

Actinium Pharmaceuticals, Inc.  
Form 10-K  
March 15, 2019

**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, 2018**

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)



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

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, smaller reporting company, or an emerging growth company. See the definitions of "large accelerated filer," "accelerated filer," "smaller reporting company," and "emerging growth company" in Rule 12b-2 of the Exchange Act.

Large accelerated filer	Accelerated filer
Non-accelerated filer	Smaller reporting company
Emerging growth company	

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

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

The aggregate market value of voting stock held by nonaffiliates of the registrant as of June 29, 2018, 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 AMERICAN on June 29, 2018 was \$70,693,197.

As of March 15, 2019, 119,136,036 shares of common stock, \$0.001 par value per share, were outstanding.

**Table of Contents**

	Page
<b><u>PART I</u></b>	
Item 1. <u>Business</u>	1
Item 1A. <u>Risk Factors</u>	13
Item 1B. <u>Unresolved Staff Comments</u>	33
Item 2. <u>Properties</u>	33
Item 3. <u>Legal Proceedings</u>	33
Item 4. <u>Mine Safety Disclosures</u>	33
<b><u>PART II</u></b>	
Item 5. <u>Market for Registrant’s Common Equity, Related Stockholders Matters, and Issuer Purchases of Equity Securities</u>	34
Item 6. <u>Selected Financial Data</u>	35
Item 7. <u>Management’s Discussion and Analysis of Financial Condition and Results of Operations</u>	36
Item 7A. <u>Quantitative and Qualitative Disclosures About Market Risk</u>	43
Item 8. <u>Financial Statements and Supplementary Data</u>	F-1
Item 9. <u>Changes in and Disagreements with Accountants on Accounting and Financial Disclosure</u>	44
Item 9A. <u>Controls and Procedures</u>	44
Item 9B. <u>Other Information</u>	45
<b><u>PART III</u></b>	
Item 10. <u>Directors, Executive Officers and Corporate Governance</u>	46
Item 11. <u>Executive Compensation</u>	60
Item 12. <u>Security Ownership of Certain Beneficial Owners and Management</u>	63
Item 13. <u>Certain Relationships and Related Transactions, and Director Independence</u>	66
Item 14. <u>Principal Accountant Fees and Services</u>	67
<b><u>PART IV</u></b>	
Item 15. <u>Exhibits, Financial Statement Schedules</u>	68
<u>Signature Page</u>	71

## 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 Report, 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 Report, 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 Report. 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 Report 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 Report to conform our statements to actual results or changed expectations.

## **PART I**

### **Item 1. Business.**

#### **Business Overview**

Actinium Pharmaceuticals Inc. is a clinical-stage, biopharmaceutical company focused on developing and potentially commercializing therapies for targeted conditioning prior to cell therapies such as a BMT or Bone Marrow Transplant or CAR-T, a type of cellular therapy that genetically alters a patient's own T cells to target and kill their cancer cells, and for other adoptive cell therapies. In addition, we are also developing potential therapies for targeting and killing of cancer cells either as single agents or in combination with other drugs. Our targeted therapies are Antibody Radiation-Conjugates or ARC's, that combine the targeting ability of a monoclonal antibody (mAb) with the cell-killing ability of a radioisotope to deliver radiation internally in a precise manner to potentially generate more potent efficacy and with less toxicity than radiation that is delivered externally. We are developing two clinical stage ARC programs that target the antigens CD45 and CD33, respectively, that are currently being studied in several hematologic indications. We employ our ARCs at higher doses of radioisotope intensity for targeted conditioning prior to a BMT and at lower doses for targeted conditioning which is also known as lymphodepletion prior to CAR-T and other adoptive cell therapies. In addition, we are pursuing development of our ARC's at low doses in combination with other therapeutic modalities such as chemotherapy, targeted agents or immunotherapy and as a monotherapy. Our ARC based clinical programs are underpinned by our AWE or Antibody Warhead Enabling technology platform where we have data in both liquid and solid tumors, intellectual property and know-how that we intend to use to create additional ARCs targeting new antigens with multiple radioisotopes such as actinium-225 or Ac-225 or and iodine-131 or I-131. Our AWE technology platform is currently being utilized in a research collaboration with Astellas Pharma, Inc. centered around our technology for Ac-225.

#### **Targeted Conditioning Pipeline**

Our lead targeted conditioning product candidate is Iomab-B, an ARC that is comprised of the anti-CD45 mAb known as apamistamab or BC8 and the radioisotope iodine-131. CD45 is expressed on leukemia, lymphoma and nucleated immune cells with an average of 200,000 copies per cell but with minimal expression outside of the hematopoietic system. Iomab-B is currently being studied in the pivotal Phase 3 SIERRA or Study of Iomab-B in Elderly Relapsed or Refractory AML clinical trial for targeted conditioning prior to a BMT for patients with active, relapsed or refractory (r/r) Acute Myeloid Leukemia or AML who are over age 55. The SIERRA trial will compare outcomes of patients randomized to receive Iomab-B and a BMT (the study arm) to those patients randomized to receive physician's choice of salvage chemotherapy (the control arm). Salvage chemotherapy is also defined as conventional care, as no standard of care exists for this patient population. Patients who fail to achieve a CR or Complete Response on the control arm are ineligible to proceed to a BMT but the trial design permits these patients to cross over to the

study arm if they meet the eligibility criteria. The primary endpoint of the SIERRA trial is dCR (durable Complete Remission) of 6 months and the secondary endpoint is 1-year Overall Survival (OS). The SIERRA trial is currently active at 18 sites in the U.S and Canada that includes many of the leading BMT sites based on volume.

Safety and feasibility data from the first 38 patients enrolled on the SIERRA trial which represents 25% of the total of 150 patients to be enrolled in the trial, was presented in an oral presentation at the American Society of Hematology (ASH) Annual Meeting in December 2018. It was reported that all patients initially randomized to the study arm that received a therapeutic dose of Iomab-B (18/18) received a BMT, with a median time to BMT of 28 days, and all patients achieved engraftment in a median time of 16 days despite a high median blast count of 30%. On the control arm, 4/19 patients received a BMT after receiving conventional care with a median time to BMT of 67 days and median blast count of 26%. Of the patients failing to achieve a CR with conventional care (15/19), 10 patients were eligible to cross over to the study arm. All cross over patients (10/10) received a BMT after receiving Iomab-B, with a median time to BMT of 66 days and all patients achieved engraftment in a median time of 17 days despite high median blast count of 45% at time of cross over. There was no (0/18) 100-day non-relapse mortality reported in the study arm, while 1 of 4 patients in the control arm and 1 of 10 cross over patients experienced 100-day non-relapse mortality.

