

Actinium Pharmaceuticals, Inc.
Form 10-K
March 16, 2017

UNITED STATES

SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 10-K

(Mark One)

Annual Report Under Section 13 Or 15(d) Of The Securities Exchange Act Of 1934

For the fiscal year ended **December 31, 2016**

or

Transition Report Under 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 Avenue, 7th Fl.

New York, NY 10016

(Address of principal executive offices) (Zip Code)

(646) 677-3870

Registrant's telephone number, including area code

Indicate by check mark if the registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act.
Yes ☐ No ☐

Indicate by check mark if the registrant is not required to file reports pursuant to Section 13 or Section 15(d) of the Exchange Act. Yes ☐ No ☐

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 website, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T (Section 232.405 of the 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 if disclosure of delinquent filers pursuant to Item 405 of Regulation S-K is not contained herein, and will not be contained, to the best of registrant's knowledge, in definitive proxy or information statements incorporated by reference in Part III of this Form 10-K or any amendment to this Form 10-K.

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, or a smaller reporting company. See the definitions of "large accelerated filer," "accelerated filer" and "smaller reporting

company” in Rule 12b-2 of the Exchange Act. (Check one):

Accelerated filer

(Do not check if a smaller reporting company) Smaller reporting company

Indicate by check mark whether the registrant is a shell company (as defined in Rule 126-2 of the act): Yes No

The aggregate market value of voting stock held by nonaffiliates of the registrant as of June 30, 2016, the last business day of the registrant's most recently completed second fiscal quarter, based on the closing price of the common stock on the NYSE MKT on June 30, 2016 was \$80,515,360.

As of March 16, 2017, 55,807,742 shares of common stock, \$0.001 par value per share, were outstanding.

Table of Contents

	Page
PART I	
<u>Item 1. Business</u>	1
<u>Item 1A. Risk Factors</u>	13
<u>Item 1B. Unresolved Staff Comments</u>	34
<u>Item 2. Properties</u>	34
<u>Item 3. Legal Proceedings</u>	34
<u>Item 4. Mine Safety Disclosures</u>	34
PART II	
<u>Item 5. Market for Registrant's Common Equity, Related Stockholders Matters, and Issuer Purchases of Equity Securities</u>	35
<u>Item 6. Selected Financial Data</u>	37
<u>Item 7. Management's Discussion and Analysis of Financial Condition and Results of Operations</u>	38
<u>Item 7A. Quantitative and Qualitative Disclosures About Market Risk</u>	45
<u>Item 8. Financial Statements and Supplementary Data</u>	F-1
<u>Item 9. Changes in and Disagreements with Accountants on Accounting and Financial Disclosure</u>	46
<u>Item 9A. Controls and Procedures</u>	46
<u>Item 9B. Other Information</u>	47
PART III	
<u>Item 10. Directors, Executive Officers and Corporate Governance</u>	48
<u>Item 11. Executive Compensation</u>	65
<u>Item 12. Security Ownership of Certain Beneficial Owners and Management</u>	73
<u>Item 13. Certain Relationships and Related Transactions, and Director Independence</u>	75
<u>Item 14. Principal Accountant Fees and Services</u>	76
PART IV	
<u>Item 15. Exhibits, Financial Statement Schedules</u>	77
<u>Signature Page</u>	82

CAUTIONARY NOTE REGARDING FORWARD-LOOKING STATEMENTS

This Annual Report on Form 10-K (this “Report”) contains forward looking statements that involve risks and uncertainties, principally in the sections entitled “Description of Business,” “Risk Factors,” and “Management’s Discussion and Analysis of Financial Condition and Results of Operations.” All statements other than statements of historical fact contained in this prospectus, including statements regarding future events, our future financial performance, business strategy and plans and objectives of management for future operations, are forward-looking statements. We have attempted to identify forward-looking statements by terminology including “anticipates,” “believes,” “can,” “continue,” “could,” “estimates,” “expects,” “intends,” “may,” “plans,” “potential,” “predicts,” “should,” or “will” or the negative of these terms or comparable terminology. Although we do not make forward looking statements unless we believe we have a reasonable basis for doing so, we cannot guarantee their accuracy. These statements are only predictions and involve known and unknown risks, uncertainties and other factors, including the risks outlined under “Risk Factors” or elsewhere in this prospectus, which may cause our or our industry’s actual results, levels of activity, performance or achievements expressed or implied by these forward-looking statements. Moreover, we operate in a very competitive and rapidly changing environment. New risks emerge from time to time and it is not possible for us to predict all risk factors, nor can we address the impact of all factors on our business or the extent to which any factor, or combination of factors, may cause our actual results to differ materially from those contained in any forward-looking statements. All forward-looking statements included in this document are based on information available to us on the date hereof, and we assume no obligation to update any such forward-looking statements.

You should not place undue reliance on any forward-looking statement, each of which applies only as of the date of this prospectus. Before you invest in our securities, you should be aware that the occurrence of the events described in the section entitled “Risk Factors” and elsewhere in this prospectus could negatively affect our business, operating results, financial condition and stock price. Except as required by law, we undertake no obligation to update or revise publicly any of the forward-looking statements after the date of this prospectus to conform our statements to actual results or changed expectations.

PART I

Item 1. Business.

Business Overview

Our most advanced products are IomabTM-B, an antibody-drug construct containing iodine 131 (I-131), used in myeloconditioning for hematopoietic stem cells transplantation (HSCT) in various indications and ActimabTM-A, an antibody-drug construct containing actinium 225 (Ac-225), currently in human clinical trials for acute myeloid leukemia (AML). We are currently conducting a pivotal Phase 3 trial of IomabTM-B for bone marrow conditioning for HSCT in patients with relapsed or refractory AML age of 55 and older, which upon successful completion of our clinical trials we intend to submit for marketing approval. We are currently conducting a Phase 3 trial of IomabTM-B for bone marrow conditioning for HSCT in patients with relapsed or refractory AML age of 55 and older, which upon successful completion of our clinical trials, we intend to submit for marketing approval. We are currently also considering filing an application with the U.S. Food and Drug Administration (FDA) for breakthrough therapy designation for ActimabTM-A and/or IomabTM-B. We are developing our cancer drugs using our expertise in radioimmunotherapy. In addition, our Ac-225 based drug development relies on the patented Alpha Particle Immunotherapy Technology (APIT) platform technology co-developed with Memorial Sloan Kettering Cancer Center (MSKCC), who is a significant stockholder in our company. The APIT technology couples monoclonal antibodies (mAb) with extremely potent but comparatively safe alpha particle emitting radioactive isotopes, in particular actinium 225. The final drug construct is designed to specifically target and kill cancer cells while minimizing side effects. We intend to develop a number of products for different types of cancer and derive revenue from partnering relationships with large pharmaceutical companies and/or direct sales of its products in specialty markets in the United States.

Business Strategy

We intend to potentially develop our most advanced clinical stage product candidates through approval in the case of IomabTM-B, and up to and including a Phase 2 proof of concept human clinical trial (a trial designed to provide data on the drug's efficacy) in the case of ActimabTM-A. If these efforts are successful, we may elect to commercialize IomabTM-B on our own or with a partner in the United States and/or outside of the United States to out-license the rights to develop and commercialize the product to a strategic partner. In the case of ActimabTM-A, we will most likely seek to enter into strategic partnerships whereby the strategic partner(s) co-fund(s) further human clinical trials of the drug that are needed to obtain regulatory approvals for commercial sale within and outside of the United States. In parallel, we intend to identify and begin initial human trials with additional actinium-225 product candidates in other cancer indications. We intend to retain marketing rights for our products in the United States whenever possible and out-license marketing rights to our partners for the rest of the world. We may also seek to in license other applicable opportunities should such technology become available.

Market Opportunity

We are competing in the marketplace for cancer treatments estimated to reach over \$83 billion in 2016 sales, according to "The Global Use of Medicines: Outlook Through 2016 Report by the IMS Institute for Healthcare Informatics, July 2012". While surgery, radiation and chemotherapy remain staple treatments for cancer, their use is limited by the fact that they often cause substantial damage to normal cells. On the other hand, targeted monoclonal

antibody therapies exert most or all of their effect directly on cancer cells, but often lack sufficient killing power to eradicate all cancer cells with just the antibody. A new approach for treating cancer is to combine the precision of antibody-based targeting agents with the killing power of radiation or chemotherapy by attaching powerful killing agents to precise molecular carriers called monoclonal antibodies (mAb). We use mAbs labeled with radioisotopes to deliver potent doses of radiation directly to cancer cells while sparing healthy tissues. The radioisotopes we use are the alpha emitter Ac-225 and the beta emitter I-131. I-131 is among the best known and well characterized radioisotopes. It is used very successfully in treatment of papillary and follicular thyroid cancer as well as other thyroid conditions. It is also attached to a monoclonal antibody in treatment of Non-Hodgkin's Lymphoma ("NHL"). It is also used experimentally with different carriers in other cancers. Ac-225 has many unique properties and we believe we are a leader in developing this alpha emitter for clinical applications using our proprietary APIT technology.

Our most advanced products are IomabTM-B, I-131 labeled mAb for preparation of relapsed and refractory AML patients for HSCT; and ActimabTM-A, Ac-225 labeled mAb for treatment of newly diagnosed AML, a cancer of the blood, in patients ineligible for currently approved therapies. IomabTM-B offers a potentially curative treatment for these patients, most of whom do not survive beyond a year after being diagnosed with this condition. IomabTM-B has also demonstrated efficacy in HSCT preparation for other blood cancer indications, including myelodysplastic syndrome ("MDS"), acute lymphoblastic leukemia ("ALL"), Hodgkin's Lymphoma, and Non-Hodgkin's Lymphoma ("NHL"). These are all follow-on indications for which IomabTM-B can be developed and it is our intention to explore these opportunities at a future date. We believe the aggregate worldwide market potential for the treatment of AML, MDS, ALL, Hodgkin's Lymphoma, multiple myeloma and NHL is approximately \$4.1 billion.

On December 16, 2015, Company announced that the FDA cleared the Company's IND filing for Iomab-B, and that it will proceed with a pivotal, Phase 3 clinical trial. Actinium anticipates the Phase 3, controlled, randomized, pivotal trial will complete enrollment of patients by 2018 and assuming that the trial meets its end points, it will form the basis for a Biologics Licensing Application ("BLA"). The Company, in its recently approved IND filing, established an agreement with the FDA that the path to a Biologics License Application submission would include a single, pivotal Phase 3 clinical study if it is successful. The population in this two arm, randomized, controlled, multicenter trial will be refractory and relapsed Acute Myeloid Leukemia ("AML") patients over the age of 55. The trial size was set at 150 patients with 75 patients per arm. The primary endpoint in the pivotal Phase 3 trial is durable complete remission, defined as a complete remission lasting at least 6 months and the secondary endpoint will be overall survival at one year. There are currently no effective treatments approved by the FDA for AML in this patient population and there is no defined standard of care. Iomab-B has completed several physicians sponsored clinical trials examining its potential as a conditioning regimen prior to HSCT in various blood cancers, including the Phase 1/2 study in relapsed and/or refractory AML patients. The results of these studies in over 300 patients have demonstrated the potential of Iomab-B to create a new treatment paradigm for bone marrow transplants by: expanding the pool to ineligible patients who do not have any viable treatment options currently; enabling a shorter and safer preparatory interval for HSCT; reducing post-transplant complications; and showing a clear survival benefit including curative potential.

In September 2016, we initiated the Phase 2 clinical trial for Actimab-A. This Phase 2 clinical trial is a multicenter, open-label study that will enroll 53 patients. Patients will receive 2.0 $\mu\text{Ci/kg}$ /fractionated dose of Actimab-A via two injections given at day 1 and day 7. The Phase 2 trial is designed to evaluate complete response rates at up to day 42 after Actimab-A administration, where complete response is defined as complete remission (CR) or complete remission with incomplete platelet recovery (CRp). A formal interim analysis is expected to occur in mid-2017 with topline results expected in the second half of 2017. The Phase 2 clinical trial includes peripheral blast burden as an inclusion criteria and in patients with high peripheral blast (PB) burden, the use of Hydroxyurea will be mandated with the goal of bringing PB burden below a key threshold number that we have identified from two previously complete Phase 1 clinical trials totaling 38 patients. In addition, the use of granulocyte colony-stimulating factors (GCSF) will be mandated. Low dose cytarabine has been eliminated from the protocol and the Phase 2 clinical trial will evaluate Actimab-A as a monotherapy. The secondary endpoint of the Phase 2 clinical trial will be overall survival.

In February 2017, we initiated a Phase 1 investigator initiated clinical trial to study Actimab-M in multiple myeloma (MM). Multiple myeloma is a cancer of plasma cells that is currently incurable. The Phase 1 trial will enroll up to 12 patients with relapsed or refractory multiple myeloma who have positive CD33 expression. This Phase 1 study is designed as a dose escalation study intended to assess safety, establish maximum tolerable dose (MTD) and assess efficacy. Patients will be administered Actimab-M on day 1 at an initial dose of 0.5 $\mu\text{Ci/kg}$ and then assessed at day 42 for safety and efficacy. The dose can be increased to 1.0 $\mu\text{Ci/kg}$ or reduced to 0.25 $\mu\text{Ci/kg}$ based on safety assessment that will evaluate dose limiting toxicities (DLTs). Patients may receive up to 8 cycles of therapy but in no event will cumulative administration exceed 4.0 $\mu\text{Ci/kg}$ of Actimab-M.

Other potential product opportunities in which significant preclinical work is being undertaken include metastatic colorectal cancer, metastatic prostate cancer and antiangiogenesis which reduces the blood supply to solid tumors. We believe the worldwide market potential for the treatment of metastatic colorectal cancer is approximately \$4.8 billion, and we believe the worldwide market potential for the treatment of metastatic prostate cancer is approximately \$6.0 billion. We also believe the worldwide market potential for the treatment of Glioblastoma Multiforme, a potential indication based on an antiangiogenesis approach, is approximately \$1.1 billion. We estimate the market potential for these indications based on company research published rates of disease incidence and company calculations based on costs of currently used therapies.

We believe that our biggest market opportunity lies in the applicability of our APIT platform technology to a wide variety of cancers. A broad range of solid and blood borne cancers can be potentially targeted by mAbs to enable treatment with the APIT technology. The APIT technology could potentially be applied to mAbs that are already approved by the FDA to create more efficacious and/or safer drugs ("biobetters").

In March 2016, the FDA granted orphan drug designation for Ioamb-B and in October 2016 the European Medicines Agency (EMA) granted orphan designation in the European Union (EU) for Iomab-B. In November 2014, the FDA granted orphan-drug designation for ActimabTM-A and in December 2016 we submitted an application to the EMA for

orphan designation in the EU for Actimab-A. The FDA, through its Office of Orphan Products Development, grants orphan status to drugs and biologic products that are intended for the safe and effective treatment, diagnosis, or prevention of rare diseases or disorders that affect fewer than 200,000 people in the United States. Orphan drug designation provides a drug developer with certain benefits and incentives, including a period of marketing exclusivity if regulatory approval is ultimately received for the designated indication; potential tax credits on United States clinical trials; eligibility for orphan drug grants; and waiver of certain administrative fees. The EMA, through its Committee for Orphan Medicinal Products (COMP), examines applications for orphan designation. To qualify for orphan designation, the prevalence of the condition must be less than 5 in 10,000, it must be life threatening or chronically debilitating and there must be no satisfactory method of treating the condition. Sponsors who obtain orphan designation receive numerous incentives including protocol assistance, a reduction or waving of fees and 10 years of market exclusivity should the therapy be approved. The process of filing and receiving the orphan medicines designation can take between eight to fourteen months in most cases.

Our Corporate History and Background

We were formed as a Nevada corporation on October 6, 1997, originally under the name Zurich U.S.A., Inc. On July 10, 2006, we changed our name to Cactus Ventures, Inc. and began pursuing our business of marketing sunglasses. The Company encountered numerous problems with various vendors and ceased its operations. The Company shifted its efforts to seeking a business combination opportunity with a business entity, and negotiated a merger of a target company into the Company. Upon ceasing its operations, the Company was considered a “blank check” or “Shell” company as such term is defined under the Securities Act. Upon completing the Share Exchange (as defined below), the Company ceased being considered a “blank check” or “Shell” company and is now a clinical-stage biopharmaceutical company developing certain cancer treatments.

On April 11, 2013, the change of domicile from the State of Nevada to the State of Delaware and the change of Cactus Ventures, Inc.’s name from Cactus Ventures, Inc. to Actinium Pharmaceuticals, Inc. became effective in accordance with Articles of Merger filed with the State of Nevada and a Certificate of Merger filed with the State of Delaware. In connection with the name change we also changed (i) the name of our subsidiary Actinium Pharmaceuticals, Inc. to Actinium Corporation, (ii) our par value to \$0.001 per share, and (iii) the number of authorized shares of preferred stock to 10 million shares. Effective April 18, 2013 our new trading symbol became ATNM. On September 25, 2013, we merged with our subsidiary, Actinium Corporation. In January 2014, we increased our authorized shares of common stock to 200 million shares and our authorized shares of preferred stock to 50 million shares.

Acquisition of Actinium

On December 28, 2012, Actinium Pharmaceuticals, Inc. (“Actinium”) completed a share exchange with Cactus, whereby Cactus acquired 21% of the issued and outstanding capital stock of Actinium Corporation from the shareholders of Actinium Corporation in exchange for the issuance of 4,333,489 shares of Common Stock of the Company to the Actinium shareholders. As part of the share exchange, Actinium Corporation paid \$250,000 to the shareholders of Cactus before the consummation of the share exchange.

The share exchange was treated as a recapitalization effected through a share exchange, with Actinium Corporation as the accounting acquirer and the Company the accounting acquiree. Unless the context suggests otherwise, when we refer in this Report to business and financial information for periods prior to the consummation of the share exchange, we are referring to the business and financial information of Actinium Corporation.

As a result of the share exchange, the Company assumed the business and operations of Actinium Corporation. On April 11, 2013, the change of domicile from the State of Nevada to the State of Delaware and the change of Cactus Ventures, Inc.’s name from Cactus Ventures, Inc. to Actinium Pharmaceuticals, Inc. became effective in accordance with Articles of Merger filed with the State of Nevada and a Certificate of Merger filed with the State of Delaware.

As we are a “reporting company” under the Exchange Act of 1934, it is required to file periodic filings with the SEC.

