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 approac