Actimab-MDS is our second pivotal program for targeted conditioning. Actimab-MDS is an ARC comprised of the anti-CD33 mAb lintuzumab linked to the radioisotope Actinium-225. CD33 is expressed in a vast majority of patients with MDS. Actimab-MDS is informed by prior experience with our CD33 ARC in multiple trials for patients with AML, MDS and for patients that progressed from MDS to AML, which is also known as secondary AML. Data from these trials showed that our CD33 ARC had single-agent activity capable of producing CRs in certain patients at varying dose levels with minimal extramedullary toxicities. However, dose dependent myelosuppression was seen in many of these patients. Given this safety and efficacy profile, it was decided to pursue a trial in targeted conditioning in high-risk MDS patients with this ARC in combination with RIC or Reduced Intensity Conditioning regimens. RIC regimens are comprised of low doses of highly toxic chemotherapies such as fludarabine, cytarabine, busulfan and melphalan. Actimab-MDS is intended to enable targeted conditioning prior to a BMT in patients with MDS or Myelodysplastic Syndrome with poor or very poor cytogenetics, which is defined as having 3 or more chromosomal abnormalities. A bone marrow transplant is the only curative treatment option for these patients. However, these patients have poor outcomes due to high relapse rates following a BMT. We believe we have developed a pathway to a pivotal trial with input from the FDA that consists of a Phase 1 dose finding clinical trial that will be followed by a Phase 3 pivotal trial. We are currently finalizing the protocol and pathway for this trial with the FDA and expect to initiate the trial in 2019.

Our Iomab-ACT construct is a lower dose of Iomab-B (CD45 – I-131) that we are developing as a targeted conditioning or lymphodepletion agent prior to CAR-T and adoptive cell therapies. CD45 is an antigen expressed on many cells that are relevant to the mechanism of CAR-T therapies including lymphocytes, regulatory T cells and macrophages that have been associated with clinical responses that limit the safety and efficacy of these CAR-T therapies including CRS or Cytokine Release Syndrome, neurotoxicity and durability of response. Some of these limitations may be attributable to the chemotherapy based conditioning agents that are being used currently prior to CAR-T therapies. Actinium's Iomab-ACT program is highly differentiated when compared to Fludarabine and Cyclophosphamide or Flu/Cy or other chemotherapy-based regimens that are used as the standard of practice today for lymphodepletion prior to CAR-T. Unlike chemotherapy, Iomab-ACT is targeted in nature and due to this targeted effect, we expect can improve CAR-T cell expansion more efficiently, potentially resulting in responses that are more durable and also with reduced CAR-T related toxicities. Importantly, the Iomab-ACT program construct enables lymphodepletion through a single-dose, outpatient administration versus Flu/Cy or other chemo-based lymphodepletion regimens that can require multiple infusions in an inpatient setting over several days. Because of this potentially superior profile, the Iomab-ACT construct could result in improved access to CAR-T therapy and also better outcomes.

### **CD33 ARC Therapeutics and Combinations**

We are applying our CD33 targeting ARC product candidate lintuzumab-Ac-225 to multiple hematologic indications as CD33 is an antigen that has been found to be expressed in a vast majority of patients with AML and MDS and 25-35% of patients with Multiple Myeloma. Our CD33 development program is examining the construct at various dose levels and dosing regimens either alone or in combination in these various disease indications. We currently have multiple clinical trials ongoing, in startup phase, or in planning, to use our CD33 ARC in combination with other therapeutic modalities such as chemotherapy, targeted agents or immunotherapy. We believe that radiation can be synergistic when used in combination with these modalities based on our own clinical data, preclinical research and supporting scientific evidence in the literature. We are also studying our CD33 ARC as a monotherapy in the case of multiple myeloma. The construct has been designated as Actimab and we add a suffix to clarify the trial for the disease area and if needed the combination. For example, in AML, our recently concluded phase 2 trial as a single agent named Actimab-A (A for AML) and our ongoing trial in AML in combination with venetoclax is called the Actimab-A: Ven trial. Our CD33 ARC development program encompasses the following ongoing and planned trials:

#### **Combination Trials:**

Phase 1 Actimab-A: Ven combination trial with the BCL-2 inhibitor Venetoclax (Abbvie/Genentech) for patients with relapsed or refractory AML at the UCLA Medical center.

Phase 1 Actimab-A: CLAG-M combination trial with the salvage chemotherapy regimen CLAG-M (cladribine, -cytarabine, filgrastim and mitoxantrone) for patients with relapsed or refractory AML at the Medical College of Wisconsin.



Phase 1 Actimab-A: Ven+HMA Combination trial with the BCL-2 inhibitor Venetoclax (Abbvie/Genentech) and a -hypomethylating Agent (HMA) for patients with relapsed or refractory AML planned at the MD Anderson Cancer center.

**Therapeutic Trials:**

-Multi-center Phase 1 Actimab-M trial for patients with penta-refractory multiple myeloma.

Planned Phase 1 trial of Actimab-A: MRD for post-remission AML patients with positive MRD or Minimal Residual Disease.

**Antibody Warhead Enabling Technology Platform**

Our proprietary Antibody Warhead Enabling or AWE Technology Platform is supported by intellectual property, know-how and trade secrets that cover the generation, development, methods of use and manufacture of ARC or Antibody Radiation-Conjugates and certain of their components. Our AWE technology patent portfolio includes 27 patent families comprised of 110 issued and pending patent applications, of which 11 are issued and 18 pending in the United States, and 81 are issued and pending internationally the useful life of which ranges from 2019 to 2039. Our proprietary technology enables the direct labeling, or conjugation and labeling of a biomolecular targeting agent to a radionuclide warhead and its development and use as a therapeutic regimen for the treatment of diseases such as cancer. Our intellectual property covers ARC compositions of matter, formulations, methods of administration, and radionuclide production. Further, our AWE intellectual property covers various methods of use for ARCs in multiple diseases, including indication, dose and scheduling, radionuclide warhead, and therapeutic combinations. In addition, due to the renewed focus on research and technology development in 2017 and 2018, we expect the useful life of new intellectual property filed by the company, if granted, to extend well beyond the current dates in several key areas including for next-generation ARC's of approved therapeutics, combination treatments and targeted radiation approaches using the isotopes Ac-225, and I-131.