On March 11, 2013, Actinium Corporation continued its share exchange with the Company, whereby we acquired an additional 36% of the issued and outstanding capital stock of Actinium Corporation from the Actinium Corporation shareholders in exchange for the issuance of 7,756,840 shares of Common Stock of the Company to the Actinium Shareholders. On August 22, 2013, Actinium Corporation continued its share exchange with the Company, whereby the Company acquired an additional 30.4% of the issued and outstanding capital stock of Actinium Corporation from the Actinium Corporation shareholders in exchange for the issuance of 6,383,475 shares of Common Stock of the Company to the Actinium Shareholders. On September 25, 2013 in accordance with a Certificate of Ownership Merging Actinium Corporation into the Company, the Company merged into itself Actinium Corporation, and Actinium Corporation ceased to exist. As a result of the merger, Actinium Corporation stock owned by the Company has been cancelled and each share of Actinium Corporation not owned by the Company was exchanged for 0.333 shares of Company common stock.

Corporate History of Actinium

Actinium Corporation was incorporated in 2000 in the state of Delaware. Until the share exchange, Actinium Corporation was a clinical-stage, privately held biopharmaceutical company with:

Two clinical-stage products, IomabTM-B and ActimabTM-A, in development for blood borne cancers;

Preclinical data in additional cancer indications;

A proprietary technology platform for novel radioimmunotherapy cancer treatments; and

A proprietary process for manufacturing of the alpha particle emitting radioactive isotope actinium 225 (Ac-225).

Iomab-B is currently in a pivotal Phase 3 trial in patients with relapsed or refractory AML who are age 55 and over prior to a HSCT. ActimabTM-A is currently in the Phase 2 portion of a Phase 1/2 trial in newly diagnosed elderly AML patients. In addition, using our patented APIT platform and via our collaboration with MSKCC, the Company has preclinical data on potential drug candidates in several other cancer indications and expects to further develop these into clinical stage drug candidates.

Actinium Corporation has one wholly owned subsidiary, MedActinium, Inc., a Delaware corporation, which is party to certain isotope related licenses and contracts on which we rely on.

Our executive office is located at 275 Madison Ave, 7th Floor, New York, NY 10016 and telephone number is (646) 677-3870. Our website address is <http://www.actiniumpharma.com>. Except as set forth below, the information on our website is not part of this Annual Report on Form 10-K.

Summary of Scientific and Business Achievements:

Our key scientific and business achievements to date include:

Iomab-B related:

- In-licensing a Phase 2 clinical stage monoclonal antibody, BC8, with safety and efficacy data in more than 250 patients in need of HSCT, currently in 7 active Phase 1 and Phase 2 clinical trials;
- Commencing pivotal Phase 3 trial for Iomab-B;
- Obtaining clearance by the FDA to proceed with the Phase 3 trial Iomab-B; and
- Commencing manufacturing development of commercial scale and quality production of Iomab-B.

Actimab-A related:

- Completing the Phase 1 portion of a Company sponsored multi-center Phase 1/2 clinical trial for ActimabTM-A in elderly AML patients;
- Commencing Phase 2 portion of Company sponsored trial for ActimabTM-A in elderly AML patients; Modifying protocol for Phase 2 portion of the trial to account for peripheral blast burden, mandating the use of hydroxyurea in certain patients and eliminate use of low-dose cytarabine;
- Developing and organizing manufacturing of Actinium's lead drug candidate ActimabTM-A which was accepted by the FDA for multi-center human use; Supporting three physician sponsored clinical trials, including a Phase 1 and a Phase 1/2 trial with the alpha emitting radioactive isotope bismuth 213 (Bi-213) based AML drug and a Phase I clinical trial with the alpha emitting radioactive isotope actinium 225 (Ac-225) based AML drug; and
- In-licensing the AML targeting monoclonal antibody known as HuM195 or Lintuzumab.

General operations:

- Establishing clinical and preclinical development relationships with world-class institutions such as MSKCC, FHCRC and University of Texas MD Anderson Cancer Center (the MD Anderson Cancer Center relationship includes clinical trials only), as well as leading clinical experts in the fields of AML and HSCT;
- Securing rights to an intellectual property estate that covers key aspects of the Company's proprietary technology platform;
- Supporting several pipeline projects, including preclinical experiments in metastatic prostate cancer, metastatic colon cancer, antiangiogenesis and breast cancer models;
- Maintaining our contractual relationship with ORNL of the DOE that provides us access to the largest known supply reserves of actinium 225; and
- Successfully developing commercial production methods for actinium 225.

Clinical Trials

Iomab™-B

Iomab™-B is our lead product candidate currently in a pivotal Phase 3 multicenter clinical trial. It consists of the monoclonal antibody BC8 and beta emitting radioisotope iodine 131 (I-131). The indication for that trial is bone marrow conditioning for HSCT in patients with relapsed and refractory AML over the age of 55.

Previous Iomab™-B clinical trials leading to the planned Phase 3 trial currently in preparation included:

Indications	N	Key Findings
AML, MDS, ALL (adult)	34	–7/34 patients with median disease free state (DFS) of 17 years. –18/34 patients in remission at day 80
AML >1st remission (adult)	23	–15/23 in remission at day 28
AML 1st remission (age 16-50)	43	–23/43 DFS from 5-16 years –30/43 in remission at day 28 –33/43 in remission at day 80
High-risk MDS, advanced AML	68 in dose escalation study	–CR (complete remission) in all patients

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

(age 50+)	31 treated at MTD	–1 yr survival ~40% for all patients –1 yr survival ~45% for pts treated at MTD maximum tolerated dose)
High-risk MDS, AML (age 18–50)	14 in dose escalation	All patients achieved full donor chimerism by day 28 post-transplant
High-risk MDS, AML –haploidentical donors (adult)	8 in dose escalation	–6/8 treated patients achieved CR by day.28 –8/8 patients 100% donor chimerism by day28

Ongoing Iomab™-B clinical trials include:

Indications	Phase
Relapsed and refractory Hodgkin Lymphoma and NHL (adult)	Phase 1
Advanced AML, ALL and MDS (adult)	Phase 2
AML 1st remission (age 16-50)	Phase 2
High-risk MDS, advanced AML (age 16-50)	Phase 2

There are additional ongoing clinical trials with BC8 antibody labeled with yttrium 90 (Y-90).

We have obtained FDA's comment and guidance on the IomabTM-B Phase 3 clinical trial design, and the FDA has identified the following design features as generally acceptable, dependent on the results of the trial:

~~-Single pivotal study, pending trial results;~~

~~-Patient population: refractory AML patients age of 55 and older, where refractory is defined as either primary failure to achieve a complete remission after 2 cycles of induction therapy; relapsed after 6 months in complete remission; second or higher relapse; or relapsed disease not responding to intensive salvage therapy;~~

~~-Trial arms: study arm and control arm with physician's choice of conventional care with curative intent; and~~

~~-Trial size: 150 patients total (75 patients per arm).~~

ActimabTM-A

ActimabTM-A is currently in the Phase 2 portion of a multicenter Phase 1/2 clinical trial in AML. It consists of the monoclonal antibody Lintuzumab and alpha emitting radioisotope actinium 225 (Ac-225). The indication in the ongoing trial is newly diagnosed AML patients over the age of 60.

Previous clinical trials leading to this trial included:

Phase 1 clinical trial with Bismab-A, the first generation product consisting of the same monoclonal antibody Lintuzumab and Bi-213 alpha emitter, a daughter of Ac-225;

Phase 1/2 clinical trial with Bismab-A, the first generation product consisting of the same monoclonal antibody Lintuzumab and Bi-213 alpha emitter, a daughter of Ac-225; and

Dose escalating pilot Phase 1 clinical trial with ActimabTM-A, the current product consisting of the Lintuzumab monoclonal antibody and Ac-225 alpha emitter.

Completed ActimabTM-A related clinical trials outcomes:

The Phase 2 arm of the Bismab-A drug study has shown signs of the drug's efficacy and safety, including reduction in peripheral blast counts and complete responses in some patients. Bi-213 is a daughter, i.e., product of the degradation of Ac-225, with cancer cell killing properties similar to Ac-225 but is less potent. The Phase 1 ActimabTM-A trial at

MSKCC with a single-dose administration of ActimabTM-A showed elimination of leukemia cells from blood in 67% of all evaluable patients who received a full dose and in 83% of those treated at dose levels above 0.5 microcuries per kilogram ($\mu\text{Ci/kg}$), and eradication of leukemia cells in both blood and bone marrow in 20% of all evaluable patients and 25% of those treated at dose levels above 0.5 $\mu\text{Ci/kg}$. Maximum tolerated single dose in this trial was established at 3 $\mu\text{Ci/kg}$.

High potency means that a relatively low amount of drug is needed to produce a given effect. In preclinical and Phase 1 clinical studies, Actimab-A (^{225}Ac -lintuzumab) has demonstrated at least 500-1000 times higher potency than the first-generation predecessor (^{213}Bi -lintuzumab) upon which it is based. This difference is due to intrinsic physicochemical properties of Actimab-A that were first established *in vitro*, in which Actimab-A killed multiple cell lines at doses at least 1000 times lower (based on LD50 values) than Bismab-A analogs. Key factors in Actimab-A's higher potency are the yield of 4 alpha-emitting isotopes per ^{225}Ac (compared to 1 alpha decay for bismuth 213) and much longer half-life (10 day for ^{225}Ac vs 46 minutes for ^{213}Bi).

In preclinical animal models, doses in the nanocurie range prolonged survival. In humans, Actimab-A was previously studied in a Phase I monotherapy trial of relapsed or refractory AML patients at MSKCC. Dose levels in that study re-confirmed the substantially higher potency of Actimab-A, as compared to equivalent dosing of the first-generation Bismab-A (^{213}Bi -lintuzumab) construct, which had nevertheless established safety and efficacy in a Phase 1/2 trial in high-risk AML with cytareduction.

Sources: Jurcic JG. Targeted Alpha-Particle Immunotherapy with Bismuth-213 and Actinium-225 for Acute Myeloid Leukemia. *J. Postgrad Med Edu Res* 2013, 47(1):14-17; ; JG Jurcic et al, Phase 1 Trial of the Targeted Alpha- Particle Nano-Generator Actinium-225 (^{225}Ac)-Lintuzumab in Acute Myeloid Leukemia (AML) *J Clin Oncol* 29:2011 (suppl, abstr 6516); McDevitt MR et al, “Tumor Therapy with Targeted Atomic Nanogenerators” *Science* 2001, 294:1537—1540; Rosenblat TL et al, “Sequential cytarabine and alpha-particle immunotherapy with bismuth-213-lintuzumab (HuM195) for acute myeloid leukemia” *Clin Cancer Res.* 2010, 16(21):5303-5311; Jurcic JG et al. “Phase I Trial of the Targeted Alpha-Particle Nano-Generator Actinium-225 (^{225}Ac)-Lintuzumab in Acute Myeloid Leukemia (AML)” *Blood* (ASH Meeting Abstracts) 2012.

Ongoing ActimabTM-A trial:

We have completed the Phase 1 portion of our first company sponsored Phase 1/2 multi-center trial with fractionated (two) doses of ActimabTM-A, for the treatment of patients newly diagnosed with AML over the age of 60. Actimab-A consists of an AML specific monoclonal antibody (HuM195, also known as LintuzumabTM) and the actinium 225 radioactive isotope attached to it. Results from the Phase 1 portion of the trial showed that 28% (5 of 18) of patients had objective responses (2CR, 1CRp and 2 Cri (complete remission with incomplete blood count recovery)) with median response duration of 9.1 months. Mean bone marrow blast reduction amongst evaluable patients (14 of 18) was 67% with 57% of patients having bone marrow blast reduction of 50% or greater and 79% (11 of 14) of patients having bone marrow blast reductions after Cycle 1 of therapy. Maximum tolerated dose (MTD) was not reached in this trial. We have elected to progress to the Phase 2 portion of the trial at 2.0 $\mu\text{Ci/kg/fraction}$, the highest dose level from the Phase 1 portion of the trial.

The Phase 2 portion of the trial will enroll 53 patients and will study Actimab-A as a monotherapy. The Company received agreement from the FDA for multiple revisions to the trial protocol for the Phase 2 portion of the trial that include:

- Removing the use of low dose cytarabine from the Phase 2 protocol,
- Stipulating Peripheral blast burden as an inclusion criteria with 200 ML being the threshold
- Mandating the use of hydroxyurea in patients with peripheral blast count above 200 ML to lower their peripheral blasts below 200ML/ prior to Actimab-A administration
- Mandating the use of granulocyte colony-stimulating factor (GCSF) support

Bismab-A trials and the Phase 1 Actimab™-A trial were focused on relapsed, refractory and other difficult to treat acute myeloid leukemia patients. The current multicenter Phase 1/2 trial is focused on newly diagnosed AML patients who have historically had better outcomes.

Actimab-M

Actimab-M is comprised of the anti-CD33 monoclonal antibody HuM-195 coupled to actinium 225, an alpha-particle emitting radioisotope, and is the same construct of Actinium's Actimab-A, which is currently being studied in a Phase 2 clinical trial in patients newly diagnosed with acute myeloid leukemia (AML) who are over the age of 60. The Phase 1 trial for Actimab-M is an, open label, dose-escalation study. Patients will be administered a starting dose level of 0.5 µCi/Kg of Actimab-M via infusion on day 1 of each cycle for up to 8 cycles with each cycle lasting 42 days. If this dose level is deemed safe, a second dose level of 1.0 µCi/kg will be explored for up to 4 cycles also of 42 days per cycle. Total dose received per patient is not to exceed 4.0 µCi/kg. In the event of dose limiting toxicities (DLTs) at the 0.5 µCi/Kg dose level, a dose level of 0.25 µCi/Kg will be explored. The Phase 1 trial will estimate maximum tolerated dose (MTD), assess adverse events, measure response rates (objective response rate, complete response rate, stringent complete response rate, very good partial response rate and partial response rate) as well as progression free survival (PFS) and overall survival (OS).

Operations

Our current operations are primarily focused on furthering the development of our lead clinical drug candidates Iomab™-B and Actimab™-A, supporting investigator initiated clinical trials that use our drug candidates and leveraging our alpha particle immunotherapy technology platform to create new clinical programs.

Operations related to Iomab™-B include progressing the ongoing multi-center Phase 3 pivotal trial (a trial that leads to registration trial marketing approved by the FDA) which include investigator engagement, site activation and supporting patient enrollment. In addition, we are focused on commercial scale manufacturing suitable for an approval trial and preparation of appropriate regulatory submissions.

In the case of Actimab-M and Actimab™-A respectively, key ongoing activities include progressing the ongoing investigator sponsored Phase 1 and multi-center Phase 2 portions of our trials, managing isotope and other materials supply chain, and managing the manufacturing of the finished drug candidate product. We have secured access to much of the currently available world reserves of Ac-225 and Bi-213 through a renewable contractual arrangement with the United States Department of Energy (DOE). We project that these quantities are sufficient to support early stages of commercialization of alpha isotopes based products. The Company has also developed its own proprietary process for industrial scale Ac-225 production in a cyclotron in quantities adequate to support full product commercialization.

For the years ended December 31, 2016, 2015 and 2014, we incurred approximately \$17.5 million, \$13.3 million and \$12.3 million, respectively, on research and development activities. These expenditures consisted of materials maintenance and purchases, supply chain development and implementation, drug candidate manufacturing expenditures, clinical trials costs and intellectual property portfolio related expenses. None of the costs of such research and development activities were borne by customers. For the years ended December 31, 2016, 2015 and 2014, our net loss was approximately \$24.3 million, \$21.0 million and \$24.7 million, respectively.

Failure to raise additional equity or debt funding in the amounts necessary to complete our programs and/or failure to out license our programs on the projected terms may result in a delay of our projected development plan or our inability to complete one or more of the planned programs.

Summary of Material Agreements Related to Our Business

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

- a. AbbVie Biotherapeutics Corp. (formerly Abbott 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 the following agreed to and contracted milestones:

Milestones	Payments
(1) when Company initiates a Phase I Clinical Trial of a licensed product	\$ 750,000
(2) when Company initiates a Phase II Clinical Trial of a licensed product	750,000
(3) when Company initiates a Phase III Clinical Trial of a licensed product	1,500,000
(4) Biological License Application filing with U.S. FDA	1,750,000
(5) First commercial sale	1,500,000
(6) after the first \$10,000,000 in net sales	1,500,000

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 paid AbbVie Biotherapeutics Corp. a milestone payment of \$750,000 on July 24, 2012. 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 accrued \$750,000 as a research and development expense.

b. Memorial Sloan Kettering Cancer Center (MSKCC) –

In February 2002, we entered into a license agreement with MSKCC that requires a technology access fee of \$50,000 upon execution, an annual maintenance fee of \$50,000 and an annual research funding of \$50,000 for as long as the agreement is in force.

We agreed to make milestone payments totaling \$2.5 million for the achievement of contracted milestones. These milestones include (i) a payment of \$750,000 upon the filing of a New Drug Application (“NDA”) or regulatory approval for each licensed product and (ii) a payment of \$1,750,000 upon the receipt of regulatory approval from the U.S. FDA for each licensed product. All the milestones and payments are related to products based on alpha emitter based products. Currently, the only such product in clinical development is Actimab-A. As of December 31, 2016, we had no outstanding balance with MSKCC.

Under the agreement, we agreed to 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. We expect to file the NDA for regulatory approval in 2018.

- 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. For the years ended December 31, 2016, 2015 and 2014, the Company purchased approximately \$1.0 million, \$0.8 million and \$0.6 million, respectively, of radioactive material with ORNL. On January 9, 2017 the Company signed a contract with ORNL to purchase \$0.7 million of radioactive material.
- c.

- Icon Clinical Research, LLC (“Icon”, formerly AptivSolutions) provides project management services for the study of the drug Ac-225-HuM195 (Actimab-A) used in the Company’s Phase 1 and Phase 2 clinical trials. The total project was estimated to cost approximately \$1.9 million and required a 12.5% down payment of the total estimated project cost. Following several amendments the total project is now estimated at approximately \$2.7 million. Icon invoices the Company when services are rendered and the Company records the related expense to research and development expense. For the years ended December 31, 2016, 2015 and 2014, the Company incurred expenses of approximately \$0.8 million, \$0.4 million and \$0.4 million, respectively, related to this agreement.
- 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 Phase 1 and Phase 2 of the clinical trial and the Company intends to start preparation for a pivotal trial leading to an FDA approval. The Company has been granted exclusive rights to the BC8 antibody and related master cell bank developed by FHCRC. The cost to develop the trial will range from \$13.2 million to \$23.5 million, depending on the trial design as required by the FDA. Under the terms of the sponsored research agreement, the Company will fund the FHCRC lab with \$0.2 million per year for the first two years and \$0.3 million thereafter. Payments made toward funding the lab will be credited toward royalty payments owed to FHCRC in the given year. 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. During the years ended December 31, 2016, 2015 and 2014, the Company recorded fees of approximately \$0.4 million, \$0.3 million and \$0.2 million, 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 anticipated to be used in our phase 3 clinical trial of Iomab-B. Total cost of the agreement is approximately \$6.8 million. The Company made a non-refundable payment of \$0.6 million upon execution of the agreement. Periodic payments will be made upon reaching certain milestones. As of December 31, 2016, the remaining cost of the service agreement (only) is approximately \$2.6 million. Goodwin bills the Company when services are rendered and the Company records the related expense to research and development costs.
- f.

