how and other protection that ensures market exclusivity. For that reason, 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 March 31, 2018 Compared to Three Months Ended March 31, 2017

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

For the Three Months Ended	
March 31,	
2018	2017

Edgar Filing: Actinium Pharmaceuticals, Inc. - Form 10-Q

Revenue	\$-	\$-
Operating expenses:		
Research and development, net of reimbursements	4,462,969	4,573,502
General and administrative	1,878,746	3,211,166
Depreciation expense	11,964	20,920
Total operating expenses	6,353,679	7,805,588
Other income (expense):		
Interest income	30,342	-
Gain (loss) on change in fair value of derivative liabilities	9,076	(255,995 )
Total other income (expense)	39,418	(255,995 )
Net loss	\$(6,314,261 )	\$(8,061,583 )

**Revenue**

We recorded no commercial revenue for the three months ended March 31, 2018 and 2017.

### **Research and Development Expense**

Research and development expenses declined by \$0.1 million to \$4.5 million for the three months ended March 31, 2018 compared to \$4.6 million for the three months ended March 31, 2017. The slight decrease was primarily attributable to higher expenses in 2017 related to Actimab-A, mostly offset by higher expenses in 2018 related to Iomab-B.

In March 2018, we entered into a research and option agreement with Astellas Pharma Inc., or 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. Payments from Astellas under this agreement will be accounted for as a reduction to research and development expense.

### **General and Administrative Expenses**

General and administrative expenses declined by \$1.3 million to \$1.9 million for the three months ended March 31, 2018 compared to \$3.2 million for the three months ended March 31, 2017. The decrease was primarily attributable to lower compensation expense as a result of lower stock option expense and the timing of bonuses for employees.

### **Other Income (Expense)**

Other income of \$39 thousand for the three months ended March 31, 2018 was primarily attributable to interest income. Other expense of \$0.3 million in the prior year period is due to a loss resulting from the valuation of our warrant derivative liability.

### **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 Three Months Ended March 31,	
	2018	2017
Cash used in operating activities	\$(5,459,244 )	\$(5,374,932)
Cash used in investing activities	(6,991 )	(8,313 )
Cash provided by financing activities	14,870,139	1,917,048
Net change in cash	\$9,403,904	\$(3,466,197)

Net cash used in operating activities was \$5.5 million and \$5.4 million for the three months ended March 31, 2018 and 2017, respectively.

Net cash provided by financing activities was \$14.8 million for the three months ended March 31, 2018, reflecting our March 2018 sale of units. During the three months ended March 31, 2017, we received net proceeds of \$1.9 million from the sale of our common stock.

As of March 31, 2018, our cash balance was \$26.8 million. We believe that we have enough cash on hand 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.

### **Seasonality**

We do not have a seasonal business cycle. Our operating results are generally derived evenly throughout the calendar year.

### **Critical Accounting Policies**

Our financial statements have been prepared in accordance with accounting principles generally accepted in the United States. To prepare these consolidated financial statements, we must make estimates and assumptions that affect the reported amounts of assets and liabilities. These estimates also affect our expenses. Judgments must also be made about the disclosure of contingent liabilities. Actual results could be significantly different from these estimates. We believe that the following discussion addresses the accounting policies that are necessary to understand and evaluate our reported financial results.

### **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.

## 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.

Management does not believe that any recently issued, but not yet effective accounting pronouncements, when adopted, will have a material effect on the accompanying consolidated financial statements.

## ITEM 3. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK.

### Common Stock Price Risk

For the three months ended March 31, 2018 and 2017, we recognized the change in the value of warrants of \$9 thousand and \$0.3 million, respectively, on the consolidated statements of operations. Fair value of the derivative instruments will be affected by estimates of various factors that may affect the respective instrument, including our stock price and expected volatility in the fair value of our stock price. As the fair value of this derivative may fluctuate significantly from period to period, the resulting change in valuation may have a significant impact on our results of operations.



**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 March 31, 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 March 31, 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**

*There have been no material changes during the three months ended March 31, 2018 to the risk factors discussed in Item 1A. Risk Factors in our Annual Report on Form 10-K for the year ended December 31, 2017.*

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

None.

**ITEM 3. DEFAULTS UPON SENIOR SECURITIES.**

None.

**ITEM 4. MINE SAFETY DISCLOSURES**

Not applicable.

**ITEM 5. OTHER INFORMATION.**

None.

## ITEM 6. EXHIBITS

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

Exhibit No.	Title of Document	Location
31.1	<u>Certification of the Principal Executive Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.</u>	Attached
31.2	<u>Certification of the Principal Financial and Accounting Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.</u>	Attached
32.1	<u>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*</u>	Attached
32.2	<u>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*</u>	Attached
101.INS	XBRL Instance Document	Attached
101.SCH	XBRL Taxonomy Extension Schema Document	Attached
101.CAL	XBRL Taxonomy Calculation Linkbase Document	Attached
101.DEF	XBRL Taxonomy Extension Definition Linkbase Document	Attached
101.LAB	XBRL Taxonomy Label Linkbase Document	Attached
101.PRE	XBRL Taxonomy Presentation Linkbase Document	Attached

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

**SIGNATURES**

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

**ACTINIUM PHARMACEUTICALS, INC.**

Date: May 10, 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)