Our proprietary technology includes methods of conjugation, labeling and use of the radionuclides Ac-225 and I-131. Our technology covers the use of the “gold standard” chelator DOTA, (tetracarboxylic acid), an organic compound used to attach, or conjugate, the radionuclide Ac-225 to monoclonal antibodies and any conceivable derivative thereof. Additionally, we possess intellectual property protection, know-how and trade secrets covering efficient methods of chelation and labeling of the targeting agent with Ac-225 as well as newer next-generation methods of chelation or labeling. We are conducting preclinical research with our AWE Technology Platform to demonstrate proof of concept in liquid and solid tumors for various indications including targeted conditioning, lymphodepletion, combinations of ARC’s with other modalities and as monotherapies to enable research collaborations, partnerships and expand our development pipeline. In March 2018, we entered into a collaborative research agreement with Astellas Pharma, Inc. (Astellas) that is utilizing our AWE technology platform to create ARCs using the Ac-225 isotope and select targeting agents owned by Astellas. In January 2019, we initiated the second module of our research collaboration with Astellas.

Our research pipeline including ongoing and planned clinical trials are summarized below:

*Fred Hutchinson Cancer Research Center is currently studying the BC8 antibody in clinical trials. Trials at the Medical College of Wisconsin, UCLA Health and MD Anderson Cancer Center are investigator-initiated trials using our product candidates. We have entered into a collaborative research partnership with Astellas for the use of our AWE Technology Platform.*

## **Business Strategy**

We intend to develop our product candidates for targeted conditioning (Iomab-B and Actimab-MDS) and lymphodepletion (Iomab-ACT) through registration studies and approval either alone or in partnership. If our efforts are successful, we may elect to commercialize our targeted conditioning products on our own, or in partnership in the United States and out-license the rights to develop and commercialize these products to one or more strategic partners outside of the United States. If we elect to commercialize one or more of our targeted conditioning product candidates independently, we intend to scale up our existing supply chain capabilities, which currently supplies in excess of 18 BMT Centers and major hospitals across our pipeline, into a commercial distribution network that can supply the top 50-80 bone marrow transplant centers in the U.S., where a majority of patients are conditioned and receive their transplants. In the case of our CD33 program trials excluding the Actimab-MDS opportunity, we intend to potentially develop these up to proof-of-concept and then seek collaborators both inside and out of the U.S. We also have the option, assuming successful monetization of one or more targeted conditioning assets via commercialization or collaboration, of developing and commercializing all or certain parts of the CD33 program ourselves. We believe this is a viable strategy as it affords operating leverage from our supply chain and presence at the largest BMT centers

which also account for a significant portion of cancer treatments. In parallel, we intend to continue to identify development opportunities with our AWE Technology Platform and extend our leadership position in the use of the radioisotope Ac-225. Our efforts at further developing our platform center around arming additional targeting agents for various cancers and rare diseases, producing next generation ARC's of approved therapies, and exploring novel combination approaches that have the potential of replacing external beam radiation with ARC's that enable delivery of targeted radiation directly to desired site of action. We will continue to monetize our AWE platform via collaborations and partnerships as we have done with Astellas Inc. 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 believe that targeted conditioning prior to a BMT could result in improved access and outcomes for patients, as well as provide a pharmacoeconomic benefit. The Center for International Blood and Marrow Transplant Research (CIBMTR) estimates that more than 23,000 patients received an autologous or allogeneic BMT in the United States in 2018. The American Cancer Society estimates that approximately 174,250 patients will be diagnosed with leukemia, lymphoma or multiple myeloma and that approximately 1.34 million patients in the United States are living with or are in remission from these diseases. According to the European Bone Marrow Transplantation, over 35,000 autologous and allogeneic BMTs were performed in 2016. BMT is a potentially curative or potentially best treatment option for certain patients with these blood-borne cancers, blood disorders and inherited immune system disorders and we intend to develop our ARC product candidates with the goal of improving BMT access and outcomes for these patients. We believe that eliminating or reducing chemotherapy-based conditioning prior to BMT can significantly increase the number of patients receiving BMT and that targeted conditioning can result in less toxicities that could lead to better outcomes. According to a study published in the Journal of Medical Economics, real-world economic burden of hematopoietic cell transplantation among a large US commercially insured population with hematologic malignancies, the healthcare cost for patients receiving an autologous BMT were \$390,000 while the healthcare costs for patients receiving an allogeneic BMT were \$745,000. We believe that reduction in toxicities and resulting hospital stays associated with current chemotherapy-based conditioning regimens could reduce these costs. We intend to collect pharmacoeconomic data in our current and future clinical trials for Iomab-B and other targeted conditioning product candidates to determine if our therapies result in a cost benefit. Iomab-B has demonstrated efficacy in targeted conditioning prior to a BMT for blood cancer indications, including AML, MDS, Acute Lymphoblastic Leukemia (ALL), Hodgkin's Lymphoma, Non-Hodgkin's Lymphoma (NHL) and Multiple Myeloma. These are indications for which Iomab-B can be developed and it is our intention to explore these opportunities.

We are also developing our Iomab-ACT program, which uses a lower dose of Iomab-B, as a targeted conditioning or lymphodepletion agent prior to CAR-T and adoptive cell therapies. There are currently two approved CAR-T therapies and several dozen CAR-T and adoptive cell therapies in development for multiple hematologic and solid tumor indications. We intend for Iomab-ACT to be utilized as a lymphodepletion agent prior to CAR-T and adoptive cell therapy that can replace or displace the chemotherapy based lymphodepletion regimens that are used in standard practice today.

For our CD33 program drug candidates, we would compete in the marketplace for cancer treatments estimated to have reached 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 relatively newer 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. 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 the treatment of papillary and follicular thyroid cancer as well as other thyroid conditions. I -131 is used in combination with a monoclonal antibody in treatment of NHL and is used in the approved drug AZEDRA® (iobenguane I -131) for the treatment of certain neuroendocrine tumors. 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 particle emitting radioisotope for clinical applications using our proprietary AWE technology platform.

## **Clinical Trials**

### ***Targeted Conditioning***

We are focused on applying our ARC product candidates for targeted conditioning prior to cell therapies such as BMT and CAR-T to improve access and outcomes to these important and potentially curative treatments. A BMT may be the only potentially curative treatment option or the best treatment option for patients with blood cancers such as leukemias, lymphomas and multiple myeloma, benign blood or marrow disorders such as inherited immune system disorders, sickle cell disease and severe aplastic anemia. Conditioning is an integral step prior to BMT or an adoptive cell therapy such as CAR-T where the current standard practice is chemotherapy and/or total body irradiation via external radiation. In the case of BMT, conditioning is intended to eliminate a patient's bone marrow and immune system to allow transplanted bone marrow stem cells the ability to engraft and reconstitute the patient's blood counts and immune function. We are currently conducting two clinical trials for product candidates focused on targeted conditioning for BMT, a pivotal phase 3 trial for Iomab-B and our pivotal Actimab-MDS program, both of which are first in their class. In our Iomab-ACT program we are studying a lower dose of apamistamab – I-131 for targeted conditioning prior to CAR-T and cell therapy to enable lymphodepletion, which eliminates lymphocytes and other immune cells but spares bone marrow stem cells.