For the years ended December 31, 2016, 2015 and 2014, the Company paid Goodwin (service fees and materials) approximately \$0.7 million, \$4.2 million and \$3.6 million, respectively. As of December 31, 2016 and 2015, the Company owed Goodwin \$0.1 million.

- On September 30, 2014, the Company entered into a research agreement with the Albert Einstein College of Medicine of Yeshiva University (“Einstein”). According to the agreement, Einstein will use certain materials provided by the Company to complete a research project. The research project will explore the feasibility of using Actinium 225 to prepare patients with blood borne cancers to receive a hematopoietic stem cell transplant. Einstein
- g.

will periodically provide the Company with reports showing project data or research. The total fixed price of the project is \$0.2 million which is payable to Einstein in three payments. During 2016, 2015 and 2014, we paid approximately \$37,000, \$0.1 million, \$0.1 million, respectfully in full of the agreement.

On February 16, 2016, the Company entered into a CRO agreement with Medpace, Inc. (“Medpace”). Medpace h. provides project management services for the Iomab-B Phase 3 clinical trial. The total project is estimated to cost approximately \$7.2 million. For the year ended December 31, 2016, the Company paid approximately \$2.6 million.

On August 4, 2016, the Company entered into a CRO agreement with Vector Oncology Solutions, LLC (“Vector”). i. Vector provides project management services for the study of Actimab-A used for our Phase 2 clinical trial. The total project is estimated to cost approximately \$4.6 million. For the year ended December 31, 2016, the Company paid approximately \$1.0 million.

Intellectual Property Portfolio

Intellectual Property

We have developed or in-licensed numerous patents and patent applications and possess substantial know-how and trade secrets relating to the development and commercialization of our products. In the past year, the Company has strengthened its IP positioning with the allowance of three additional patents and further allowances are anticipated in 2017. As of March 10, 2017 our patent portfolio includes: 61 issued and pending patents, of which 10 are issued in the United States, 50 are issued or pending internationally, and 1 is pending in the United States. Additionally, several non-provisional patent applications are expected to be filed in 2017 based on provisional patent applications filed in 2016. This is part of an ongoing strategy to continue to strengthen the company’s IP position. About half of our patents are in-licensed from third parties and half are held by us. These patents cover key areas of our business, including use of the actinium-225 and other alpha emitting isotopes attached to cancer specific carriers like monoclonal antibodies, methods for manufacturing key components of our product candidates including actinium-225 alpha emitting radioisotope and carrier antibodies, and methods for manufacturing finished product candidates for use in cancer treatment. The table below classifies these patents by related family:

Area	Description	US Expiration	US Status	Owner/ Licensor
Platform technology	Antibody conjugates with DOTA chelators; methods of treating cancer using the same	2021	Issued	MSKCC
Platform technology	Radioimmunoconjugate generation	2029	Issues	Owned
Drug preparation methods	Actinium 225 labeling method (binding to an antibody)	2030	Pending	Owned
Drug preparation methods	Bismuth 213 labeling method (binding to an antibody)	2019	Issued	MSKCC

Isotope production
methods

Actinium 225 manufacturing in a cyclotron

2026/2027 Issued Owned

A patent whose claims address methods of treating hematopoietic malignancies with Iomab™-B is pending; still, we have developed a proprietary strategy based on trade secret protection and the potential for orphan drug and data exclusivities. The BC8 antibody, cell line and related know-how has been exclusively licensed by us from the Fred Hutchinson Cancer Research Center (FHCRC) in exchange for milestones, royalties and research support.

Patents related to the antibody component of Actimab-A have been exclusively licensed by us from AbbVie Biotherapeutics Corp. for use with alpha-emitting radioisotopes in exchange for future development and commercialization milestones, a royalty on net sales for a period of 12.5 years from first commercial sale, a negotiation right to be our clinical and/or commercial antibody supplier, a negotiation right to co-promote Actimab™-A in the United States on terms to be negotiated, and the grant-back of IP rights covering improvements to the antibody for use other than with an alpha-emitting isotope. Patents covering actinium-225 conjugated to antibodies have been exclusively licensed by us from MSKCC in exchange for license fees, research support payments, development milestones, 2% royalties on net sales for the term of the licensed patents or, if later, 10 years from first commercial sale, and 15% of any sublicense income we may receive. We source actinium-225 under an agreement with the Oak Ridge National Laboratory (ORNL) that expires at the end of 2017. We believe, but cannot guarantee, that we will be able to renew this contract for additional annual periods.

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 believe that the key elements for our market success include:

Clinical results to date could imply lower development risk for its lead drug candidates: Our lead drug candidates have been tested in over 300 patients and demonstrated favorable safety and efficacy profiles. Iomab™-B has been administered to more than 300 patients with leukemia in a number of Phase 1 and Phase 2 trials and has shown a clear survival benefit in the indication for which it is being developed. Bismab®-A and Actimab™-A, drugs based on the APIT platform have to date been tested in almost 90 patients in 4 clinical trials. In each trial they exhibited few side effects and have shown indications of efficacy. The current proof-of-concept Actimab™-A Phase 1/2 clinical trial is directed at a patient population that is generally easier to treat (newly diagnosed vs. relapsed/refractory in previous trials), and employs a more potent treatment regimen (two doses of Actimab™-A vs. a single dose of Actimab™-A in the physician sponsored trial).

Additional product opportunities from the APIT platform: Our APIT technology has the potential for broad applicability for the treatment of many cancer types, which allows us to add new product candidates to its pipeline based on well-defined patent protected methods.

Collaboration with MSKCC: Our collaboration with MSKCC includes licensing, research and clinical trial arrangements involving MSKCC labs and clinicians and included financial support with respect to certain pre-2012 R&D-related expenses.

Scientific backing of leading experts: Our clinical advisory board and collaborators include some of the most recognized clinicians and scientists working at some of the highest regarded medical institutions in the United States and the world, including MSKCC, Johns Hopkins University, University of Pennsylvania, FHCC and MD Anderson Cancer Center. This is expected to be beneficial to us both in clinical development and market acceptance assuming its drug candidates are approved.

Isotope supply secured for clinical trials: We have a contractual relationship with ORNL of the DOE that provides us access to the largest known supply reserves of actinium 225. Iodine 131 is readily available from a number of qualified pharmaceutical supply vendors.

Proprietary alpha emitting isotope manufacturing technology fully developed: We have developed our own proprietary technology for commercial scale manufacturing of actinium 225. This is expected to ensure commercial supply of Ac-225 for Actimab™-A, Actimab™-B and other actinium-linked products should they be approved.

cGMP Actimab™-A manufacturing developed: We have developed at a contractor's site full cGMP (current good manufacturing practices) manufacturing processes for our drug candidate Actimab™-A.

Substantial IP portfolio: We have an intellectual property portfolio in excess of 60 patents and patent applications, both in the United States and other countries, which cover clinical applications of the APIT technology and methods of manufacturing actinium 225 thus giving us control over both the applications of our technology and a supply chain of our key ingredients, actinium 225 and bismuth 213 alpha emitting isotopes.

Competition Overview

To our knowledge, there are no other commercial entities that have significant clinical programs in place for developing Ac-225- or Bi-213-based drugs. In the wider field of medical oncology, we face competition from: developers of other alpha emitter based drug candidates, other radioimmunotherapy based technologies, technologies for labeling antibodies with toxic drugs (antibody-drug conjugates), and for each disease indication from all drugs available and/or in development.

For our lead indication, acute myeloid leukemia, there are a number of companies developing drugs for AML. These drugs are most often small molecules and as such have different safety profiles and mechanisms of action compared to our drug candidates. Acute myeloid leukemia in older patients remains an area of high medical need that could accommodate many new products with favorable safety and efficiency profiles.

In the field of hematopoietic stem cell transplantation, pharmaceuticals currently used for bone marrow ablation/conditioning are generic drugs and to our knowledge there are no significant industry efforts to advance clinical programs in this area that are directly competitive, especially in older patients.

Government Regulation

Governmental authorities in the United States and other countries extensively regulate, among other things, the research, development, testing, manufacture, labeling, promotion, advertising, distribution and marketing of radioimmunotherapy pharmaceutical products such as those being developed by us. In the United States, the FDA regulates such products under the Federal Food, Drug and Cosmetic Act (FDCA) and implements regulations. Failure to comply with applicable FDA requirements, both before and after approval, may subject us to administrative and judicial sanctions, such as a delay in approving or refusal by the FDA to approve pending applications, warning letters, product recalls, product seizures, total or partial suspension of production or distribution, injunctions and/or criminal prosecution.

U.S. Food and Drug Administration Regulation

Our research, development and clinical programs, as well as our manufacturing and marketing operations, are subject to extensive regulation in the United States and other countries. Most notably, all of our products that may in the future be sold in the United States are subject to regulation by the FDA. Certain of our product candidates in the

United States require FDA pre-marketing approval of a BLA pursuant to 21 C.F.R. § 314. Foreign countries may require similar or more onerous approvals to manufacture or market these products.

Failure by us or by our suppliers to comply with applicable regulatory requirements can result in enforcement action by the FDA, the Nuclear Regulatory Commission or other regulatory authorities, which may result in sanctions, including but not limited to, untitled letters, warning letters, fines, injunctions, consent decrees and civil penalties; customer notifications or repair, replacement, refunds, recall, detention or seizure of our products; operating restrictions or partial suspension or total shutdown of production; refusing or delaying our requests for BLA premarket approval of new products or modified products; withdrawing BLA approvals that have already been granted; and refusal to grant export.

Employees

As of March 15, 2017, we have 23 full-time employees. None of these employees are covered by a collective bargaining agreement, and we believe our relationship with our employees is good. We also engage consultants on an as-needed basis to supplement existing staff.

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 Annual Report on Form 10-K. Factors that could cause or contribute to differences in our actual results include those discussed in the following subsection, as well as those discussed 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 have generated no revenue from commercial sales to date and our future profitability is uncertain.

We have a limited operating history and our business is subject to all of the risks inherent in the establishment of a new business enterprise. Our likelihood of success must be considered in light of the problems, expenses, difficulties, complications and delays frequently encountered in connection with this development and expansion. Since we began our business, we have focused on research, development and clinical trials of product candidates, and have incurred losses since inception. As of December 31, 2016, we had an accumulated deficit of approximately \$136.6 million. If we continue to incur operating losses and fail to become a profitable company, we may be unable to continue our operations. 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, and the extent of our future losses and the timing of our profitability are highly uncertain.

If we fail to obtain the capital necessary to fund our operations, we will be unable to continue or complete our product development and you will likely lose your entire investment.

Although we believe we have enough working capital for operations for the next 12 months, we do not currently have sufficient capital for the development and commercialization of our lead product candidate and we will need to continue to seek capital from time to time to continue development of our lead 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 2018 and we do not expect that the partnering revenues it will generate will be sufficient to fund our ongoing operations. Our cash balance as of December 31, 2016 was approximately \$20.5 million. Throughout the year ended December 31, 2016, we raised total net proceeds of approximately \$16.0 million from the completion of public offerings of common stock, warrants and stock option exercises. We expect that we will need approximately \$14.6 million over the next 12 months to finance research and development and to cover our ongoing working capital needs.

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 capital we may 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 capital. The capital markets have been unpredictable in the recent past for radio-immunotherapy 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.

If we fail to obtain or maintain necessary FDA approval for our radio-immunotherapy products, or if such approvals are delayed, we will be unable to commercially distribute and market our products.

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 a radio-immunotherapy 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 Company 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 radio-immunotherapy 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 than 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.

Our radio-immunotherapy product candidates are in the early stages of development; and we have not demonstrated that any of our products are safe and effective for any indication.

We currently have only two products in clinical development. In December 2015, the FDA cleared our IND filing for Iomab-B, and we have initiated the pivotal, Phase 3 clinical trial. We are currently conducting a Phase 3, controlled, randomized, pivotal trial. Assuming that the trial meets its end points, it will form the basis for a BLA. Additionally, there are a number of physician IND trials at the FHCRC that have been conducted or are currently ongoing at FHCRC with IomabTM-B and the BC8 antibody we licensed. We have completed the Phase 1 portion of the Phase 1/2 multi-center AML trial with fractionated doses of ActimabTM-A under its own federal IND and have commenced the Phase 2 portion of the trial.

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), 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.

Additionally, changes in regulatory requirements and guidance may occur and we may need to amend clinical trial protocols to reflect these changes. Amendments may require us to resubmit our clinical trial protocols to IRBs for

reexamination, which may impact the cost, timing or successful completion of a clinical trial.

In addition, neither we nor any relevant collaborative partner(s) has yet undertaken any clinical assessment or investigation of Company's radio-immunotherapy product candidates for other indications, including colon cancer or prostate cancer. Significant further investment may be required to acquire antibody rights and to undertake necessary research and continued development. Further laboratory and specific clinical testing will be required prior to regulatory approval of any product candidates. Adverse or inconclusive results from pre-clinical testing or clinical trials of product candidates may substantially delay, or halt entirely, any further development of one or more of our products. The projected timetables for continued development of the technologies and related product candidates by us may otherwise be subject to delay or suspension.

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 can be 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 harm our future growth.

There is no guarantee that the FDA will approve BLAs for our product candidates and failure to obtain necessary approvals for our product candidates would adversely affect our ability to grow our business.

In June 2012, we acquired rights to BC8 (Iomab™), a clinical stage monoclonal antibody with safety and efficacy data in more than 300 patients in need of HSCT. Iomab-B is our product candidate that links Iodine-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 recently commenced the Phase 2 portion of a multi-center Phase 1/2 clinical trial for our product candidate, Actimab™-A, in AML and in the future expect to submit a BLA to the FDA for approval of this product. Actimab-A consists of the anti-CD33 antibody lintuzumab linked with the isotope actinium-225. This product candidate is also the subject of an ongoing human safety trial being conducted under a physician IND at MSKCC. Product candidates utilizing this 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. Indeed, 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 an adverse effect on our ability to expand our business.

Clinical trials necessary to support approval of BLAs for our product candidates will be time consuming and expensive. Delays or failures in our clinical trials may prevent us from commercializing our product candidates and will adversely affect our business, operating results and prospects and could cause us to cease operations.

Initiating and completing clinical trials necessary to support FDA approval of a BLA for Iomab-B, Actimab™-A 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 HSCT. 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, and on October 6, 2008, and January 5, 2009, we submitted IND amendments to the FDA for the conduct of a multi-center Phase 1/2 clinical trial for treatment of AML. 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.

The issued patents, which are licensed by us for the HuM-195 antibody, our acute myeloid leukemia targeting antibody, may expire before we have commercialized Actimab™-A.

The humanized antibody which we use in the conjugated Actimab™-A product candidate is covered by the claims of issued patents that we license from Facet Biotech Corporation, a wholly-owned subsidiary of AbbVie Laboratories. After these patents expire, 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 actinium 225. Any competing product based on the HuM-195 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 can affect the Company's business in the future.

Additionally, because we expect that certain of these patents will expire prior to commercialization of Actimab™-A, we expect that in order to attract a commercialization partner for that product candidate, we may need to reach an agreement with AbbVie to reduce the milestone payments and royalties currently required to be paid under our license agreement for HuM-195. There can be no assurance that the parties will be able to agree on an amendment to the terms of the license. Failure to reach such an agreement could materially adversely affect our ability to find a commercialization partner for Actimab™-A which may materially harm our business.

Iomab™-B is not patent protected.

Neither the antibody portion nor the composition of matter as a whole for the conjugated Iomab™ product candidate is covered by the claims of any issued or pending patents. Accordingly, there are no patents that would prevent others from using an antibody with the same antibody sequence in any drug product (e.g., those comprising iodine 131 or alpha particle emitters). 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 the Company's business in the future.

We may be unable to obtain a sufficient supply of Ac-225 medical grade isotope in order to continue clinical trials and to allow for the manufacture of commercial quantities of Actimab™-A

There are limited quantities of Ac-225 available today. The existing supplier of Ac-225 to us is the ORNL, which is a science and energy national laboratory in the Department of Energy system. ORNL manufactures Ac-225 by eluting it from its supply of Thorium-229. Although this has proven to be a very reliable source of production for a number of years, it is limited by the quantity of Thorium-229 at ORNL. We believe that the current approximate maximum of Ac-225 production from this source is sufficient for approximately 1,000–2,000 patient treatments per year. Since our

needs are significantly below that amount at this time, and will continue to be below that prior to commercializing a product with a potential of selling more than 2,000 patient doses per year. We believe that this supply will be sufficient for completion of clinical trials and early commercialization. To secure supplies beyond this amount, we have developed what we believe to be a scalable cost-effective process for manufacturing Ac-225 in a cyclotron at an estimated cost in excess of \$5 million. This work has been conducted at Technical University Munich (TUM) in Germany. We are now in possession of preparing detailed descriptions of all the developed manufacturing procedures and securing rights to all relevant patent applications and other intellectual property. However, we do not currently have access to a commercial cyclotron capable of producing medical grade Ac-225. Although beam time on such cyclotrons is commercially available, we do not currently have a relationship with any entity that owns or controls a suitable cyclotron. We have identified possible sources and estimate that we could secure the necessary beam time when needed at a cost of approximately \$2 million per year. Our contract for supply of this isotope from ORNL must be renewed yearly, and the current contract extends through the end of 2017. While we expect this contract will be renewed at the end of its term, however, there can be no assurance that ORNL will renew the contract or that the United States Department of Energy will not 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 ActimabTM-A and would materially harm our business.

Conducting successful clinical studies may require the enrollment of large numbers of patients, and suitable patients may be difficult to identify and recruit.

Patient enrollment in clinical trials and completion of patient participation and follow-up depends on many factors, including the size of the patient population; the nature of the trial protocol; the availability of approved effective treatments for the relevant disease; competition from other clinical trial programs for similar indications; the attractiveness of, or the discomforts and risks associated with, the treatments received by enrolled subjects; the availability of appropriate clinical trial investigators; support staff; and proximity of patients to clinical sites and ability to comply with the eligibility and exclusion criteria for participation in the clinical trial and patient compliance. For example, patients may be discouraged from enrolling in our clinical trials if the trial protocol requires them to undergo extensive post-treatment procedures or follow-up to assess the safety and effectiveness of our product candidates or if they determine that the treatments received under the trial protocols are not attractive or involve unacceptable risks or discomforts. Patients may also not participate in our clinical trials if they choose to participate in contemporaneous clinical trials of competitive product candidates. In addition, patients participating in refractory AML 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.

Development of sufficient and appropriate clinical protocols to demonstrate safety and efficacy are required and we may not adequately develop such protocols to support approval.

The FDA may require us to submit data on a greater number of patients than we originally anticipated and/or for a longer follow-up period or change the data collection requirements or data analysis applicable to our clinical trials. It may also require additional data on certain categories of patients, should it emerge during the conduct of our clinical trials that certain categories of patients are likely to be affected in different and/or additional manners than the rest of the patient population. In addition to FDA requirements, our clinical trials require the approval of the IRB at each site selected. We have submitted our clinical trial protocol for our current Actimab™-A clinical trial to the IRBs at participating sites for approval and we have thus far obtained approval from ten IRBs. Our clinical trial protocols have not been rejected by any IRB to date.

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, causing us to incur additional costs and delay our receipt of any revenue from potential product sales.

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.

Serious injury or death resulting from a failure of one of our product candidates during current or future clinical trials could also result in the FDA delaying our clinical trials or denying or delaying approval of a product candidate.

The Phase 1 portion of the ongoing Phase 1/2 clinical trial for Actimab™-A being conducted at seven clinical centers in the United States (MSKCC, MD Anderson Cancer Center, Fred Hutchinson Cancer Research Center, Johns Hopkins Medicine, University of Pennsylvania Health System, Baylor Summons Cancer Center and Columbia University Medical Center) was designed to establish the maximum tolerated dose of the product. As the Company expected, patients receiving highest dose of the drug administered in the trial had prolonged bone marrow suppression which could lead to fatal infections and other severe consequences. Consequently, the dose levels of our drug in that trial were reduced as we continue our work on establishing maximum tolerated dose.

Even though an adverse event may not be the result of our product candidate, the FDA or an IRB could delay or halt a clinical trial for an indefinite period of time while an adverse event is reviewed, and likely would do so in the event of multiple such events.

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.

If the third parties on which we rely to conduct our clinical trials and to assist us with pre-clinical development do not perform as contractually required or expected, or fail to comply with applicable regulations and standards, 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.

To date, we believe our consultants, contract research organizations and other similar entities with which we are working have performed well; however, if these third parties 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. Accordingly, we may be delayed in obtaining regulatory approvals for our product candidates and may be delayed in our efforts to successfully develop 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 ongoing clinical, nonclinical and preclinical programs. If these third parties do not successfully carry out their contractual duties or regulatory obligations or meet expected deadlines, if these third parties need to be replaced, 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 may be adversely affected. Furthermore, our third-party clinical trial investigators may be delayed in conducting our clinical trials for reasons outside of their control.

The future results of our current or future clinical trials may not support our product candidate claims or may result in the discovery of unexpected adverse side effects.

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, ActimabTM-A, 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. In addition, our clinical trials for ActimabTM-A involve a relatively small patient population. Because of the small sample size, their results may not be indicative of future results.

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.

Iomab-B, ActimabTM-A and future product candidates may never achieve market acceptance.

Iomab-B, ActimabTM-A and future product candidates that we may develop or gain market acceptance among physicians, patients and the medical community. The degree of market acceptance of any of product will depend on a number of factors, including the actual and perceived effectiveness and reliability of the product; the results of any long-term clinical trials relating to use of the product; the availability, relative cost and perceived advantages and disadvantages of alternative technologies; the degree to which treatments using the product are approved for reimbursement by public and private insurers; the strength of our marketing and distribution infrastructure; and the level of education and awareness among physicians and hospitals concerning the product.

Failure of Iomab-B, ActimabTM-A 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.

To be commercially successful, physicians must be persuaded that using our product candidates for treatment of AML and other cancers, if approved for those indications, are effective alternatives to existing therapies and treatments.

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.

Both before and after marketing approval, our product candidates are subject to ongoing regulatory requirements and continued regulatory review, and if we fail to comply with these continuing regulatory requirements, we could be subject to a variety of sanctions and the sale of any approved products could be suspended.

Both before and after regulatory approval to market a particular product candidate, the manufacturing, labeling, packaging, adverse event reporting, storage, advertising, promotion, distribution and record keeping related to the product are subject to extensive, ongoing regulatory requirements enforced by FDA and other similar regulatory bodies. Additionally, because our product candidates include radio-active isotopes, they will be subject to additional regulation and oversight from the United States Nuclear Regulatory Commission (NRC) and similar bodies in other jurisdictions. The FDA regulatory requirements include submissions of safety and other post-marketing information and reports, registration, as well as continued compliance with cGMP requirements and GCP requirements for any clinical trials that we conduct post-approval. Any regulatory approvals that we receive for our product candidates may also be subject to limitations on the approved indicated uses for which the product may be marketed or to the conditions of approval, or contain requirements for potentially costly post-marketing testing, including Phase IV clinical trials, and surveillance to monitor the safety and efficacy of the product candidate. Later discovery of previously unknown problems with a product, including adverse events of unanticipated severity or frequency, or with our third-party manufacturers or manufacturing processes, or failure to comply with the regulatory requirements of the FDA and other applicable U.S. and foreign regulatory authorities could subject us to administrative or judicially imposed sanctions, including:

restrictions on the marketing of our products or their manufacturing processes;

warning letters;

civil or criminal penalties;

finest;

injunctions;

product seizures or detentions;

import or export bans;

voluntary or mandatory product recalls and related publicity requirements;

suspension or withdrawal of regulatory approvals;

total or partial suspension of production; and

refusal to approve pending applications for marketing approval of new products or supplements to approved applications.

The FDA's policies may change and additional government regulations may be enacted that could prevent, limit or delay regulatory approval of our product candidates. 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, which would adversely affect our business, prospects and ability to achieve or sustain profitability.

Even if regulatory approval of a product candidate is granted, such approval may be subject to limitations on the intended uses for which a product may be marketed and reduce the potential to successfully commercialize that product and generate revenue from that product. If the FDA determines that the product promotional materials, labeling, training or other marketing or educational activities constitute promotion of an unapproved use, it could request that we or our commercialization partners cease or modify our training or promotional materials or subject us to regulatory enforcement actions. It is also possible that other federal, state or foreign enforcement authorities might take action if they consider such training or other promotional materials to constitute promotion of an unapproved use, which could result in significant fines or penalties under other statutory authorities, such as laws prohibiting false claims for reimbursement.

Our revenue stream will depend upon third party coverage and reimbursement 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 have no manufacturing capacity and 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 lack experience in drug manufacturing, and we lack the resources and the capabilities to manufacture any of our product candidates on a clinical or commercial scale. As a result, we rely on a third-party manufacturer 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, producing additional losses and depriving us of potential product revenue.

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; however, we do not have control over third-party manufacturers' compliance with these regulations and standards.

If a contract manufacturer cannot perform as agreed, we may be required to replace it. We may incur added costs and delays in identifying and qualifying replacements because the FDA must approve any replacement manufacturer prior to manufacturing our product candidates. Such approval would require new testing and compliance inspections. In addition, a new manufacturer would have to be educated in, or develop substantially equivalent processes for, production of our product candidates after receipt of FDA approval.

We anticipate continued reliance on third parties for manufacturing and marketing, if we are successful in obtaining marketing approval from the FDA and other regulatory agencies for any of our product candidates. If we are not able to secure favorable arrangements with such third parties, our business and financial condition would be harmed, and our commercialization of any of our product candidates may be halted, delayed or made less profitable if those third parties fail to obtain such approvals, fail to provide us with sufficient quantities of product or fail to do so at acceptable quality levels or prices.

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 also intend to partner with larger pharmaceutical companies for the commercialization of any of our product candidates that may be approved. In connection with our efforts to commercialize our product candidates, we will seek to secure favorable arrangements with third parties to distribute, promote, market and sell them. If we are not able to secure favorable commercial terms or arrangements with third parties for distribution, marketing, promotion and sales of our product candidates, we may have to retain promotional and marketing rights and seek to develop the commercial resources necessary to promote or co-promote or co-market certain or all of our product candidates to the appropriate channels of distribution in order to reach the specific medical market that we are targeting. We may not be able to enter into any partnering arrangements on this or any other basis. If we are not able to secure favorable partnering arrangements, or are unable to develop the appropriate resources necessary for the commercialization of our product candidates, our business and financial condition could be harmed. In addition, we will have to hire additional employees or consultants, since our current employees have limited experience in these areas. Sufficient employees with relevant skills may not be available to us. Any increase in the number of our employees would increase our expense level, and could have an adverse effect on our financial position.

In addition, we, or our potential commercial partners, may not successfully introduce our product candidates or they may not achieve acceptance by patients, health care providers and insurance companies. Further, it is possible that we may not be able to secure arrangements to manufacture, market, distribute, promote and sell our product candidates at favorable commercial terms that would permit us to make a profit. To the extent that corporate partners conduct clinical trials, we may not be able to control the design and conduct of these clinical trials.

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.

Upon commercialization of our product candidates, we may be dependent on third parties to market, distribute and sell them.

Our ability to generate revenues may be dependent upon the sales and marketing efforts of any future co-marketing partners and third-party distributors. At this time, we have not entered into an agreement with any commercialization partner and only plan to do so after the successful completion of Phase 2 clinical trials and prior to commercialization. If we fail to reach an agreement with any commercialization partner, or if upon reaching such an agreement that partner fails to sell a large volume of our products, it may have a negative impact on our business, financial condition and results of operations.

Our product candidates will face significant competition in the markets for them, and if they are unable to compete successfully, our business will suffer.

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 chief competitors include companies such as Bayer AG, GlaxoSmithKline Plc and Spectrum Pharmaceuticals, Inc. and others.

If side effects are identified during the time our product candidates are in development or after they are approved and on the market, we may choose to or be required to perform lengthy additional clinical trials, discontinue development of the affected product candidate, change the labeling of any such products, or withdraw or recall any such products from the market, any of which would hinder or preclude our ability to generate revenues.

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.

Our business depends upon securing and protecting critical intellectual property.

Our commercial success will depend in part on our obtaining and maintaining patent, trade secret, 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. We will only be able to protect our technologies from unauthorized use by third parties to the extent that valid and enforceable intellectual property protection, such as patents or trade secrets law, cover them. In particular, we place considerable emphasis on obtaining patent and trade secret protection for significant new technologies, products and processes. Furthermore, the degree of future protection of our proprietary rights is uncertain because legal means afford only limited protection and may not adequately protect our rights or permit us to gain or keep our competitive advantage. Moreover, 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 involves 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 foreign 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 may not be successful in hiring and retaining key employees.

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 or her employment with us, such a departure may 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 work force 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.

Healthcare legislative reform measures may have a material adverse effect on our business and results of operations.

In March 2010, former President Obama signed the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act (collectively, “PPACA”), which makes changes that are expected to significantly impact the pharmaceutical industries. One of the principal aims of the PPACA as currently enacted is to expand health insurance coverage to approximately 32 million Americans who are currently uninsured. The consequences of this significant coverage expansion on the sales of our products, once they are developed, are unknown and speculative.

The PPACA contains a number of provisions designed to generate the revenues necessary to fund the coverage expansions among other things. This includes fees and taxes on manufacturers of certain branded prescription drugs, an abbreviated pathway for approval of biosimilar products, a new methodology by which rebates owed by manufacturers under the Medicaid Drug Rebate Program are calculated for drugs that are inhaled, infused, instilled, implanted or injected, increases in the minimum Medicaid rebates owed by manufacturers under the Medicaid Drug Rebate Program and an extension of the rebate program to individuals enrolled in Medicaid managed care organizations, and a new Medicare Part D coverage gap discount program, in which manufacturers must agree to offer 50% point-of-sale discounts off negotiated prices of applicable brand drugs to eligible beneficiaries during their coverage gap period, as a condition for the manufacturer’s outpatient drugs to be covered under Medicare Part D.

The PPACA provisions on comparative clinical effectiveness research extend the initiatives of the American Recovery and Reinvestment Act of 2009, also known as the stimulus package, which included \$1.1 billion in funding to study the comparative effectiveness of health care treatments and strategies. This stimulus funding was designated for, among other things, conducting, supporting or synthesizing research that compares and evaluates the risks and benefits, clinical outcomes, effectiveness and appropriateness of products. The PPACA appropriates additional funding to comparative clinical effectiveness research. Although Congress has indicated that this funding is intended to improve the quality of health care, it remains unclear how the research will impact current Medicare coverage and reimbursement or how new information will influence other third-party payor policies. There is a risk that President Donald Trump's administration could repeal or amend the PPACA, and it is uncertain what the effect of such repeal or amendments would have on our business, financial condition and results of operations.

In addition, other legislative changes have been proposed and adopted since the PPACA was enacted. On August 2, 2011, former President Obama signed into law the Budget Control Act of 2011, which, among other things, creates the Joint Select Committee on Deficit Reduction to recommend proposals in spending reductions to Congress. The Joint Select Committee did not achieve a targeted deficit reduction of at least \$1.2 trillion for the years 2013 through 2021, which threatened to trigger the legislation's automatic reduction to several government programs. This includes aggregate reductions of Medicare payments to providers of 2% per fiscal year, which went into effect in April 2013 and will stay in effect through 2024 unless additional Congressional action is taken. On January 2, 2013, Congress passed and former President Obama signed the American Taxpayer Relief Act of 2012 which, among other things, further reduced Medicare payments to certain providers, including physicians, hospitals and cancer treatment centers. We expect that the PPACA, as well as other federal or state health care reform measures that may be adopted in the future, could have a material adverse effect on our industry generally and our ability to successfully commercialize our products or could limit or eliminate our spending on certain development projects. The taxes imposed by the PPACA and the expansion in the government's role in the U.S. healthcare industry may result in decreased profits to us, lower reimbursement by payors for our products, and/or reduced medical procedure volumes, all of which may adversely affect our business, financial condition and results of operations.

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 believe we need up to \$14.6 million in cash to finance research and development and to cover our ongoing working capital needs for the next 12 months. We have financed our operations primarily through sales of stock and the issuance of convertible promissory notes. It is likely that during the next twelve months we will seek to raise additional capital through the sales of stock and/or issuance of convertible debentures 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 private placement offering could result in dilution to the 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 vendor. 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.

During the fiscal year 2013 and through the first quarter of 2017 our common stock has or had been a penny stock, therefore, when our stock is considered a penny stock trading in our securities may be subject to penny stock considerations. Broker-dealer practices in connection with transactions in "penny stocks" are regulated by certain penny stock rules adopted by the SEC.

Penny stocks generally are equity securities with a price of less than \$5.00 (other than securities registered on certain national securities exchanges or quoted on the NYSE MKT system). 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 unrelated to our operations.

The trading volume of our common stock has been and may continue to be extremely limited and sporadic. As a result of such trading activity, the quoted price for our common stock on the NYSE MKT may not necessarily be a reliable indicator of its fair market value.

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 the Company's competitors or the Company itself. 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.

Because we do not intend to pay dividends, stockholders will benefit from an investment in our Common Stock only if it appreciates in value.

We have never declared or paid any cash dividends on our Preferred Stock or 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 Preferred Stock or Common Stock. As a result, the success of an investment in our Preferred Stock or Common Stock will depend upon any future appreciation in its value. There is no guarantee that our Preferred Stock or 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 the 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 SEC 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 to the registration of resale of the Common Stock.

Applicable regulatory requirements, including those contained in and issued under the Sarbanes-Oxley Act, may make it difficult for us to retain or attract qualified officers and directors, which could adversely affect the management of its business and its ability to obtain or retain listing of our Common Stock.

We may be unable to attract and retain those qualified officers, directors and members of board committees required to provide for effective management because of the rules and regulations that govern publicly held companies, including, but not limited to, certifications required by principal executive officers. The enactment of the Sarbanes-Oxley Act has resulted in the issuance of a series of related rules and regulations and the strengthening of existing rules and regulations by the SEC, as well as the adoption of new and more stringent rules by the stock exchanges. The perceived increased personal risk associated with these changes may deter qualified individuals from accepting roles as directors and executive officers.

Further, some of these changes heighten the requirements for board or committee membership, particularly with respect to an individual's independence from the corporation and level of experience in finance and accounting matters. We may have difficulty attracting and retaining directors with the requisite qualifications. If we are unable to attract and retain qualified officers and directors, the management of our business and our ability to obtain or retain listing of our shares of Common Stock on any stock exchange (assuming we elect to seek and are successful in obtaining such listing) could be adversely affected.

If we fail to maintain an effective system of internal controls, we may not be able to accurately report our financial results or detect fraud. Investors could lose confidence in our financial reporting and this may decrease the trading price of our Common Stock.

We must maintain effective internal controls to provide reliable financial reports and detect fraud. As disclosed in this report, we have previously identified material weaknesses in our internal control over financial reporting because we did not have sufficient written policies and procedures for accounting and financial reporting and we did not have effective controls over period end financial disclosures and reporting processes. During 2014, our management remediated these previously identified material weaknesses. In future periods, we may identify additional deficiencies in our system of internal controls over financial reporting that may require remediation. There can be no assurances that any such future deficiencies identified may not be material weaknesses that would be required to be reported in future periods. Failure to maintain an effective system of internal controls could harm our operating results and cause investors to lose confidence in our reported financial information. Any such loss of confidence would have a negative effect on the trading price of our Common Stock.

The price of our common stock may become volatile, which could lead to losses by investors and costly securities litigation.

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 Company resources, which could harm our business and financial condition.

ITEM 1B. UNRESOLVED STAFF COMMENTS.

None.

ITEM 2. PROPERTIES.

The Company does not own any real property. On March 10, 2016 and effective as of January 1, 2016, Actinium entered into an Office Space License Agreement (the "License") with Relmada Therapeutics, Inc. ("Relmada"), with whom we share two common board members, for office space located at 275 Madison Avenue, 7th Floor, New York, NY 10016. The License represents a substantial reduction in the per person cost over Actinium's prior lease and the space allows for future growth. Both companies' boards authorized the transaction. The term of the License is three years from the effective date, with an automatic renewal provision. The cost of the License is on a pass through basis for Relmada, and is approximately \$17,000 per month for Actinium, subject to customary escalations and adjustments.

In August 2016, the Company expanded its office space at 275 Madison Avenue, 6th Floor, New York, NY 10016, for an additional \$2,400 per month over a 12-month term.

ITEM 3. LEGAL PROCEEDINGS.

From time to time, we may become involved in various lawsuits and legal proceedings, which arise in the ordinary course of business. Litigation is subject to inherent uncertainties, and an adverse result in these or other matters may arise from time to time that may harm business. We are currently not aware of any such legal proceedings or claims that will have, individually or in the aggregate, a material adverse effect on our business, financial condition or operating results.

ITEM 4. MINE SAFETY DISCLOSURES.

Not Applicable.

PART II

ITEM 5. MARKET FOR REGISTRANT'S COMMON EQUITY, RELATED STOCKHOLDERS MATTERS, AND ISSUER PURCHASE OF EQUITY SECURITIES.