**Iomab-B Pivotal Phase 3 Program – SIERRA Trial**

We licensed Iomab-B from the Fred Hutchinson Cancer Research Center, or FHCRC, where it was developed and studied extensively in numerous clinical trials in a range of hematologic indications and patient populations. Iomab-B consists of the anti-CD45 monoclonal antibody apamistamab (BC8) and the beta emitting radioisotope Iodine-131 (I-131). Apamistamab has been studied in over 10 Phase 1 and Phase 2 clinical trials in patients with AML, MDS, ALL, multiple myeloma and lymphomas in patients with newly diagnosed, relapsed or refractory and first remission disease.

Previous Iomab-B clinical trials leading to our current pivotal Phase 3 trial included:

<b>Indications</b>	<b>N</b>	<b>Key Findings</b>
Advanced ALL, AML, MDS (age 16 – 55)	44	- 95% engraftment rate
Advanced AML/ALL (age 15 – 55)	21	– Median overall survival 2.8 years
AML 1st remission/1 <sup>st</sup> relapse (age 16-50)	46	– 100% engraftment rate – 63% 3-year overall survival
Relapsed/Refractory AML/High-risk MDS (age 50+)	68 in dose escalation study 31 treated at MTD	–100% engraftment rate –1-year survival ~40% for all patients
Relapsed/Refractory AML and High-risk MDS (age 18–50)	16	-94% engraftment rate - Median overall survival 4.4 years
Relapsed/Refractory lymphoma	15	– 100% engraftment rate – 18-month median overall survival
Relapsed/Refractory AML/Advanced ALL, HR MDS	25	- 100% engraftment rate - 42% 1-year overall survival
Multiple Myeloma	15	- 100% engraftment rate - 77% 2-year overall survival

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

Relapsed/Refractory AML and HR MDS	15	- 100% engraftment rate - 66% 1-year overall survival
High-risk lymphoma (with BEAM chemotherapy)	19	- 100% engraftment rate - 63% 1-year progression free survival
High-risk AML, ALL or MDS	Ongoing	

The indication selected for our pivotal phase 3 trial is bone marrow conditioning for patients with active, relapsed or refractory AML over the age of 55. We selected this indication because of the compelling data from the phase 2 proof of concept trial that showed improved survival after Iomab-B and a BMT compared to historical clinical outcomes when they received conventional care or salvage chemotherapy. In addition, the choice of this indication is also attractive due to a combination of factors including; the lack of available effective treatment options for this population of patients who have a very poor survival prognosis of 3.3 months and who are currently ineligible for a bone marrow transplant due to their poor condition and advanced state of disease.

### **Pivotal Phase 3 SIERRA Trial**

We are currently studying Iomab-B in the SIERRA or Study of Iomab-B in Elderly Relapsed or Refractory AML clinical trial, a 150-patient pivotal Phase 3 multi-center randomized trial that will compare outcomes of patients who receive Iomab-B and a BMT (the study arm) to those patients receiving physician's choice of salvage chemotherapy (the control arm). Salvage chemotherapy is defined as conventional care, as no standard of care exists for this patient population. Patients randomized to receive the control arm who do not achieve a Complete Remission (CR) are able to cross over to the study arm and receive Iomab-B and a BMT if they meet certain eligibility criteria. Patients with active, relapsed or refractory AML have dismal prognoses and are typically not offered potentially curative transplant as an option, largely because salvage treatments have a limited ability to produce a complete remission, which is necessary prior to conventional BMT if conventional BMT is to be successful. The SIERRA trial is the only pivotal trial offering BMT as an option to patients with active, relapsed or refractory Acute Myeloid Leukemia age 55 and above. The primary endpoint of the SIERRA trial is dCR or durable Complete Remission of 6 months and the secondary endpoint is 1-year Overall Survival (OS). The SIERRA trial is currently enrolling patients at 18 sites in the U.S and Canada that includes many of the leading BMT sites based on volume.

Safety and feasibility data from the first 38 patients (25% of planned enrollment) in the SIERRA trial were presented in an oral presentation at the 61<sup>st</sup> American Society of Hematology (ASH) Annual Meeting & Exposition and in a late breaking oral session at the 2019 Transplantation & Cellular Therapy Meetings™ of ASBMT and CIBMTR (TCT Meetings). It was reported that all patients receiving a therapeutic dose of Iomab-B engrafted despite active disease with high blast counts with median blast counts of 30% for patients randomized to the Iomab-B arm and a median of 45% for patients that crossed over to receive Iomab-B. 15 of 19 (79%) patients in the control arm failed to achieve a complete response and 67% (10/15) of these patients were eligible for crossover with all (10/10) being successfully transplanted after treatment with Iomab-B. Patients receiving Iomab-B received a BMT more quickly post-randomization (28 days) than patients receiving conventional care (67 days) and in the conventional care arm, there was no difference in time to BMT for patients that crossed over to Iomab-B (66 days) compared to those achieving complete remission with conventional care (67 days). No Grade 3 or 4 Iomab-B infusion related reactions with all Iomab-B infusions completed and there was no 100-Day non-relapse mortality in patients randomized to Iomab-B arm. Approximately 94% of patients initially randomized to receive Iomab-B and a BMT (17/18) achieved Full Donor Chimerism and 90% of patients who crossed-over to receive Iomab-B and a BMT (9/10), after salvage chemotherapy in the control arm failed to produce a CR or Complete Response, also achieved Full Donor Chimerism prior to day 100. Additional safety and feasibility analyses will occur when 76 (50%) and 114 (75%) of patients have been enrolled.



## **Actimab-MDS Program**

Our Actimab-MDS pivotal program is studying our CD33 ARC that consists of the anti-CD33 mAb lintuzumab conjugated with the radioisotope Ac-225, which has been studied in multiple Phase 1 and Phase 2 clinical trials in patients with AML and MDS. In 2018, we completed the Phase 2 Actimab-A clinical trial of our CD33 ARC in patients newly diagnosed with AML age 60 and above ineligible for standard induction therapy. Each patient in a dose cohort received fractionated doses a week apart. Single agent activity was reported with an Overall Response Rate or ORR of 69% for patients receiving 2.0  $\mu\text{Ci}/\text{kg}/\text{fraction}$  and 22% in patients receiving 1.5  $\mu\text{Ci}/\text{kg}/\text{fraction}$ . Minimal extramedullary toxicities were observed; however, myelosuppression was a Dose Limiting Toxicity (DLT) that was observed at both dose cohorts. The Actimab-MDS pivotal program is designed to leverage the observed myelosuppression capabilities and minimal extramedullary toxicities of our CD33 ARC as a targeted conditioning agent prior to a BMT in MDS patients with poor or very poor cytogenetics, which is defined as having 3 or more chromosomal mutations. In this patient population, BMT is the only treatment option with curative potential and a BMT also has the ability to reverse myelosuppression as transplanted cells can reconstitute the patient's blood and immune function.