Market Information

Our common stock is listed for quotation on the NYSE MKT under the symbol "ATNM". The following table sets forth, for the quarters indicated, the high and low sale per share sales prices of our common stock as reported by the NYSE MKT or www.otcbb.com, as applicable. On March 26, 2014 our common stock commenced trading on the NYSE MKT. Prior to March 26, 2014, our common stock is listed on the OTCQB, under the symbol "ATNM".

Quarterly Common Stock Price Ranges

Fiscal Year 2016, Quarter Ended:	High	Low
March 31, 2016	\$3.40	\$1.74
June 30, 2016	\$2.04	\$1.63
September 30, 2016	\$2.00	\$1.33
December 31, 2016	\$1.40	\$0.86

Fiscal Year 2015, Quarter Ended:	High	Low
March 31, 2015	\$6.07	2.45
June 30, 2015	\$3.94	2.38
September 30, 2015	\$2.69	1.68
December 31, 2016	\$3.23	1.71

Fiscal Year 2014, Quarter Ended:	High	Low
March 31, 2014	\$12.49	\$4.51
June 30, 2014	\$15.00	\$6.74
September 30, 2014	\$7.77	\$5.93
December 31, 2014	\$8.12	\$5.05

Holder

As of March 15, 2017 there were 55,807,742 shares of common stock issued and outstanding, which were held by 102 holders of record. There are no shares of preferred stock outstanding. On March 15, 2016, the closing price of our common stock as reported on the NYSE MKT as \$1.34 per share.

Of the 55,807,742 shares of common stock issued and outstanding, 645,735 of such shares are restricted shares under the Securities Act. None of these restricted shares are eligible for resale absent registration or an exemption from registration under the Securities Act. As of the date hereof, until the provisions of Rule 144 are complied with, the exemption from registration provided by Rule 144 under the Securities Act is not available for these shares pursuant to Rule 144(i).

Registration Rights

On December 21, 2015, Actinium entered into an Investor Rights Agreement (the “Investor Rights Agreement”) with Memorial Sloan Cancer Center (“MSKCC”). Under the terms of the Investor Rights Agreement, MSKCC has agreed to forebear from transferring or otherwise disposing of its approximately 5.7 million Actinium shares (other than pursuant to a piggyback registration as described below) until the start of the Actimab-A Phase 2 clinical study (but, in no event until later than March 31, 2016). Thereafter MSKCC shall be permitted to sell its shares subject to a weekly volume limitation of 150,000 shares (which limit may be increased to up to 250,000 shares per week to the extent any prior weekly allotments were not fully used) and applicable law so long as MSKCC maintains at least 25% of its current shareholding in Actinium through December 31, 2016. Actinium has granted MSKCC piggyback registration rights that would be triggered in the event Actinium were to engage in a public registered offering of its shares for its own account where other shareholders are participating as selling shareholders or where such public registered offering is for the account of other selling shareholders. In addition, following December 31, 2016, Actinium has granted MSKCC unlimited Form S-3 registration rights with respect to its shares.

Dividends

We have never declared or paid a cash dividend. Any future decisions regarding dividends are made by our Board of Directors. We currently intend to retain and use any future earnings for the development and expansion of our business and do not anticipate paying any cash dividends in the foreseeable future. Our Board of Directors has complete discretion on whether to pay dividends. Even if our Board of Directors decides to pay dividends, the form, frequency and amount will depend upon our future operations and earnings, capital requirements and surplus, general financial condition, contractual restrictions and other factors that the Board of Directors may deem relevant.

Securities Authorized for Issuance under Equity Compensation Plans

The Company currently has two equity compensation plans defined as follows:

In December 2013, our shareholders approved the Company's 2013 Stock Plan. The expiration date of the plan is September 9, 2023 and the total number of underlying shares of the Company's common stock available for grant to employees, directors and consultants of the Company under the plan is currently 12,750,000 shares.

In December 2013, our shareholders approved the Company's 2013 Equity Incentive Plan. The expiration date of the plan is September 9, 2023 and the total number of shares of our common stock available for grant to employees, directors and consultants of us under the plan is 1,000,000 shares.

The following table indicates shares of common stock authorized for issuance under our equity compensation plans as of December 31, 2016:

Plan category	Number of securities to be issued upon exercise of outstanding options, warrants and rights	Weighted-average price of outstanding options, warrants and rights	Number of securities remaining available for future issuance
Equity compensation plans approved by security holders	5,906,886	\$ 3.52	7,328,484

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

Equity compensation plans not approved by security holders	—	—	—
Total	5,906,886	\$ 3.52	7,328,484

ITEM 6. SELECTED FINANCIAL DATA.

The following selected financial data should be read in conjunction with our consolidated financial statements and related notes and the “Management’s Discussion and Analysis of Financial Condition and Results of Operations” and other financial data included elsewhere in this Form 10-K. The selected statements of operations and the selected balance sheet data are derived from our consolidated audited financial statements.

	Year Ended December 31,				
	2016	2015	2014	2013	2012
Statements of Operations Data:					
Revenues	\$-	\$-	\$-	\$-	\$-
Loss from operations	\$(26,847,481)	\$(24,829,764)	\$(22,480,544)	\$(6,591,892)	\$(7,947,298)
Net loss	\$(24,321,724)	\$(21,025,314)	\$(24,687,509)	\$(10,773,792)	\$(8,361,205)
Net loss per common share:					
Basic and diluted	\$(0.50)	\$(0.55)	\$(0.90)	\$(0.47)	\$(7.58)
Weighted-average common shares outstanding:					
Basic and diluted	48,463,268	38,158,480	27,363,748	22,752,752	1,103,521

	As of December 31,				
	2016	2015	2014	2013	2012
Balance Sheet Data:					
Cash and cash equivalents	\$20,519,294	\$25,643,273	\$6,706,802	\$5,533,366	\$5,618,669
Total assets	\$22,528,886	\$26,587,581	\$7,569,086	\$5,765,675	\$5,788,822
Total liabilities	\$4,520,557	\$4,613,533	\$9,491,616	\$7,325,220	\$4,643,187
Stockholders' equity (deficit)	\$18,008,329	\$21,974,048	\$(1,922,530)	\$(1,559,545)	\$1,145,635

ITEM 7. MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATION.

The information and financial data discussed below is derived from the audited consolidated financial statements of Actinium Pharmaceuticals, Inc. for its fiscal years ended December 31, 2016, 2015 and 2014. The consolidated financial statements of Actinium Pharmaceuticals, Inc. were prepared and presented in accordance with generally accepted accounting principles in the United States. The information and financial data discussed below is only a summary and should be read in conjunction with the historical financial statements and related notes of Actinium Pharmaceuticals, Inc. contained elsewhere in this Report. The financial statements contained elsewhere in this Report fully represent Actinium Pharmaceuticals, Inc.'s financial condition and operations; however, they are not indicative of the Company's future performance. See "Cautionary Note Regarding Forward Looking Statements" above for a discussion of forward-looking statements and the significance of such statements in the context of this Report.

Overview

Actinium is a biopharmaceutical company developing innovative targeted therapies for patients with cancers lacking effective treatment options. Our proprietary platform utilizes monoclonal antibodies to deliver radioisotopes directly to cells of interest in order to kill those cells safely and effectively. Our lead product candidate Iomab-B is designed to be used, upon approval, in preparing patients for a hematopoietic stem cell transplant, commonly referred to as bone marrow transplant. A bone marrow transplant is often the only potential cure for patients with blood-borne cancers but the current standard preparation for a transplant requires chemotherapy and/or total body irradiation that result in significant toxicities. We believe Iomab-B will enable a faster and less toxic preparation of patients seeking a bone marrow transplant, leading to increased transplant success and survival rates. We are currently conducting a single pivotal 150-patient, multicenter Phase 3 clinical study of Iomab-B in patients with relapsed or refractory acute myeloid leukemia (AML) age 55 and older. Our second product candidate, Actimab-A, is currently in a multicenter open-label, 53-patient Phase 2 trial for patients newly diagnosed with AML age 60 and over. Actimab-A is being developed to induce remissions in elderly patients with AML who lack effective treatment options and often cannot tolerate the toxicities of standard frontline therapies. In addition, we are developing Actimab-M, which is being studied in patients with relapsed or refractory multiple myeloma in a Phase 1, investigator sponsored clinical trial. We are also utilizing its alpha-particle immunotherapy (APIT) technology platform to generate new drug candidates based on antibodies linked to the element Actinium-225 that are directed at various cancers that are blood-borne or form solid tumors.

On March 26, 2014, we began trading our common stock on the NYSE MKT market.

Plan of Operation

We develop drugs for the treatment of cancer with the intent to cure or significantly improve survival of the affected patients. None of our drugs have been approved for sale in the United States or elsewhere. We have no commercial operations in sales or marketing of our products. All our product candidates are under development. In order to market and sell our products we must conduct clinical trials on patients and obtain regulatory approvals from appropriate regulatory agencies like the Food and Drug Administration (FDA) in the United States and similar agencies elsewhere in the world.

Our products under development are monoclonal antibodies labeled with radioisotopes. We have one program with an antibody labeled with a beta emitter and several programs based on a proprietary patent protected platform technology called APIT. Our APIT technology is based on attaching actinium 225 (Ac-225) or bismuth 213 (Bi-213) alpha emitting radioisotopes to monoclonal antibodies. Alpha emitting radioisotopes are unstable chemical elements that decay by releasing alpha particles. Alpha particles can kill any cell in the immediate proximity of where they are released. Monoclonal antibodies are genetically engineered proteins that specifically target certain cells, including cancer cells. It is crucial for the success of our drug candidates to contain monoclonal antibodies that can successfully seek cancer cells and can kill them with the attached isotope while not harming nearby normal cells. We do not have technology and operational capabilities to develop and manufacture such monoclonal antibodies and we therefore rely on collaboration with third parties to gain access to such monoclonal antibodies. We have secured rights to two monoclonal antibodies, HuM195 (Lintuzumab), in 2003 through a collaborative licensing agreement with AbbVie Biotherapeutics Corp and BC8 in 2012 with the Fred Hutchinson Cancer Research Center ("FHCRC"). We expect to negotiate collaborative agreements with other potential partners that would provide us with access to additional monoclonal antibodies. Establishing and maintaining such collaborative agreements is a key to our success as a company.

Under our own sponsorship as well as activity at FHCRC, we have five product candidates in active clinical trials: Actimab-A and Actimab-M (HuM195-Ac-225), Iomab-B (BC8-I-131), BC8-Y-90 and BC8-SA. At this time, the Company is actively pursuing development of Actimab-A and Iomab-B while Actimab-M, BC8-Y-90 and BC8-SA are in physician sponsored clinical phase 1 trials at Baylor and latter two at the FHCRC. Actimab-A is a combination of the monoclonal antibody we have in-licensed, Lintuzumab (HuM195), and the alpha emitting isotope actinium 225. Actimab-A has shown promising results throughout preclinical development and an ongoing clinical trial started in 2006 in AML in the elderly. We have expanded the number of patients and number of clinical centers by commencing a new AML clinical trial which we launched in 2012. This trial targets newly diagnosed AML patients over the age of 60. In order to conduct the trial we are engaged in funding, monitoring and quality assurance and control of the Lintuzumab antibody; procurement of actinium 225 isotope; funding, monitoring and quality assurance and control of the drug candidate Actimab-A manufacturing and organizing and monitoring clinical trials. We estimate that the direct costs to completion of both parts of the ongoing Phase 1/2 trial will be approximately \$7 million. Iomab-B is a combination of the in-licensed monoclonal antibody BC8 and the beta emitting radioisotope iodine 131. This construct has been extensively tested in Phase 1 and Phase 2 clinical trials in approximately 300 patients with different blood cancer indications who were in need of HSCT. Iomab-B is used to condition the bone marrow of these patients by destroying blood cancer cells in their bone marrow and elsewhere thus allowing for a subsequent transplant containing healthy donor bone marrow stem cells. We have decided to develop this drug candidate by initially focusing on the patients over 50 with active acute myeloid leukemia in relapse and/or refractory to existing treatments. On December 17, 2015, the FDA cleared our IND filing for Iomab-B, and that we are proceeding with the pivotal, Phase 3 clinical trial. We anticipate that the Phase 3, controlled, randomized, pivotal trial will continue enrolling patients in 2017. We estimate the direct costs of such a trial to completion anticipated in 2018 will be approximately \$25 million.

We have primarily management position employees and consultants who direct, organize and monitor the activities described above through contractors. Much of the in-vivo laboratory and clinical work contracted for by the Company was conducted at MSKCC in New York. We also made clinical trial arrangements with other well-known cancer centers. Our Actimab-A and Actimab-M drug candidates and its components are contract manufactured and maintained under our supervision by specialized contract manufacturers and suppliers in the United States, including IsoTex Diagnostics, Oak Ridge National Laboratory, Pacific GMP, Fischer Bioservices, BioReliance and others.

We have never generated revenue. Currently we do not have a recurring source of revenues to cover our operating costs. As of December 31, 2016 and 2015, our accumulated deficit was \$136.6 million and \$112.2 million, respectively. Our net loss was \$24.3 million, \$21.0 million, and \$24.7 million for the years ended December 31, 2016, 2015, and 2014, respectively. As of December 31, 2016, our cash balance was \$20.5 million. We believe that we have enough cash on hand to fund our operations through the next 12 months.

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. This will in turn depend on our ability to continue our collaboration with MSKCC and our Clinical Advisory Board members. In addition, we plan to continue and expand other research and clinical trial collaborations. Moreover, we will have to maintain sufficient supply of actinium 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 iodine 131 and actinium 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 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 and constantly increasing 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 – Year Ended December 31, 2016 Compared to the Year Ended December 31, 2015

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

	For the year ended December 31,		Increase Decrease
	2016	2015	
Revenues	\$-	\$-	\$-
Operating expenses:			
Research and development, net of reimbursements	17,501,364	13,311,739	4,189,625
General and administrative	9,268,594	11,464,560	(2,195,966)
Depreciation and amortization	77,523	53,465	24,058
Total operating expenses	26,847,481	24,829,764	2,017,717
Other income (expense)			
Interest expense	(5,007)	(7,868)	2,861
Gain (loss) from change in fair value of derivative liabilities	2,530,764	3,812,318	(1,281,554)
Total other income (expense)	2,525,757	3,804,450	(1,278,693)
Net loss	\$(24,321,724)	\$(21,025,314)	\$(3,296,410)

Revenues

We recorded no commercial revenues for the years ended December 31, 2016 and 2015.

Research and Development Expense

Research and development expenses, net of reimbursements, increased by approximately \$4.2 million to approximately \$17.5 million for the year ended December 31, 2016 compared to approximately \$13.3 million for the year ended December 31, 2015. The increase was primarily attributable to increase in Actimab-A costs of approximately \$3.1 million. In addition, there was an increase in compensation cost of approximately \$1.3 million as a result of an increase in headcount related to research and development personnel.

We expect to incur increased research and development costs in the future in connection with the planned Phase 3 trial of Iomab-B and Phase 2 trial of Actimab-A.

General and Administrative Expenses

Overall, total general and administrative expenses decreased by approximately \$2.2 million to \$9.3 million for the year ended December 31, 2016 compared to approximately \$11.5 million for the year ended December 31, 2015. The decrease was largely attributable to a decrease of approximately \$2.5 million for stock based compensation, a decrease of approximately \$0.6 million for financial consulting and investor relations service fees, and a decrease of approximately \$0.4 million for legal fees. These decreases were offset by an increase in payroll expenses of approximately \$0.5 million, an increase in marketing expense of approximately \$0.2 million and an increase in rent expense of approximately \$0.1 million.

We expect to incur increased general and administrative costs in the future in connection with the planned Phase 3 trial of Iomab-B and Phase 2 trial of Actimab-A.

Other Income (Expense)

Other income (expense) was \$2.5 million and \$3.8 million for the years ended December 31, 2016 and 2015, respectively. The year over year change is mainly attributable to the fluctuation of the Company's stock price and its impact on the derivative value of certain warrants the Company issued in connection with the December 2012 financing.

Net Loss

Net loss increased by approximately \$3.3 million to approximately \$24.3 million for the year ended December 31, 2016 compared to approximately \$21.0 million for the year ended December 31, 2015. The increase was primarily due to a decrease of the gain on the change in fair value of the Company's derivative warrant liabilities and a decrease in general and administrative expenses which were partially offset by additional costs incurred by the Company in research and development expenses.

Results of Operations – Year Ended December 31, 2015 Compared to the Year Ended December 31, 2014

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

	For the year ended December 31,		Increase (Decrease)
	2015	2014	
Revenues	\$-	\$-	\$-
Operating expenses:			
Research and development, net of reimbursements	13,311,739	12,267,313	1,044,426
General and administrative	11,464,560	10,175,323	1,289,237
Depreciation and amortization	53,465	37,908	15,557
Total operating expenses	24,829,764	22,480,544	2,349,220
Other income (expense)			
Interest expense	(7,868)	(866)	(7,002)
Gain (loss) from change in fair value of derivative liabilities	3,812,318	(2,206,099)	6,018,417
Total other income (expense)	3,804,450	(2,206,965)	6,011,415
Net loss	\$(21,025,314)	\$(24,687,509)	\$3,662,195

Revenues

We recorded no commercial revenues for the years ended December 31, 2015 and 2014.

Research and Development Expense

Research and development expenses, net of reimbursements, increased by approximately \$1.0 million to approximately \$13.3 million for the year ended December 31, 2015 compared to approximately \$12.3 million for the year ended December 31, 2014. The increase was primarily attributable to increase in compensation cost of approximately \$1.3 million as a result of an increase in headcount and also an increase in stock-based compensation related to research and development personnel. In 2015, the Company decreased its on-going Actimab-A clinical costs of approximately \$0.2 million.

General and Administrative Expenses

Overall, total general and administrative expenses increased by approximately \$1.3 million to approximately \$11.5 million for the year ended December 31, 2015 compared to approximately \$10.2 million for the year ended December 31, 2014. The increase was largely attributable to increase of approximately \$0.9 million for financial consulting services, increases in stock-based compensation costs and salaries and benefits of approximately \$0.2 million, and approximate increase of \$0.2 million in Directors and Offices insurance and payments.

Other Income (Expense)

Other income (expense) was \$3.8 million and (\$2.2 million) for the years ended December 31, 2015 and 2014, respectively. The year over year change is mainly attributable to the fluctuation of the Company's stock price and its impact on the derivative value of certain warrants the Company issued in connection with the December 2012 financing.

Net Loss

Net loss decreased by approximately \$3.7 million to approximately \$21.0 million for the year ended December 31, 2015 compared to approximately \$24.7 million for the year ended December 31, 2014. The decrease was primarily due to a gain on the change in fair value of the Company's derivative warrant liability which was partially offset by additional costs incurred by the Company in research and development expenses, non-cash stock-based compensation costs and professional fees.

Liquidity and Capital Resources

We have financed our operations primarily through sales of the Company's stock.

We did not have any cash or cash equivalents held in financial institutions located outside of the United States as of December 31, 2016 and 2015. We do not anticipate this practice will change in the future.

The following tables sets forth selected cash flow information for the periods indicated:

	For the year ended December 31,		
	2016	2015	2014
Cash used in operating activities	\$(20,789,237)	\$(18,543,768)	\$(14,348,754)
Cash used in investing activities	(109,819)	(47,788)	(186,421)
Cash provided by financing activities	15,775,077	37,528,027	15,708,611
Net change in cash	\$(5,123,979)	\$18,936,471	\$1,173,436

For the years ended December 31, 2016 and 2015

Net cash used in operating activities was approximately \$20.8 million for the year ended December 31, 2016 compared to approximately \$18.5 million used in operations for the same period in 2015. Cash used in operations increased due to the increase in spending related to the preparations for and eventual launch and conduct of a multicenter clinical trial and an increase in spending related to professional fees combined with an increase in payroll-related expenses.

Net cash used in investing activities was approximately \$0.1 million for the year ended December 31, 2016 compared to approximately \$48,000 used in investing activities for the same period in 2015. Cash used in investing activities increased for additional computers and lab equipment purchases as required by new employees during 2016 compared to the prior year.

Net cash provided by financing activities was approximately \$15.8 million and approximately \$37.5 million for each of the years ended December 31, 2016 and 2015, respectively. During the year ended December 31, 2016, the Company issued common stock and received net proceeds of approximately \$16.0 million and approximately \$18,000 from the exercise of options. During the year ended December 31, 2015, the Company issued common stock and received net proceeds of approximately \$37.6 million and approximately \$0.2 million from the exercise of warrants and options. These increases were offset by payments on notes payable of \$0.3 million for the years ended December 31, 2016 and 2015.

For the years ended December 31, 2015 and 2014

Net cash used in operating activities was approximately \$18.5 million for the year ended December 31, 2015 compared to approximately \$14.3 million used in operations for the same period in 2014. Cash used in operations increased due to the increase in spending related to the preparations for and eventual launch and conduct of a multicenter clinical trial and an increase in spending related to professional fees combined with an increase in payroll-related expenses.

Net cash used in investing activities was approximately \$48,000 for the year ended December 31, 2015 compared to approximately \$0.2 million used in investing activities for the same period in 2014. Cash used in investing activities decreased due to fewer purchases of computers and lab equipment during 2015 compared to the prior year.

Net cash provided by financing activities was approximately \$37.5 million and approximately \$15.7 million for each of the years ended December 31, 2015 and 2014, respectively. During the year ended December 31, 2015, the Company issued common stock and received net proceeds of approximately \$37.6 million and approximately \$0.2 million from the exercise of warrants and options. During the year ended December 31, 2014, the Company issued common stock and received net proceeds of approximately \$15.4 million and approximately \$0.4 million from the exercise of warrants and options. These increases were offset by payments on notes payable of \$0.3 million and \$0.2 million for the year ended December 31, 2015 and 2014, respectively.

We have cumulative losses of approximately \$136.6 million and a stockholders' equity of \$18.0 million at December 31, 2016.

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, revenues 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 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.

Derivatives

All derivatives are recorded at fair value and recorded on the balance sheet. Fair values for securities traded in the open market and derivatives are based on quoted market prices. Where market prices are not readily available, fair values are determined using market based pricing models incorporating readily observable market data and requiring judgment and estimates.

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. The fair value hierarchy is as follows:

Level 1 Inputs – Unadjusted quoted prices in active markets for identical assets or liabilities that the reporting entity has the ability to access at the measurement date.

Level 2 Inputs – Inputs other than quoted prices included in Level 1 that are observable for the asset or liability, either directly or indirectly. These might include quoted prices for similar assets or liabilities in active markets, quoted prices for identical or similar assets or liabilities in markets that are not active, inputs other than quoted prices that are observable for the asset or liability (such as interest rates, volatilities, prepayment speeds, credit risks, etc.) or inputs that are derived principally from or corroborated by market data by correlation or other means.

Level 3 Inputs – Unobservable inputs for determining the fair values of assets or liabilities that reflect an entity's own assumptions about the assumptions that market participants would use in pricing the assets or liabilities.

Income Taxes

The Company uses the asset and liability method in accounting for income taxes. Under this method, deferred tax assets and liabilities are determined based on differences between financial reporting and income tax carrying amounts of assets and liabilities and are measured 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.

Research and Development Costs

Research and development costs are expensed as incurred. Research and development reimbursements and grants are recorded by the Company as a reduction of research and development costs.

Share-Based Payments

We estimate the fair value of each stock option award at the grant date by using the Black-Scholes option pricing model and common shares based on the market price of the Company's common stock on the date of the share grant. 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. As share-based compensation expense is recognized based on awards ultimately expected to vest, we reduce the expense for estimated forfeitures based on historical forfeiture rates. Previously recognized compensation costs may be adjusted to reflect the actual forfeiture rate for the entire award at the end of the vesting period. Excess tax benefits, if any, are recognized as an addition to paid-in capital.

Recent Accounting Pronouncements

In April 2016, the Financial Accounting Standards Board ("FASB") issued Accounting Standards Update ("ASU") No. 2016-09, "*Compensation – Stock Compensation*" (topic 718). The FASB issued this update to improve the accounting for employee share-based payments and affect all organizations that issue share-based payment awards to their employees. Several aspects of the accounting for share-based payment award transactions are simplified, including: (a) income tax consequences; (b) classification of awards as either equity or liabilities; and (c) classification on the statement of cash flows. The updated guidance is effective for annual periods beginning after December 15, 2016, including interim periods within those fiscal years. Early adoption of the update is permitted. The Company is currently evaluating the impact of the new standard.

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 other recently issued, but not yet effective accounting pronouncements, if adopted, would have a material effect on the accompanying consolidated financial statements.

Subsequent Event

On January 22, 2017, the Company issued 500 shares of common stock to an employee for vested restricted stock grant.

On February 22, 2017, the Company issued 500 shares of common stock to an employee for vested restricted stock grant.

On February 27, 2017, the Company issued 5,000 shares of common stock to a consultant for vested stock grant.

On January 17, 2017, the Company granted an employee options to purchase 325,000 common shares at \$1.04 per share.

On March 14 2017, the Company granted its employees options to purchase 1,425,500 common shares at \$1.39 per share and granted its Board members options to purchase 225,000 common shares at \$1.39 per share.

On March 14, 2017, the Company canceled warrant to purchase Common Stock of the Company, dated December 19, 2012, issued to its Executive Chairman in the amount of 57,212 warrant shares (the “Old Warrant”) and issued a new warrant to its Executive Chairman in the amount of 57,212 warrant shares with the term of the warrant expiring on February 11, 2022 (the “New Warrant”). The New Warrant has the same exercise price in effect as the exercise price as the Old Warrant but the expiration date was modified from December 19, 2017 to February 11, 2022. The Company also amended the warrant to purchase Common Stock of the Company, dated January 31, 2012, issued to its Executive Chairman and an entity affiliated with its Executive Chairman in the amount of 64,746 and 99,617 warrant shares, respectively. Pursuant to the terms of the warrant amendments the term of the warrants were extended to February 11, 2022 from January 31, 2019.

ITEM 7A. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK.

Interest rate risk

Our cash and cash equivalents include all highly liquid investments with an original maturity of three months or less. Because of the short-term maturities of our cash and cash equivalents, we do not believe that an increase in market rates would have a significant impact on the realized value of our investments. We place our cash and cash equivalents on deposit with financial institutions in the United States. The Federal Deposit Insurance Corporation covers \$0.2 million for substantially all depository accounts. We may from time to time have amounts on deposit in excess of the insured limits. As of December 31, 2016, we had approximately \$20.5 million of cash and cash equivalents, which exceeded these insured limits.

Foreign currency exchange risk

We currently have limited, but may in the future have increased, clinical and commercial manufacturing agreements which are denominated in Euros or other foreign currencies. As a result, our financial results could be affected by factors such as a change in the foreign currency exchange rate between the U.S. dollar and the Euro or other

applicable currencies, or by weak economic conditions in Europe or elsewhere in the world. We are not currently engaged in any foreign currency hedging activities.

Market indexed security risk

We have issued derivative warrants to various holders underlying shares of our common stock. These warrant investments are re-measured to their fair value at each reporting period with changes in their fair value recorded as derivative gain (loss) in the accompanying consolidated statement of operations. We use a modified binomial valuation model for valuation of the derivative warrants.

ITEM 8. FINANCIAL STATEMENTS AND SUPPLEMENTARY DATA.

REPORT OF MANAGEMENT

The management of Actinium Pharmaceutical, Inc. (“Actinium”) is responsible for establishing and maintaining adequate internal control over financial reporting, as defined in Rule 13a-15(f) or 15d-15(f) under the Securities Exchange Act of 1934. Actinium's internal control system was designed to provide reasonable assurance to the company's management and Board of Directors regarding the preparation and fair presentation of published financial statements.

Actinium management assessed the effectiveness of the company's internal control over financial reporting as of December 31, 2016. In making this assessment, it used the criteria set forth by the Committee of Sponsoring Organizations of the Treadway Commission (COSO) in Internal Control – Integrated Framework (2013 framework). Based on its assessment, Actinium management believes that, as of December 31, 2016, the Company's internal control over financial reporting is effective based on those criteria.

GBH CPAs, PC, the independent registered public accounting firm that audited the financial statements included in this Annual Report, has issued an attestation report on the company's internal control over financial reporting.

/s/ Kaushik J. Dave

Kaushik J. Dave

Chief Executive Officer, Interim Chief Financial Officer and Director

March 17, 2017

REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM
ON INTERNAL CONTROL OVER FINANCIAL REPORTING

To the Board of Directors and Stockholders of

Actinium Pharmaceuticals, Inc.

New York, NY

We have audited Actinium Pharmaceutical, Inc.'s internal control over financial reporting as of December 31, 2016, based on criteria established in Internal Control—Integrated Framework (2013) issued by the Committee of Sponsoring Organizations of the Treadway Commission (COSO). Actinium Pharmaceutical, Inc.'s management is responsible for maintaining effective internal control over financial reporting and for its assessment of the effectiveness of internal control over financial reporting included in the accompanying 10-K. Our responsibility is to express an opinion on the company's internal control over financial reporting based on our audit.

We conducted our audit in accordance with the standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audit to obtain reasonable assurance about whether effective internal control over financial reporting was maintained in all material respects. Our audit of internal control over financial reporting included obtaining an understanding of internal control over financial reporting, assessing the risk that a material weakness exists, and testing and evaluating the design and operating effectiveness of internal control based on the assessed risk. Our audit also included performing such other procedures as we considered necessary in the circumstances. We believe that our audit provides a reasonable basis for our opinion.

A company's internal control over financial reporting is a process designed to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles. A company's internal control over financial reporting includes those policies and procedures that (1) pertain to the maintenance of records that, in reasonable detail, accurately and fairly reflect the transactions and dispositions of the assets of the company; (2) provide reasonable assurance that transactions are recorded as necessary to permit preparation of financial statements in accordance with generally accepted accounting principles, and that receipts and expenditures of the company are being made only in accordance with authorizations of management and directors of the company; and (3) provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use, or disposition of the company's assets that could have a material effect on the financial statements.

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

Because of its inherent limitations, internal control over financial reporting may not prevent or detect misstatements. Also, projections of any evaluation of effectiveness to future periods are subject to the risk that controls may become inadequate because of changes in conditions, or that the degree of compliance with the policies or procedures may deteriorate.

In our opinion, Actinium Pharmaceutical, Inc. maintained, in all material respects, effective internal control over financial reporting as of December 31, 2016, based on criteria established in Internal Control—Integrated Framework (2013) issued by the Committee of Sponsoring Organizations of the Treadway Commission (COSO).

We have also audited, in accordance with the Public Company Accounting Oversight Board (United States), the consolidated financial statements as of and for the year ended December 31, 2016, of the company and our report dated March 16, 2017, expressed an unqualified opinion on those financial statements.

/s/ GBH CPAs, PC

GBH CPAs, PC

www.gbhcpas.com

Houston, Texas

March 16, 2017

REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM
ON CONSOLIDATED FINANCIAL STATEMENTS

To the Board of Directors and Stockholders of

Actinium Pharmaceuticals, Inc.

New York, NY

We have audited the accompanying consolidated balance sheets of Actinium Pharmaceuticals, Inc. as of December 31, 2016 and 2015, and the related consolidated statements of operations, stockholders' equity (deficit) and cash flows for each of the three years in the period ended December 31, 2016. Actinium Pharmaceuticals, Inc.'s management is responsible for these financial statements. Our responsibility is to express an opinion on these financial statements based on our audits.

We conducted our audits in accordance with the standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement. An audit includes examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements, assessing the accounting principles used and significant estimates made by management, as well as evaluating the overall financial statement presentation. We believe that our audits provide a reasonable basis for our opinion.

In our opinion, the consolidated financial statements referred to above present fairly, in all material respects, the financial position of Actinium Pharmaceuticals, Inc. as of December 31, 2016 and 2015 and the results of its operations and its cash flows for each of the three years ended December 31, 2016 in conformity with accounting principles generally accepted in the United States of America.

We also have audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States), Actinium Pharmaceutical Inc.'s internal control over financial reporting as of December 31, 2016, based on criteria established in Internal Control—Integrated Framework (2013) issued by the Committee of Sponsoring Organizations of the Treadway Commission and our report dated March 16, 2017, expressed an unqualified opinion on the Company's internal control over financial reporting.

/s/ GBH CPAs, PC

GBH CPAs, PC

www.gbhcpas.com

Houston, Texas

March 16, 2017

F-3

Actinium Pharmaceuticals, Inc.**Consolidated Balance Sheets**

	December 31, 2016	December 31, 2015
<u>Assets</u>		
Current Assets:		
Cash and cash equivalents	\$20,519,294	\$25,643,273
Restricted cash - current	34,733	34,733
Prepaid expenses and other current assets	1,836,451	803,463
Total Current Assets	22,390,478	26,481,469
Property and equipment, net of accumulated depreciation	88,549	106,112
Security deposit	49,859	-
Total Assets	\$22,528,886	\$26,587,581
Liabilities and Stockholders' Equity		
Current Liabilities:		
Accounts payable and accrued expenses	\$4,194,874	\$1,473,936
Accounts payable and accrued expenses - related parties	25,000	25,000
Notes payable	-	265,695
Derivative liabilities	300,683	2,848,902
Total Current Liabilities	4,520,557	4,613,533
Total Liabilities	4,520,557	4,613,533
Commitments and contingencies		
Stockholders' Equity:		
Preferred stock, \$0.001 par value; 50,000,000 authorized, 0 shares issued and outstanding	-	-
Common stock, \$0.001 par value; 200,000,000 shares authorized; 55,801,742 and 44,066,541 shares issued and outstanding, respectively	55,802	44,067
Additional paid-in capital	154,504,329	134,160,059
Accumulated deficit	(136,551,802)	(112,230,078)
Total Stockholders' Equity	18,008,329	21,974,048
Total Liabilities and Stockholders' Equity	\$22,528,886	\$26,587,581

See accompanying notes to consolidated financial statements.

F-4

Actinium Pharmaceuticals, Inc.**Consolidated Statements of Operations**

	For the Year Ended December 31,		
	2016	2015	2014
Revenue	\$-	\$-	\$-
Operating expenses:			
Research and development, net of reimbursements	17,501,364	13,311,739	12,267,313
General and administrative	9,268,594	11,464,560	10,175,323
Depreciation expense	77,523	53,465	37,908
Total operating expenses	26,847,481	24,829,764	22,480,544
Loss from operations	(26,847,481)	(24,829,764)	(22,480,544)
Other income (expense):			
Interest expense	(5,007)	(7,868)	(866)
Gain (loss) on change in fair value of derivative liabilities	2,530,764	3,812,318	(2,206,099)
Total other income (expense)	2,525,757	3,804,450	(2,206,965)
Net loss	\$(24,321,724)	\$(21,025,314)	\$(24,687,509)
Net loss per common share - basic and diluted	\$(0.50)	\$(0.55)	\$(0.90)
Weighted average common shares outstanding - basic and diluted	48,463,268	38,158,480	27,363,748

See accompanying notes to consolidated financial statements.

Actinium Pharmaceuticals, Inc.**Consolidated Statement of Changes in Stockholders' Equity (Deficit)****For the Years Ended December 31, 2016, 2015 and 2014**

	Common Stock		Additional	Accumulated	Stockholders'
	Shares	Amount	Paid-In Capital	Deficit	Equity (Deficit)
Balance, January 1, 2014	24,565,447	\$24,565	\$64,933,145	\$(66,517,255)	\$(1,559,545)
Stock-based compensation	379,901	381	6,280,248	-	6,280,629
Proceeds from the sale of common stock, net of offering costs	2,379,433	2,380	15,432,925	-	15,435,305
Issuance of common stock from exercise of options	310,400	310	274,843	-	275,153
Issuance of common stock from exercise of warrants	2,336,658	2,336	157,658	-	159,994
Direct costs incurred before shares are issued	-	-	(30,000)	-	(30,000)
Transfer of warrant derivatives from liability to equity classification	-	-	2,203,443	-	2,203,443
Net loss	-	-	-	(24,687,509)	(24,687,509)
Balance, December 31, 2014	29,971,839	29,972	89,252,262	(91,204,764)	(1,922,530)
Stock-based compensation	344,784	345	7,061,277	-	7,061,622
Proceeds from the sale of common stock and warrants, net of offering costs	11,993,641	11,994	37,625,965	-	37,637,959
Issuance of common stock from exercise of options	20,000	20	15,660	-	15,680
Issuance of common stock from exercise of warrants	1,736,277	1,736	156,204	-	157,940
Transfer of warrant derivatives from liability to equity classification	-	-	48,691	-	48,691
Net loss	-	-	-	(21,025,314)	(21,025,314)
Balance, December 31, 2015	44,066,541	44,067	134,160,059	(112,230,078)	21,974,048
Stock-based compensation	81,700	82	4,297,696	-	4,297,778
Proceeds from the sale of common stock and warrants, net of offering costs	11,504,427	11,504	16,011,163	-	16,022,667
Issuance of common stock from exercise of options	23,212	23	18,082	-	18,105
Issuance of common stock from exercise of warrants	125,862	126	(126)	-	-
Transfer of warrant derivatives from liability to equity classification	-	-	17,455	-	17,455

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

Net loss	-	-	-	(24,321,724)	(24,321,724)
Balance, December 31, 2016	55,801,742	\$55,802	\$154,504,329	\$(136,551,802)	\$18,008,329

See accompanying notes to consolidated financial statements.