We met with the FDA to discuss our Actimab-MDS program and based on these discussions we will conduct a Phase 1 dose confirming study that will be followed by a pivotal, randomized registration trial. The Phase 1 trial will enroll 7-18 patients where patients will receive 2.0 – 4.0  $\mu\text{Ci}/\text{kg}$  of lintuzumab – Ac-225 in a single infusion. The pivotal, randomized registration trial will study our CD33 ARC in combination with RIC or Reduced Intensity Conditioning regimens prior to bone marrow transplant. RIC regimens are comprised of low doses of highly toxic chemotherapies such as fludarabine, cytarabine, busulfan and melphalan.

### **Iomab-ACT Program**

Our Iomab-ACT program uses a lower dose of Iomab-B (CD45 – I-131) that we are developing as a targeted conditioning agent for lymphodepletion prior to CAR-T and adoptive cell therapies. Currently, lymphodepletion for CAR-T and adoptive cell therapies utilizes Fludarabine and Cyclophosphamide or Flu/Cy and other chemotherapies. The dose range for the Iomab-ACT program is supported by clinical data with Iomab-B, pharmacokinetic modeling and preclinical data supporting its effectiveness at selective targeting of cells necessary to achieve effective lymphodepletion. In February 2019, we presented data from our preclinical findings at the 2019 Transplantation & Cellular Therapy Meetings™ of ASBMT and CIBMTR (TCT Meetings) that showed that a single infusion of an anti-CD45 antibody labelled with Iodine-131 can effectively deplete greater than 90% of lymphocytes, including CD4 and CD8 T cells, CD19 B cells and NK cells, which is necessary for adoptive cell therapies like CAR-T to expand and persist. Tregs or regulatory T cells, including CD4+, CD25+ and FoxP3+ Tregs, which can exert negative pressure on cell therapy expansion and persistence, were suppressed for at least 21 days post lymphodepletion with Iomab-ACT. The multi-modal mechanism of action directed at CD45 expressing cells also depleted macrophages, which are implicated in the development of CRS or Cytokine Release Syndrome, and splenocytes while red blood cells, platelets, neutrophils and bone marrow stem cells were preserved. Additionally, MicroSPECT/CT imaging showed that Iomab-ACT homed to immune privileged sites including lymph nodes, spleen, liver and bone marrow. Finally, an in vivo animal model showed that adoptively transferred cytotoxic T cells persisted in mice following administration of CD45 targeted lymphodepletion and were able to control tumor cells compared to untreated mice. We intend to study our Iomab-ACT program in a human clinical trial in 2019. We are currently speaking with potential investigators and collaborators from academia and industry and evaluating possible clinical trial protocols.

### **CD33 ARC Therapeutics and Combinations**

We are developing our ARC product candidate that consists of the anti-CD33 mAb lintuzumab and the radioisotope Ac-225 for multiple hematologic malignancies including AML, MDS and Multiple Myeloma. The CD33 development program is examining the construct at various dose levels and dosing regimens either alone or in combination in these various disease indications. Our CD33 ARC is a second-generation construct that was developed at the Memorial Sloan Kettering Cancer Center, or MSKCC. The first-generation product consisted of the same monoclonal antibody lintuzumab but utilized the radioisotope bismuth-213 or Bi-213. In preclinical and Phase 1 clinical studies lintuzumab-Ac-225 has demonstrated at least 500-1000 times higher potency than the first-generation predecessor lintuzumab-Bi-21 upon which it is based. This difference is due to intrinsic physicochemical properties of

lintuzumab-Ac-225 that were first established in vitro, in which lintuzumab-Ac-225 killed multiple cell lines at doses at least 1,000 times lower based on LD50 values than lintuzumab-Bi-213 analogs. Key factors in lintuzumab-Ac-225's higher potency is the yield of 4 alpha-emitting isotopes per Ac-225 compared to 1 alpha decay for bismuth 213 and much longer half-life of 10 days for Ac-225 vs 46 minutes for Bi-213.

We currently have multiple clinical trials ongoing, in startup phase, or in planning, to use our CD33 ARC in combination with other therapeutic modalities such as chemotherapy, targeted agents or immunotherapy. We believe that radiation can be synergistic when used in combination with these modalities based on our own clinical data, preclinical research and supporting scientific evidence in the literature. We are also studying our CD33 ARC as a monotherapy in the case of multiple myeloma. The construct has been designated as Actimab and we add a suffix to clarify the trial for the disease area and if needed the combination. For example, in AML, our recently concluded phase 2 trial as a single agent named Actimab-A (A for AML) and our ongoing trial in AML in combination with venetoclax is called the Actimab-A: Ven trial. Our CD33 ARC development program encompasses the following ongoing and planned trials.

7

**Combination Trials:**

**Phase 1 Actimab-A combination trial with the BCL-2 inhibitor Venetoclax for patients with relapsed or refractory AML**

We have initiated a Phase 1 investigator initiated clinical trial at the UCLA Medical Center that will study our CD33 ARC in combination with Venetoclax (VEN), a BCL-2 inhibitor that is jointly developed and marketed by Abbvie and Genentech. Venetoclax is approved for patients with CLL or Chronic Lymphocytic Leukemia and SLL or Small Lymphocytic Leukemia as well as patients newly diagnosed with AML who are 75 and older who are ineligible for standard chemotherapy in combination with a hypomethylating agent or low-dose cytarabine. BCL-2 is one of several proteins encoded by the BCL2 gene family, which regulates apoptosis or programmed cell death. MCL-1 is another protein encoded by the BCL2 gene family that is also overexpressed in cancers, including relapsed or refractory AML, that prevents apoptosis and promotes resistance to venetoclax, which does not bind to MCL-1. It has been demonstrated that MCL-1 levels can be depleted with radiation but only external radiation was used in these studies. In our preclinical studies, it was demonstrated that our CD33 ARC combined with venetoclax resulted in increased cancer cell death than either agent alone. Our Actimab-A: VEN trial will study our CD33 ARC in combination with Venetoclax alone and will be a 3+3 dose-escalation study that is intended to determine the MTD or maximum tolerable dose of our CD33 ARC, determine ORR and evaluate OS.