F-6

Actinium Pharmaceuticals, Inc.**Consolidated Statements of Cash Flows**

	For the Year Ended December 31,		
	2016	2015	2014
Cash Flows From Operating Activities:			
Net loss	\$(24,321,724)	\$(21,025,314)	\$(24,687,509)
Adjustments to reconcile net loss to net cash used in operating activities:			
Stock-based compensation expense	4,297,778	7,061,622	6,280,629
Depreciation expense	77,523	53,465	37,908
(Gain) loss on change in fair value of derivative liabilities	(2,530,764)	(3,812,318)	2,206,099
Changes in operating assets and liabilities:			
(Increase) decrease in:			
Prepaid expenses and other current assets	(1,032,988)	162,083	(193,894)
Increase (decrease) in:			
Accounts payable and accrued expenses	2,720,938	(793,949)	1,874,841
Accounts payable and accrued expenses - related party	-	(189,357)	133,172
Net Cash Used In Operating Activities	(20,789,237)	(18,543,768)	(14,348,754)
Cash Flows From Investing Activities:			
Payment of security deposit	(49,859)	-	-
Restricted cash	-	-	(34,733)
Purchase of property and equipment	(59,960)	(47,788)	(151,688)
Net Cash Used In Investing Activities	(109,819)	(47,788)	(186,421)
Cash Flows From Financing Activities:			
Payments on note payable	(265,695)	(283,552)	(161,841)
Sales of stock, net of offering costs	16,022,667	37,637,959	15,435,305
Proceeds from the exercise of options	18,105	15,680	275,153
Proceeds from the exercise of warrants	-	157,940	159,994
Net Cash Provided By Financing Activities	15,775,077	37,528,027	15,708,611
Net change in cash	(5,123,979)	18,936,471	1,173,436
Cash at beginning of year	25,643,273	6,706,802	5,533,366
Cash at end of year	\$20,519,294	\$25,643,273	\$6,706,802
Supplemental disclosures of cash flow information:			
Cash paid for interest	\$5,007	\$7,868	\$866
Cash paid for taxes	\$-	\$-	\$-
Supplemental disclosure of non-cash investing and financing activities:			
	\$-	\$-	\$30,000

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

Stock issuance costs included in accounts payable and accrued expenses

Insurance prepaid through premium finance	\$-	\$265,695	\$287,568
Fair value of warrants issued with stock	\$-	\$4,738,161	\$-
Transfer from derivative liability classification to equity classification	\$17,455	\$48,691	\$2,203,443

See accompanying notes to consolidated financial statements.

F-7

Actinium Pharmaceuticals, Inc.

Notes to Consolidated Financial Statements

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

Nature of Business - Actinium Pharmaceuticals, Inc. (the “Company” or “Actinium”) is a biotechnology company committed to developing breakthrough therapies for life threatening diseases using its alpha particle immunotherapy (“APIT”) platform and other related and similar technologies. Actinium, together with its wholly owned subsidiary, MedActinium, Inc., is hereinafter referred to collectively as “Actinium” or the “Company”. The Company’s most advanced products are Actimab™-A, an antibody-drug construct containing actinium 225 (Ac-225), currently in human clinical trials for acute myeloid leukemia (“AML”) and Iomab™-B, an antibody-drug construct containing iodine 131 (“I-131”), used in myeloconditioning for hematopoietic stem cells transplantation (“HSCT”) in various indications. The Company initiated its pivotal Phase 3 trial of Iomab™-B for bone marrow conditioning for HSCT in relapsed and refractory AML patient’s age of 55 and older. Upon successful completion of the Phase 3 trial we intend to submit an application for marketing approval with the U.S. Food and Drug Administration (“FDA”). Actinium is also considering filing an application with the FDA for breakthrough therapy designation for Actimab™-A and/or Iomab™-B. The Company is developing its cancer drugs using its expertise in radioimmunotherapy. In addition, the Company’s Ac-225 based drug development relies on the patented APIT platform technology co-developed with Memorial Sloan Kettering Cancer Center (“MSKCC”), a significant stockholder in the Company. The APIT technology couples monoclonal antibodies (mAb) with extremely potent but comparatively safe alpha particle emitting radioactive isotopes, in particular actinium 225 and bismuth 213. The final drug construct is designed to specifically target and kill cancer cells while minimizing side effects. Actinium intends to develop a number of products for different types of cancer and derive revenue from partnering relationships with large pharmaceutical companies and/or direct sales of its products in specialty markets in the United States.

In December 2015, the Company announced that the FDA cleared the Company's IND filing for Iomab-B, and that it will proceed with a pivotal, Phase 3 clinical trial. In June 2016, Actinium announced the pivotal Phase 3 clinical trial for Iomab-B was initiated and assuming that the trial meets its end points, it will form the basis for a Biologics Licensing Application (“BLA”) with the FDA. The Company, in its recently approved IND filing, established an agreement with the FDA that the path to a Biologics License Application submission would include a single, pivotal Phase 3 clinical study if it is successful. The population in this two arm, randomized, controlled, multicenter trial will be refractory and relapsed AML patients over the age of 55. The trial size was set at 150 patients with 75 patients per arm. The primary endpoint in the pivotal Phase 3 trial is durable complete remission, defined as a complete remission lasting at least 6 months and a secondary endpoint that will be overall survival at one year. There are currently no effective treatments approved by the FDA for AML in this patient population and there is no defined standard of care. Iomab-B has completed several physicians sponsored clinical trials examining its potential as a conditioning regimen prior to HSCT in various blood cancers, including the Phase 1/2 study in relapsed and/or refractory AML patients. The results of these studies in almost 300 patients have demonstrated the potential for Iomab-B to create a new treatment paradigm for bone marrow transplants by: expanding the pool to ineligible patients who do not have any viable treatment options currently; enabling a shorter and safer preparatory interval for HSCT; reducing

post-transplant complications; and showing a clear survival benefit including curative potential.

In September 2016, we announced that we initiated a Phase 2 clinical trial for Actimab-A. This Phase 2 clinical trial is a multicenter, open-label study that will enroll 53 patients. Patients will receive 2.0 $\mu\text{Ci/kg}$ /fractionated dose of Actimab-A via two injections given at day 1 and day 7. The Phase 2 trial is designed to evaluate complete response rates at up to day 42 after Actimab-A administration, where complete response is defined as complete remission (“CR”) or complete remission with incomplete platelet recovery (CRp). A formal interim analysis is expected to occur in mid-2017 with topline results expected in the second half of 2017. The Phase 2 trial will include peripheral blast burden as an inclusion criteria and in patients with high peripheral blast (“PB”) burden, the use of Hydroxyurea will be mandated with the goal of bringing PB burden below a key threshold number that we have identified from two previously complete Phase 1 clinical trials totaling 38 patients. In addition, the use of granulocyte colony-stimulating factors (“GCSF”) will be mandated. Low dose cytarabine has been eliminated from the protocol and the Phase 2 clinical trial will evaluate Actimab-A as a monotherapy. The secondary endpoint of the Phase 2 trial will be overall survival.

In February 2017, we initiated a Phase 1 investigator initiated clinical trial to study Actimab-M in multiple myeloma (MM). Multiple myeloma is a cancer of plasma cells that is currently incurable. The Phase 1 trial will enroll up to 12 patients with relapsed or refractory multiple myeloma who have positive CD33 expression. This Phase 1 study is designed as a dose escalation study intended to assess safety, establish maximum tolerable dose (MTD) and assess efficacy. Patients will be administered Actimab-M on day 1 at an initial dose of 0.5 $\mu\text{Ci/kg}$ and then assessed at day 42 for safety and efficacy. The dose can be increased to 1.0 $\mu\text{Ci/kg}$ or reduced to 0.25 $\mu\text{Ci/kg}$ based on safety assessment that will evaluate dose limiting toxicities (DLTs). Patients may receive up to 8 cycles of therapy but in no event will cumulative administration exceed 4.0 $\mu\text{Ci/kg}$ of Actimab-M.

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 revenues 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 FDIC insured limits. At December 31, 2016 and 2015, all of the Company's cash was deposited in one bank.

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.

Impairment of Long-Lived Assets - Management reviews long-lived assets for impairment whenever events or changes in circumstances indicate that the carrying amount may not be realizable or at a minimum annually during the fourth quarter of the year. If an evaluation is required, the estimated future undiscounted cash flows associated with the asset are compared to the asset's carrying value to determine if an impairment of such asset is necessary. The effect of any impairment would be to expense the difference between the fair value of such asset and its carrying value.

Derivatives - All derivatives are recorded at fair value on the balance sheet. Fair values for securities traded in the open market and derivatives are based on quoted market prices. Where market prices are not readily available, fair values are determined using market based pricing models incorporating readily observable market data and requiring judgment and estimates.

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. The fair value hierarchy is as follows:

Level 1 Inputs - Unadjusted quoted prices in active markets for identical assets or liabilities that the reporting entity has the ability to access at the measurement date.

Level 2 Inputs - Inputs other than quoted prices included in Level 1 that are observable for the asset or liability, either directly or indirectly. These might include quoted prices for similar assets or liabilities in active markets, quoted prices for identical or similar assets or liabilities in markets that are not active, inputs other than quoted prices that are observable for the asset or liability (such as interest rates, volatilities, prepayment speeds, credit risks, etc.) or inputs that are derived principally from or corroborated by market data by correlation or other means.

Level 3 Inputs - Unobservable inputs for determining the fair values of assets or liabilities that reflect an entity's own assumptions about the assumptions that market participants would use in pricing the assets or liabilities.

The following tables set forth assets and liabilities measured at fair value on a recurring and non-recurring basis by level within the fair value hierarchy as of December 31, 2016 and 2015. 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.

	Level 1	Level 2	Level 3	Total
Derivative liabilities:				
At December 31, 2016	-	-	\$300,683	\$300,683
At December 31, 2015	-	-	\$2,848,902	\$2,848,902

Income Taxes - The Company uses the asset and liability method in accounting for income taxes. Under this method, deferred tax assets and liabilities are determined based on differences between financial reporting and income tax carrying amounts of assets and liabilities and are measured 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.

Research and Development Costs – Research and development costs are expensed as incurred. Research and development reimbursements and grants are recorded by the Company as a reduction of research and development costs.

Share-Based Payments – The Company estimates the fair value of each stock option award at the grant date by using the Black-Scholes option pricing model. The fair value determined represents the cost for the award and is recognized over the vesting period during which an employee is required to provide service in exchange for the award. As share-based compensation expense is recognized based on awards ultimately expected to vest, the Company reduces the expense for estimated forfeitures based on historical forfeiture rates. Previously recognized compensation costs may be adjusted to reflect the actual forfeiture rate for the entire award at the end of the vesting period. Excess tax benefits, if any, are recognized as an addition to paid-in capital.

Earnings (Loss) Per Common Share – Basic earnings (loss) per common share is computed by dividing the net income (loss) available to common stockholders by the weighted average number of common shares outstanding during the reporting period. For the years ended December 31, 2016, 2015 and 2014, 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 be anti-dilutive.

	December 31, 2016	December 31, 2015	December 31, 2014
Options	5,906,886	3,971,583	3,013,084
Warrants	8,964,752	9,018,470	7,698,497
Total	14,871,638	12,990,053	10,711,581

Recent Accounting Pronouncements – In April 2016, the Financial Accounting Standards Board ("FASB") issued Accounting Standards Update ("ASU") No. 2016-09, "*Compensation – Stock Compensation*" (topic 718). The FASB issued this update to improve the accounting for employee share-based payments and affect all organizations that issue share-based payment awards to their employees. Several aspects of the accounting for share-based payment award transactions are simplified, including: (a) income tax consequences; (b) classification of awards as either equity or liabilities; and (c) classification on the statement of cash flows. The updated guidance is effective for annual periods beginning after December 15, 2016, including interim periods within those fiscal years. The Company adopted ASU 2016-09 on the consolidated financial statements in 2016.

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 other recently issued, but not yet effective accounting pronouncements, when adopted, will have a material effect on the accompanying consolidated financial statements.

Subsequent Events – The Company's management reviewed all material events through the date of the consolidated financial statements were issued for subsequent event disclosure consideration. See Note 10.

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 MSKCC, a majority shareholder of the Company. 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 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 years ended December 31, 2016, 2015 and 2014, the Company incurred \$0.1 million, \$0.2 million and \$0.3 million, respectively, for maintenance fees and research conducted by MSKCC. As of December 31, 2016 and 2015, the Company did not have an outstanding payable to MSKCC.

On December 21, 2015, Actinium entered into an investor rights agreement with MSKCC. Under the terms of the agreement, MSKCC has agreed to forebear from transferring or otherwise disposing of its approximately 5.7 million shares of the Company's common stock (other than pursuant to a piggyback registration as described below) until the start of the Actimab-A Phase 2 clinical study. The Company started the Actimab-A Phase 2 clinical study in September 2016. Thereafter MSKCC is permitted to sell its shares subject to a weekly volume limitation of 150,000 shares (which limit may be increased to up to 250,000 shares per week to the extent any prior weekly allotments are not fully used) and applicable law so long as MSKCC maintains at least 25% of its current shareholding in Actinium through December 31, 2016. Actinium has granted MSKCC piggyback registration rights that would be triggered in the event Actinium were to engage in a public registered offering of its shares for its own account where other shareholders are participating as selling shareholders or where such public registered offering is for the account of other selling shareholders. In addition, Actinium granted MSKCC unlimited Form S-3 registration rights with respect to its shares following December 31, 2016.

Placement Agent:

On December 9, 2013, the Company entered into an engagement agreement with a Healthcare Investment Bank (“Placement Agent”) as its placement agent for the 2013 Common Stock Offering whereby a director of the Company was the former Head of its Healthcare Investment Banking team (“the 2013 Offering”). The 2013 Offering was completed in two tranches, December 9, 2013 and January 10, 2014. The agreement entered in on December 9, 2013 included a cash fee equal to 10% of the gross proceeds raised, a non-accountable expense reimbursement equal to 2% of the gross proceeds raised and warrants to purchase shares of the Company’s Common Stock in an amount equal to 10% of the shares of common stock issued or issuable. Subsequent to the closing of the 2013 Offering, the placement agent continued to provide certain financial advisory services to the Company until six months after the Company had up-listed its securities for trading on a U.S. National Exchange for a monthly fee of \$25,000. On May 28, 2014, the Company and the placement agent agreed to terminate the December 9, 2013 engagement agreement. As of December 31, 2016 and 2015, the Company owed this placement agent \$25,000.

For the year ended December 31, 2014, the placement agent received a cash fee of \$397,303 from the 2013 Offering and was issued warrants to purchase 68,976 shares of the Company’s Common Stock at \$9 per share for a period of 5 years.

On July 10, 2014, the Company completed another public offering pursuant to a shelf registration statement previously filed where the placement agent acted as lead manager. The placement agent received a cash fee of \$455,108.

On February 11, 2015, the Company completed a public offering that totaled 4,444,444 common shares, representing gross proceeds of approximately \$20.0 million and net proceeds of approximately \$18.5 million after deducting the underwriting discount and the other offering expenses. The Placement Agent acted as the sole book-running manager for the offering. The offering was made pursuant to a shelf registration statement previously filed with and declared effective by the U.S. Securities and Exchange Commission. The placement agent received a cash fee of approximately \$1.4 million.

On June 9, 2015, the Company completed a registered direct offering of \$5.0 million of its common stock. Under the terms of the subscription agreements, the Company issued an aggregate of 1,923,078 shares of the Company's common stock at a purchase price of \$2.60 per share. The Placement Agent acted as the sole placement agent with respect to the offering. The Placement Agent received a cash fee of approximately \$0.4 million.

Note 3 – Prepaid Expenses and Other Current Assets

Prepaid expenses and other current assets consisted of the following at December 31, 2016 and 2015:

	December 31, 2016	December 31, 2015
Prepaid insurance	\$ 332,809	\$ 376,906
Prepaid clinical trial expense	1,093,441	283,430
Other prepaid expenses	410,201	143,127
Total prepaid expenses and other current assets	\$ 1,836,451	\$ 803,463

Note 4 – Property and Equipment

Property and equipment consisted of the following at December 31, 2016 and 2015:

	Lives	December 31, 2016	December 31, 2015
Lab equipment	3 years	\$ 116,070	\$ 116,070
Office equipment	3 years	142,933	82,974
Less: accumulated depreciation		(170,454)	(92,932)
Property and equipment, net		\$ 88,549	\$ 106,112

Depreciation expense for the years ended December 31, 2016, 2015 and 2014 was \$77,523, \$53,465 and \$37,908, respectively.

Note 5 – Note Payable

On December 28, 2015, the Company entered into a premium finance agreement for its director and officer liability insurance policy in the amount of \$0.3 million. Pursuant to the agreement, the Company was required to pay \$30,077 in monthly installments for nine months.

As of December 31, 2016 and 2015, the outstanding balance related to the premium finance agreements was \$0 and \$0.3 million, respectively.

Note 6 – Derivatives

The Company has determined that certain warrants the Company has issued contain provisions that protect holders from future issuances of the Company's common stock at prices below such warrants' respective exercise prices and these provisions could result in modification of the warrants' exercise price based on a variable that is not an input to the fair value of a "fixed-for-fixed" option as defined under FASB ASC Topic No. 815 - 40. The warrants granted in connection with the issuance of the 2012 Common Stock Offering, and the placement agent warrants contain anti-dilution provisions that provide for a reduction in the exercise price of such warrants in the event that future common stock (or securities convertible into or exercisable for common stock) is issued (or becomes contractually issuable) at a price per share (a "Lower Price") that is less than the exercise price of such warrant at the time. The amount of any such adjustment is determined in accordance with the provisions of the warrant agreement and depends upon the number of shares of common stock issued (or deemed issued) at the Lower Price and the extent to which the Lower Price is less than the exercise price of the warrant at the time.

Activities for derivative warrant instruments during the years ended December 31, 2016 and 2015 were as follows:

	Shares subject to warrants	Fair Value
Balance, December 31, 2014	1,649,329	\$6,709,911
Transfer from liability to equity classification	(21,960)	(48,691)
Change in fair value	-	(3,812,318)

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

Balance, December 31, 2015	1,627,369	2,848,902
Transfer from liability to equity classification	(12,109)	(17,455)
Change in fair value	-	(2,530,764)
Balance, December 31, 2016	1,615,260	\$300,683

During the year ended December 31, 2016, 183,718 warrants were exercised, of which 12,109 were derivative warrants. The fair value of these derivative warrants totaling \$17,455 were measured on the various exercise dates and reclassified to additional paid-in capital.

During the year ended December 31, 2015, 2,013,360 warrants were exercised, of which 21,960 were derivative warrants. The fair value of these derivative warrants totaling \$48,691 were measured on various exercise dates and reclassified to additional paid-in capital.

The fair values of the derivative warrants were calculated using a modified binomial valuation model with the following assumptions at each balance sheet date.

	December 31, 2016		December 31, 2015	
Market value of common stock on measurement date (1)	\$ 0.88		\$ 3.23	
Adjusted exercise price	\$ 2.34		\$ 2.48	
Risk free interest rate (2)	0.85	%	1.06	%
Warrant lives in years	2.0 years		2.0 years	
Expected volatility (3)	61 - 69	%	87	%
Expected dividend yield (4)	-		-	
Probability of stock offering in any period over 5 years (5)	100	%	100	%
Offering price (6)	\$ 1.25		\$ 2.60	

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

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

(3) The volatility was estimated using the historical volatilities of the Company's common stock traded in NYSE MKT market.

(4) Management determined the dividend yield to be 0% based upon its expectation that it will not 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 7 – 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 is 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 ^a 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 the following agreed to and contracted milestones:

Milestones	Payments
(1) when Company initiates a Phase I Clinical Trial of a licensed product	\$ 750,000
(2) when Company initiates a Phase II Clinical Trial of a licensed product	750,000
(3) when Company initiates a Phase III Clinical Trial of a licensed product	1,500,000
(4) Biological License Application filing with U.S. FDA	1,750,000
(5) First commercial sale	1,500,000
(6) after the first \$10,000,000 in net sales	1,500,000

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 on July 24, 2012. 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 accrued \$750,000 as a research and development expense. As of December 31, 2016, the \$750,000 accrual was included in the accounts payable and accrued liabilities 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. During the years ended December 31, c. 2016, 2015, and 2014, the Company purchased approximately \$1.0 million, \$0.8 million and \$0.6 million, respectively, of radioactive material with ORNL. On January 9, 2017, the Company signed a contract with ORNL to purchase \$0.7 million of radioactive material.

Icon Clinical Research, LLC (“Icon”, formerly AptivSolutions) provides project management services for the study of the drug Ac-225-HuM195 (Actimab-A) used in the Company’s Phase 1 and Phase 2 clinical trials. The total project was estimated to cost approximately \$1.9 million and required a 12.5% down payment of the total estimated project cost. The down payment totaling \$0.2 million was paid in 2007 and 2012. On August 6, 2012, October 22, 2012 and May 16, 2013, the agreement was amended to provide for additional services. The total project is now estimated at approximately \$2.7 million. Icon invoices the Company when services are rendered and the Company records the related expense to research and development expense. d.

For the years ended December 31, 2016, 2015 and 2014, the Company incurred expenses of approximately \$0.8 million, \$0.4 million and \$0.4 million, respectively, related to this agreement.

e. 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 and the Company intends to start preparation for a pivotal trial leading to an FDA approval. The Company has been granted exclusive rights to the BC8 antibody and related master cell bank developed by FHCRC. The cost to develop the trial will range from \$13.2 million to \$23.5 million, depending on the trial design as required by the FDA. Under the terms of the sponsored research agreement, the Company will fund the FHCRC lab with \$0.2 million per year for the first two years and \$0.3 million thereafter. Payments made toward funding the lab will be credited toward royalty payments owed to FHCRC in the given year. 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 years ended December 31, 2016, 2015 and 2014, the Company incurred expenses of approximately \$0.4 million, \$0.3 million and \$0.2 million, respectively, related to this agreement.

F-15

f. 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 anticipated to be used in the phase 3 clinical trial of Iomab-B. Total cost of the agreement is \$6.8 million. The Company made a non-refundable payment of \$0.6 million upon execution of the agreement. Periodic payments will be made upon reaching certain milestones. As of December 31, 2016, the remaining cost of the service agreement (only) is approximately \$2.6 million. Goodwin bills the Company when services are rendered and the Company records the related expense to research and development costs.

For the years ended December 31, 2016, 2015 and 2014, the Company paid Goodwin, services fees and materials, approximately \$0.7 million, \$4.2 million and \$3.6 million, respectively. As of December 31, 2016 and 2015, the Company owed Goodwin \$0.1 million.

g. On September 30, 2014, the Company entered into a research agreement with the Albert Einstein College of Medicine of Yeshiva University ("Einstein"). According to the agreement, Einstein will use certain materials provided by the Company to complete a research project. The research project will explore the feasibility of using Actinium 225 to prepare patients with blood borne cancers to receive a hematopoietic stem cell transplant. Einstein will periodically provide the Company with reports showing project data or research. The total fixed price of the project is \$0.2 million which is payable to Einstein in three payments.

During the years ended December 31, 2016, 2015 and 2014, the Company paid Einstein approximately \$37,000, \$0.1 million and \$0.1 million, respectively, in full satisfaction of the agreement.

h. On February 16, 2016, the Company entered into a CRO agreement with Medpace, Inc. ("Medpace"). Medpace provides project management services for the study of Iomab-B used for the intended Phase 3 clinical trial. The total project is estimated to cost approximately \$7.2 million.

For the year ended December 31, 2016, the Company paid approximately \$2.6 million.

i. On August 4, 2016, the Company entered into a CRO agreement with Vector Oncology Solutions, LLC ("Vector"). Vector provides project management services for the study of Actimab-A used for the intended Phase 2 clinical trial. The total project is estimated to cost approximately \$4.6 million.

For the year ended December 31, 2016, the Company paid Vector approximately \$1.0 million.

Lease Agreements

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

The Company does not own any real property. On March 10, 2016, effective as of January 1, 2016, Actinium entered into an Office Space License Agreement (the “License”) with Relmada Therapeutics, Inc. (“Relmada”), with whom we share two common board members, for office space located at 275 Madison Avenue, 7th Floor, New York, NY 10016. The License represents a substantial reduction in the per person cost over Actinium’s prior lease and the space allows for future growth. Both companies’ boards authorized the transaction. The term of the License is three years from the effective date, with an automatic renewal provision. The cost of the License is on a pass through basis for Relmada, and is approximately \$17,000 per month for Actinium, subject to customary escalations and adjustments.

In August 2016, the Company expanded its office space at 275 Madison Avenue, 6th Floor, New York, NY 10016, for an additional \$2,400 per month over a 12-month term.

Future minimum obligations on the lease are:

For the year ending December 31, 2017	\$218,464
For the year ending December 31, 2018	199,440
Total	\$417,904

F-16

Note 8 – Equity

On December 9, 2013, the Company entered into an engagement agreement with its placement agent for the 2013 Common Stock Offering. The 2013 Offering was completed in two tranches, on December 9, 2013 and January 10, 2014.

In January 2014, the Company completed the final tranche of the 2013 Offering and received approximately \$3.3 million total gross proceeds from accredited investors (“2014 Closing”). The Company paid its placement agent total cash fees of approximately \$0.4 million and paid attorney fees of \$40,000 for their services resulting in net proceeds of \$2.9 million. In the 2014 Closing, the Company sold 551,810 shares of common stock at \$6.00 per share and granted 137,952 units of five-year warrants with an exercise price of \$9.00 per share. The warrants are exercisable for a period of five years from the date of issuance. The transaction date fair value of the warrants of \$0.6 million was determined utilizing the Black-Scholes option pricing model utilizing the following assumptions: risk free interest rate - 1.64%, expected volatility - 88%, expected dividend yield - 0%, and a contractual life of 5 years.

During January 2014, in connection with the 2014 Closing, the Company issued the Placement Agent warrants to purchase an aggregate of 68,976 shares of common stock with an exercise price of \$9.00 per share. The transaction date fair value of the warrants of \$0.3 million was determined utilizing the Black-Scholes option pricing model utilizing the following assumptions: risk free interest rate – 1.64%, expected volatility - 88%, expected dividend yield - 0%, and a contractual life of 5 years.

On March 24, 2014, the Company filed a shelf registration statement on Form S-3 (the “Registration Statement”) which was effective on April 17, 2014. This Registration Statement contained two prospectuses: (i) a base prospectus which covers the offering, issuance and sale by the Company of up to \$200 million of its common stock, preferred stock, warrants and/or units; and (ii) a sales agreement prospectus covering the offering, issuance and sale by us of up to a maximum aggregate offering price of \$75,000,000 of its common stock that may be issued and sold under a sales agreement (the “Sales Agreement”) with MLV & Co. LLC (“MLV”) dated March 24, 2014. The Company will pay MLV in cash, upon the sale of common stock pursuant to the Sales Agreement, an amount equal to 3.0% of the gross proceeds from the sale of common stock. On April 28, 2014, the Company issued 500 shares and received net proceeds of \$6,000 under the Sales Agreement with MLV. During the year ended December 31, 2015, the Company issued 5,626,119 common shares with an average price of \$2.52 per share. The Company received \$15.1 million gross proceeds (net proceeds of \$14.7 million) from the issuances. During the year ended December 31, 2016, the Company issued 3,504,427 common shares with an average price of \$1.96 per share. The Company received gross proceeds of \$7.0 million (net proceeds of \$6.8 million) from the issuances.

On June 30, 2014, the Company received gross proceeds of \$12.5 million from a public offering of 1,670,000 shares of the Company’s common stock, \$0.001 par value, at a price to the public of \$7.50 per share less underwriting

discounts. The Company paid an underwriting discount of \$0.9 million, paid other offering expenses of \$0.1 million, and paid attorney and auditor fees of \$0.1 million resulting in net proceeds of \$11.5 million. Under the terms of the underwriting agreement, the Company also granted the underwriters a 30-day option to purchase up to an additional 250,000 shares of common stock to cover over-allotments, if any, at the offering price.

F-17

On July 10, 2014, the underwriter exercised their over-allotment option to purchase an additional 157,123 shares from the Company for \$7.50 per share. Including the exercise of the over-allotment option of \$1.2 million, in gross proceeds, the Company's June offering totaled 1,827,123 shares, representing gross proceeds of approximately \$13.7 million and \$12.6 million net after deducting the underwriting discount and other offering expenses.

On February 11, 2015, the Company completed an underwritten offering of 4,444,444 shares of its common stock and warrants to purchase an aggregate of 3,333,333 shares of its common stock at a price to the public of \$4.50 per share. The warrants will be exercisable for a period of 4 years at an exercise price of \$6.50 per share and have a relative fair value of \$3,540,659 on the issuance date. The Company received net proceeds of approximately \$18.5 million, after deducting underwriting discounts and commissions and estimated offering expenses payable by us, and excluding the underwriters' over-allotment option.

On June 9, 2015, the Company closed a financing with certain investors in which it raised approximately \$5,000,000 in gross proceeds or \$4,480,000 in net proceeds, after deducting placement agent's fees and other offering expenses. Investors purchased 1,923,078 shares of the Company's common stock, at a price per share of \$2.60.

On October 4, 2016, the Company sold 8,000,000 shares of its common stock at a price of \$1.25 per share to the public through an underwritten public offering.

During the year ended December 31, 2016, the Company issued 125,862 common shares for the cashless exercise of warrants. During the year ended December 31, 2016, the Company also issued 23,212 common shares for \$18,105 cash received from the exercise of options.

During the year ended December 31, 2015, the Company issued 1,532,124 common shares for the cashless exercise of warrants. During the year ended December 31, 2015, the Company also issued 224,153 common shares for \$173,620 cash received from the exercise of options and warrants.

During the year ended December 31, 2014, the Company issued 2,162,181 common shares for the cashless exercise of warrants. During the year ended December 31, 2014, the Company also issued 484,877 common shares for \$435,147 cash received from the exercise of options and warrants.

Approval of the 2013 Amended and Restated Stock Plan

In September 2013, the Board of Directors of the Company approved the Company's 2013 Stock Plan. The expiration date of the plan is September 9, 2023 and the total number of underlying shares of the Company's common stock available for grant to employees, directors and consultants of the Company under the plan is 2,750,000 shares. In December 2015, the shareholders of the Company approved the second amendment to the plan and increased the number of shares authorized under the plan to 9,250,000 shares. In December 2016, the shareholders of the Company approved the fifth amendment to the plan and increased the number of shares authorized under the plan to 12,750,000 shares.

Approval of the Equity Incentive Plan

In September 2013, the Board approved the Company's 2013 Equity Incentive Plan. The expiration date of the plan is September 9, 2023 and the total number of shares of the Company's common stock available for grant to employees, directors and consultants of the Company under the plan is 450,000 shares. In December 2013, the shareholders of the Company approved the plan and increased the number of shares authorized under the plan to 1,000,000 shares.

Restricted Stock

During the year ended December 31, 2014, the Company granted 633,041 shares of restricted stock and cancelled 50,000 shares of restricted stock. Of the total shares of restricted stock granted, 20,000 shares vest 3 months from the grant date, 30,374 shares vest 1 year from the grant date, 30,000 shares have a vesting period of 2 years, 202,497 shares have a vesting period of 4 years and 350,000 shares vest at the date of grant. The shares granted during the year ended December 31, 2014 were valued at \$4.9 million based on the stock price on the grant dates.

During the year ended December 31, 2015, the Company granted 479,651 shares of restricted common stock to consultants with a fair value of \$2.3 million based on the stock price on the grant dates. Of the 479,651 restricted share awards granted in 2015, 329,651 shares vested at the date of grant and 150,000 shares vest over a six-month period.

During the year ended December 31, 2015, the Company cancelled 126,265 shares of restricted stock originally granted to employees and issued a total of 152,499 options (see below). As a result of the cancellation of the 126,265 restricted shares, the Company recorded an expense of \$0.8 million for the grant-date fair value of the restricted stock for which the requisite service is expected to be rendered.

During the year ended December 31, 2016, the Company granted 250,700 shares of restricted common stock to consultants with a fair value of \$0.4 million based on the stock price on the grant dates. Of the 250,700 restricted share awards granted in 2016, 60,700 shares vested at the date of grant, 150,000 shares vest over a six-month period and 40,000 shares vest over 2 years.

During the year ended December 31, 2016, the Company issued common shares totaling 21,000 for restricted shares granted in 2015 and prior years and 60,700 for restricted shares granted in 2016.

During the year ended December 31, 2016, 2015 and 2014, the Company recorded approximately \$0.6 million, \$3.4 million and \$3.7 million, respectively, in stock-based compensation for all of the restricted shares granted.

Stock Options

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

Following is a summary of option activities for the years ended December 31, 2016, 2015 and 2014:

	Number of Units	Weighted Average Exercise Price	Weighted Average Remaining Contractual Term (in years)	Aggregate Intrinsic Value
Outstanding, December 31, 2013	1,985,384	3.23	8.34	5,908,696
Issued	1,338,100	8.86		
Exercised	(310,400)	0.95		
Outstanding, December 31, 2014	3,013,084	5.98	8.35	4,728,842
Issued	1,554,499	2.78		
Cancelled	(576,000)	8.70		
Exercised	(20,000)	0.78		
Outstanding, December 31, 2015	3,971,583	4.34	8.01	2,964,146
Issued	2,225,000	1.92		
Cancelled	(266,485)	2.51		
Exercised	(23,212)	0.78		
Outstanding, December 31, 2016	5,906,886	3.52	7.90	51,704
Exercisable, December 31, 2016	2,601,947	\$ 4.67	6.31	\$51,704

During the year ended December 31, 2014, the Company granted employees, consultants, and its board members 1,338,100 options to purchase the Company's common stock with exercise prices ranging from \$0.78 to \$11.95 with a 10 year term vesting over a 4-year period. The options have an aggregated fair value of \$8.7 million that was calculated using the Black-Scholes option-pricing model. Variables used in the Black-Scholes option-pricing model include: (1) discount rate of 1.77% - 2.07% (2) expected life of 6 years, (3) expected volatility of 82.47% - 87.76%, and (4) zero expected dividends.

During the year ended December 31, 2015, the Company granted employees, consultants, and its board members 1,554,499 options to purchase the Company's common stock with exercise prices ranging from \$1.79 to \$3.58 and a 10 year with vesting ranging from 1 to 4.17 years. The options have an aggregated fair value of \$3.2 million that was calculated using the Black-Scholes option-pricing model. Variables used in the Black-Scholes option-pricing model include: (1) discount rate of 1.56% - 1.91% (2) expected life of 6 years, (3) expected volatility of 85.01% - 94.89%, and (4) zero expected dividends.

During the year ended December 31, 2016, the Company granted employees, consultants, and its board members 2,225,000 options to purchase the Company's common stock with exercise prices ranging from \$0.95 to \$2.25 with a 10 year term vesting over a 4 year period. The options have an aggregated fair value of \$3.1 million that was calculated using the Black-Scholes option-pricing model. Variables used in the Black-Scholes option-pricing model include: (1) discount rate of 1.28% - 1.97% (2) expected life of 6 years, (3) expected volatility of 81.45% - 87.95%, and (4) zero expected dividends.

During the years ended December 31, 2016, 2015 and 2014, the Company received gross proceeds of \$18,105, \$15,680 and \$0.3 million for exercise of options for 23,212 shares, 20,000 shares and 310,400 shares, respectively, of the Company's common stock.

All options issued and outstanding are being amortized over their respective vesting periods. The unrecognized compensation expense at December 31, 2016 and 2015 was \$6.7 million and \$7.2 million, respectively. During the years ended December 31, 2016, 2015 and 2014, the Company recorded option expense of \$3.6 million, \$3.4 million and \$2.4 million, respectively.

Warrants

Following is a summary of warrant activities for the years ended December 31, 2016, 2015 and 2014:

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

	Number of Units	Weighted Average Exercise Price	Weighted Average Remaining Contractual Term (in years)	Aggregate Intrinsic Value
Outstanding, December 31, 2013	9,737,729	\$ 1.06	4.89	\$47,396,307
Granted	491,928	8.33		
Exercised	(2,501,993)	0.67		
Forfeited	(29,167)	6.70		
Outstanding, December 31, 2014	7,698,497	1.64	3.97	34,317,224
Granted	3,333,333	6.50		
Exercised	(2,013,360)	0.41		
Outstanding, December 31, 2015	9,018,470	3.73	2.93	10,199,230
Granted	130,000	0.96		
Exercised	(183,718)	0.90		
Outstanding, December 31, 2016	8,964,752	3.72	1.95	1,445,786
Exercisable, December 31, 2016	8,612,252	3.66	1.79	1,445,786

F-20

During the year ended December 31, 2014, the Company granted warrants to purchase 137,952 shares of the Company's common stock to investors and warrants to purchase 68,976 shares of the Company's common stock to its placement agent in connection with the January 2014 closing.

During the year ended December 31, 2014, the Company also granted three consultants warrants to purchase 285,000 shares of the Company's common stock with exercise prices ranging from \$5.55 to \$11.66 per share and a term of 10 years. These warrants vest when certain milestones are met. The fair value of the warrants was \$2.1 million on the grant date and was calculated using the Black-Scholes option-pricing model. Variables used in the Black-Scholes option-pricing model include (1) discount rate of 1.56% - 1.66%, (2) expected term of 5 years, (3) expected volatility of 82.47-87.76%, and (4) zero expected dividends. As of December 31, 2014, unrecognized compensation expense related to the warrants was \$1.5 million.