**Phase 1 Actimab-A combination trial with salvage chemotherapy regimen CLAG-M (cladribine, cytarabine, filgrastim and mitoxantrone) for patients with relapsed or refractory AML**

We are conducting a Phase 1 investigator initiated clinical trial at the Medical College of Wisconsin that is studying our CD33 ARC in combination with the CLAG-M salvage chemotherapy regimen in patients with relapsed or refractory AML. Our Actimab-A: CLAG-M trial is a 3+3 design, dose escalation study evaluating safety and tolerability, response rates, rates of BMT, PFS or progression-free survival and OS. Dosing began at 0.25 uCi/kg and in February 2019, we announced that we successfully completed the first patient cohort and that no dose limiting toxicities (DLTs) were observed. We have initiated the second patient cohort in which patients will receive 0.50 uCi/kg of Actimab-A. Assuming no DLTs are observed in the second cohort, the study will progress to the third and final cohort where patients will receive a dose of 0.75 uCi/kg.

**Phase 1 Actimab-A Combination trial with BCL-2 inhibitor Venetoclax and a Hypomethylating Agent for patients with relapsed or refractory AML**

We intend to initiate a Phase 1 investigator-initiated trial at the University of Texas MD Anderson Cancer Center that will study our CD33 ARC in combination with Venetoclax and a hypomethylating agent for patients with relapsed or refractory AML. Venetoclax is approved for patients newly diagnosed with AML who are 75 and older who are ineligible for standard chemotherapy in combination with a hypomethylating agent or low-dose cytarabine. Similar to our combination trial with Venetoclax alone, this Actimab-A: VEN+HMA trial will study the potential for our CD33 ARC to reduce MCL-1 levels thereby removing a potential resistance mechanism to Venetoclax making the AML cells susceptible to apoptosis or programmed cell death. This trial will be a 3+3 design, dose-escalation study that is intended to determine the MTD or maximum tolerable dose of our CD33 ARC, determine ORR and evaluate OS.

### **Therapeutic Trials:**

#### **Multi-center Phase 1 Actimab-M trial for patients with penta refractory multiple myeloma**

CD33 expression has been identified in 25-35% of patients with multiple myeloma. Like other hematologic malignances, multiple myeloma is sensitive to radiation. Therefore, we are studying our CD33 ARC in patients with penta refractory multiple myeloma in the multi-center Phase 1 Actimab-M open label, dose escalation trial which is a 3+3 design, dose-escalation study. This trial was initiated as an investigator sponsored study at one site but the was subsequently brought in house and is now being pursued under company IND as a multi-center trial. Per the protocol, patients are administered a starting dose level of 0.5  $\mu\text{Ci}/\text{Kg}$  via infusion on day 1 of each cycle for up to 8 cycles with each cycle lasting 42 days. Assuming safety at this dose level, escalation to a second dose level of 1.0  $\mu\text{Ci}/\text{kg}$  for up to 4 cycles, also of 42 days per cycle is planned. The total dose received per patient is not to exceed 4.0  $\mu\text{Ci}/\text{kg}$ . In the event of dose limiting toxicities (DLTs) at the 0.5  $\mu\text{Ci}/\text{Kg}$  dose level, a dose level of 0.25  $\mu\text{Ci}/\text{Kg}$  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). To our knowledge, we are the only company developing a CD33 targeting agent for patients with multiple myeloma and the only company studying an alpha-particle (Actinium-225) radioisotope in this indication.

### **Phase 1 trial of Actimab-A for post-remission AML patients with positive MRD or Minimal Residual Disease**

We are planning a Phase 1 clinical trial that will study our CD33 ARC in patients with AML that have achieved remission but have detectable MRD. Patients with detectable MRD after achieving remission with induction therapy have a higher probability of relapse and therefore poorer long-term outcomes. Consolidation therapy often follows induction therapy that today consists of chemotherapy, HMAs, targeted agents, BMT or supportive care. However, following induction therapy patients may be ineligible or unable to tolerate these therapies. This planned Actimab-A: MRD trial will be a 3+3 design, dose escalation study where patients will receive a single infusion of a low dose (0.5 – 1.0  $\mu\text{Ci/Kg}$ ) of our CD33 ARC for up to 4 cycles with patients being assessed for MRD status on day  $29 \pm 7$  days. This study will evaluate safety and tolerability and establish MTD as well as assess effect on MRD, PFS and OS. The goal of our efforts in patients with detectable MRD is to use our CD33 ARC to prevent relapse and put the patient's disease in a manageable chronic state with a chemotherapy free treatment that is well tolerated with minimal extramedullary toxicities.

### **Antibody Warhead Enabling Technology Platform and Program**

Our proprietary Antibody Warhead Enabling or AWE Technology Platform is supported by intellectual property, know-how and trade secrets that cover the generation, development, methods of use and manufacture of ARC or Antibody Radiation-Conjugates and certain of their components. As of March 2019, we have 27 patent families comprising 110 issued and pending patent applications, of which 11 are issued and 18 are pending in the United States that are related to our AWE Technology Platform in the U.S. having expirations between 2019 and 2039 and 81 issued or pending patents outside of the U.S. Our proprietary technology enables the direct labeling, or conjugation and labeling of a biomolecular targeting agent to a radionuclide warhead and its development and use as a therapeutic regimen for the treatment of diseases such as cancer. Our intellectual property covers ARC compositions of matter, formulations, methods of administration, and radionuclide production. Further, our AWE intellectual property covers various methods of use for ARCs in multiple diseases, including indication, dose and scheduling, radionuclide warhead, and therapeutic combinations. In addition, due to the renewed focus on research and technology development in 2017 and 2018, we expect the useful life of new intellectual property filed by the company, if granted, to extend well beyond the current dates in several key areas including for next generation ARCs, combination treatments and targeted radiation approaches using the isotopes Ac-225 and I-131.

In March 2017, we announced the availability of our proprietary AWE Technology Platform for partnerships and collaborations. In tandem, we demonstrated the utility of the AWE Technology Platform intellectual property, know-how and trade secrets to generate a next generation ARC of an approved therapeutic molecule by generating preclinical results showing the dramatic enhancement in anti-tumor potency following the conjugation and labeling of a therapeutic antibody, daratumumab, with Ac-225. Daratumumab is an anti-CD38 antibody which is marketed by Johnson & Johnson (JNJ) under the trade name Darzalex<sup>®</sup> for the treatment of multiple myeloma. We successfully demonstrated the efficient labeling daratumumab with Ac-225 without compromising CD38 target engagement and antibody effector function. Furthermore, pre-clinical testing of the Ac-225-daratumumab asset in an *in vivo* xenograft

tumor model was also performed. Specifically, Ac-225-daratumumab was well tolerated in mice and was shown to increase the *in vivo* potency over naked daratumumab by at least 30-fold and led to a survival advantage in this model.

We applied our AWE Technology Platform to the development of our Iomab-ACT program. The patent estate related to our Iomab-ACT program covers composition of matter, formulation and methods of use. Actinium believes this patent estate is important to potential partners in industry and academia as it may enable the optimization of CAR-Ts through improved lymphodepletion, which may not be possible with Flu/Cy given patents that exist on its use in conjunction with CAR-T. In addition, the patent estate is broad and is applicable to indications where CAR-Ts have already been approved and to emerging indications that the growing field of CAR-T developers are pursuing such as solid tumors. Key filings of the estate cover claims including composition and methods of use in targeted lymphodepletion prior to adoptive cell therapies such as CAR-T with autologous and allogeneic cell therapy in solid or hematologic cancer indications. The filings also include methods of use for targeted lymphodepletion in combination with genetically engineered CAR cells, including those that lack expression of endogenous checkpoint receptors or T cell receptors and targeted conditioning in preparation for administration of gene edited cell therapy for the treatment of non-malignant inherited genetic disorders.

We have led and successfully demonstrated the adaptability and robust labeling that can be achieved with the AWE Technology Platform. AWE-derived ARCs provide versatility in use as demonstrated by the applicability as anti-cancer therapies as single agents or in combination, but also as modalities for targeted conditioning prior to cell therapies such as bone marrow transplant or adoptive cell therapies. Moreover, the AWE Program provides a potential partner with access to the technology, the know-how, and the capabilities and facilities to execute on ARC generation and development. The studies with daratumumab-Ac-225 provides one example of the enhanced therapeutic effect that can be achieved from the utilization of our core platform technology to potently radiolabel an asset with a radionuclide warhead, positioning the generation of ARCs as a viable therapeutic approach. Iomab-ACT demonstrates how our AWE Technology Platform can be applied to create ARCs for specific indications and applications as we were able to use our apamistamab-I-131 construct and develop a lower dose version when compared to Iomab-B that is intended to be used for lymphodepletion as opposed to myeloablation.

In March 2018, we entered into a collaborative research partnership with Astellas Pharma, Inc. (Astellas) to utilize our AWE Technology Platform with selected targeting agents owned by Astellas. Under the agreement, we are conducting preclinical validation studies. In exchange, we received an upfront fee and Astellas provides funding for the ongoing preclinical research. In January 2019, we announced that we successfully completed the first module of and that we initiated the second module of the collaboration.

We intend to utilize our AWE technology platform to enable future additional collaborations and partnerships. In addition to our CSO, we have 3 PhD level employees that contribute to our efforts related to AWE in addition to an external VP of R&D and post-doctoral associate. We also utilize a network of external R&D facilities and personnel that perform work on our behalf.

## **Operations**



Our current operations are primarily focused on furthering the development of our clinical drug candidates for targeted conditioning, our CD33 program combination and monotherapy trials, supporting investigator-initiated clinical trials that use our drug candidates, actively managing our current supply chain, supporting collaborations and further developing our AWE platform and supporting our pre-commercial market development and supply chain activities.

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 includes investigator engagement, site activation and supporting patient enrollment. In addition, we are focused on commercial-scale manufacturing of apamistamab suitable for an approval trial and preparation of appropriate regulatory submissions. We are also focused on producing final Iomab-B drug product material that consists of apamistamab labelled with the isotope I-131. We have secured access to I-131 from multiple commercial global suppliers. We project that these suppliers have sufficient I-131 production capacity to meet our commercial needs for the Iomab-B program. We are aware of other global manufacturers and suppliers of I-131 with whom we believe we can secure commercial supply agreement if necessary. Operations related to our Actimab-MDS pivotal program include preparation for appropriate regulatory submissions, protocol development and investigator engagement. For our Iomab-ACT program we are producing preclinical data supporting its use as a targeted conditioning agent to enable lymphodepletion prior to CAR-T and other adoptive cell therapies, evaluation potential clinical trials and related protocols and developing a regulatory strategy for our planned clinical development.

In the case of our CD33 program, key ongoing activities include planning, initiating and progressing our Phase 1 trials including our two combination trials with venetoclax, our combination trial with CLAG-M, Actimab-M trial in for patients with multiple myeloma and our MRD trial, managing isotope and other materials supply chain and managing the manufacturing of the finished drug candidate product. We have secured access to Ac-225 through a renewable contractual arrangement with the United States Department of Energy, or DOE. We project that these quantities are sufficient to support early stages of commercialization of actinium isotope-based products and that the DOE's accelerator route of production of Ac-225 has the potential to provide commercial quantities of Ac-225. We have also developed our own proprietary process for industrial-scale Ac-225 production in a cyclotron in quantities adequate to support full product commercialization. In addition, we are aware of numerous sources from which we may secure additional quantities of the Ac-225 isotope.

In addition to our clinical programs, we are conducting research and development with our AWE Technology Platform to support existing clinical programs and develop new clinical opportunities. We are also executing on our collaborative research partnership with Astellas. Related to our supply chain, we are undertaking planning and evaluation activities to support our future needs related to infrastructure, commercialization or clinical trial site expansion. Activities related to market development are ongoing and include physician engagement and education, referral pattern analysis, site evaluation and patient advocacy engagement.

## **Intellectual Property Portfolio and Regulatory Protections**

### ***Intellectual Property***

We have developed or in-licensed numerous patents and patent applications and possess substantial know-how and trade secrets related to the development and manufacture of our products. As of March 2019, our patent portfolio includes: 28 patent families comprised of 111 issued and pending patent applications, of which 12 are issued and 18 are pending in the United States, and 81 are issued and pending internationally. Several non-provisional patent applications are expected to be filed in 2019 based on provisional patent applications filed in 2018. This is part of an ongoing strategy to strengthen our intellectual property position. About one fifth of our patents are in-licensed from third parties and the remainder are Actinium-owned. These patents cover key areas of our business, including use of actinium-225 and other alpha- or beta-emitting isotopes attached to cancer specific carriers like monoclonal antibodies, methods for manufacturing key components of our product candidates including actinium-225, an alpha particle emitting radioisotope and carrier antibodies, or Iodine-131, a beta particle emitting radioisotope, and methods for manufacturing finished product candidates for use in cancer treatment.

We own five issued patents including one divisional patent in the United States and 47 patents outside of the United States, including one divisional patent related to the manufacturing of actinium-225 in a cyclotron, that will expire between 2024 – 2030. Four related global patents are pending. We own or have licensed the rights to six issued patents

in the United States and 14 issued patents outside of the United States related to the generation of radioimmunoconjugates that will expire between 2019 and 2030. Nine related United States or global patents are pending. Further, we own the rights to 20 additional pending patents in the United States and abroad related to radioimmunoconjugate composition, formulation administration, and methods of use in solid or liquid cancers. This matter includes composition, administration, and methods of treatment for our products Actimab-A and Iomab-B. In addition, for Iomab-ACT, we own 4 patents pending and 1 provisional patent application covering methods of use and composition in cancer and non-malignant disease.

### ***Regulatory Protections***

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

## Competition Overview

In the field of targeted conditioning, pharmaceuticals currently used for myeloablation prior to a bone marrow transplant or lymphodepletion prior to CAR-T are largely generic chemotherapeutic agents and/or radiation. In targeted conditioning, we face competition from Magenta Therapeutics, Inc., who is developing an anti-CD45 and anti-117 Antibody Drug Conjugate (ADC) and Allogene Therapeutics who is developing an anti-CD52 monoclonal antibody. However, both programs are at the preclinical stage. To our knowledge, we are the only company with a pivotal Phase 3 trial for a targeting conditioning agent and the only anti-CD45 ARC in clinical development.

For our CD33 ARC, there are several companies developing drugs for AML, MDS and Multiple Myeloma based on numerous approaches/modalities including chemotherapy, targeted agents, antibody drug conjugates naked monoclonal antibodies, bispecific antibodies, immunotherapies and cellular therapies. Specific to CD33, Mylotarg™, an ADC developed and marketed by Pfizer is the only FDA approved CD33 targeted therapy for adult patients and children two years and older with relapsed or refractory CD33-positive AML. Seattle Genetics was developing SGN-CD33A, a CD33 targeting ADC, but discontinued the development of its clinical trials associated with this product candidate in June 2017. Immunogen is also developing a CD33 targeting ADC, IMGN779, that is currently in a Phase 1 clinical trial for r/r AML patients age 18 and above. Amgen is developing a CD3/CD33 bispecific BiTE (AMG330) as is Amphivena (AMV-564), both of which are in Phase 1 clinical trial for r/r AML patients age 18 and above. Boehringer Ingelheim is developing a CD33 targeting naked antibody (BI836858) for patients with r/r AML or MDS age 18 and above. These drugs have different safety profiles and mechanisms of action compared to our drug candidates. AML in older patients remains an area of high medical need that could accommodate many new products with favorable safety and efficiency profiles. We have begun studying our CD33 ARC in combination with the salvage chemotherapy regimen CLAG-M for patients with relapsed or refractory AML. Combination therapies are commonly used in hematologic indications, but we believe we are the only Ac-225 based product candidate that is being explored in combination studies in hematologic indications. To our knowledge, we are the only company with a CD33 targeting drug and the only AC-225 based ARC product candidate for patients with multiple myeloma.

## 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, 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, 2019, we have 30 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 above in “Management’s Discussion and Analysis of Financial Condition and Results of Operations” and elsewhere throughout this Annual Report on Form 10-K. Each of the following risk factors, either alone or taken together, could adversely affect our business, operating results and financial condition, as well as adversely affect the value of an investment in our company. The risks and uncertainties described below are not the only ones we face. Additional risks not currently known to us or other factors not perceived by us to present significant risks to our business at this time also may impair our business operations.*

### Risks Related to Our Business

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

Our recurring losses from operations and negative cash flows from operations raise substantial doubt about our ability to continue as a going concern and as a result, our independent registered public accounting firm included an explanatory paragraph in its report on our consolidated financial statements for the year ended December 31, 2018 with respect to this uncertainty. Substantial doubt about our ability to continue as a going concern may create negative reactions to the price of the common shares of our stock and we may have a more difficult time obtaining financing.

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

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

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

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

We are not profitable and have incurred losses in each period since our inception. As of December 31, 2018, we had an accumulated deficit of \$186.9 million. For the years ended December 31, 2018 and 2017, we reported a net loss of \$23.7 million and \$26.6 million, respectively. We expect to continue to operate at a net loss as we continue our research and development efforts, continue to conduct clinical trials and develop manufacturing, sales, marketing and distribution capabilities. There can be no assurance that the products under development by us will be approved for sale in the United States or elsewhere. Furthermore, there can be no assurance that if such products are approved they will be successfully commercialized, which would have an adverse effect on our business prospects, financial condition and results of operation.

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

We do not currently have sufficient funding for the completion of development nor commercialization of our product candidates and we will need to continue to seek capital from time to time to continue development of our product candidates and to acquire and develop other product candidates. Our first product candidate is not expected to be commercialized, if approved, until at least 2020 and any partnering revenues that it may generate may not be sufficient to fund our ongoing operations. Our cash balance as of December 31, 2018 was \$13.7 million. During the year ended December 31, 2018, we raised total net proceeds of approximately \$17.0 million from the sale of our common stock and warrants.

Presently, with no further source of capital either via a financing or a collaboration, we project that we may run out of funds in 2019. We currently do not have any additional source of capital secured. If we are unable to raise additional funds, we could be required to reduce our spending plans, reduce our workforce, license one or more of our products or technologies that we would otherwise seek to commercialize ourselves, sell all or some of our assets, cease operations or even declare bankruptcy. We will require additional cash in order to maximize the commercial opportunity and continue clinical development of our product candidates. Alternatives available to us to sustain our operations include collaborative agreements, equity financing, debt and other financing arrangements with potential

corporate partners and other sources. However, there can be no assurance that any such collaborative agreements or other sources of funding will be available to us on favorable terms, if at all.



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

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

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

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

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

We have limited access to the capital markets to raise funds. The capital markets have been unpredictable in the recent past for radioisotope and other oncology companies and unprofitable companies such as ours. In addition, it is generally difficult for development-stage companies to raise capital under current market conditions. The amount of capital that a company such as ours is able to raise often depends on variables that are beyond our control. As a result,

we may not be able to secure financing on terms attractive to us, or at all. If we are able to consummate a financing arrangement, the amount raised may not be sufficient to meet our future needs. If adequate funds are not available on acceptable terms, or at all, our business, including our technology licenses, results of operations, financial condition and our continued viability will be materially adversely affected.

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

Iomab-B, which we licensed from the Fred Hutchinson Cancer Research Center, in June 2012 is our lead program to which we allocate a significant portion of our resources. We are currently enrolling patients in the pivotal Phase 3 SIERRA trial (Study of Iomab-B in Elderly Relapsed or Refractory AML), a 150-patient multi-center randomized trial that will compare outcomes of patients who receive Iomab-B and a BMT to those patients receiving physician's choice of salvage chemotherapy, defined as conventional care, as no standard of care exists for this patient population. The SIERRA trial may be unsuccessful and fail to demonstrate a safety and efficacy profile that is necessary to receive favorable regulatory approval. The trial's DMC or Data Monitoring Committee may recommend that the trial be stopped early for safety or efficacy concerns, which could prevent us from completing the SIERRA trial. Even if Iomab-B receives favorable regulatory approval, we may not be successful in securing adequate reimbursement or establishing successful commercial operations. Any or all of these factors could have a material adverse impact on our business and ability to continue operations.

*We may be unable to establish sales, marketing and commercial supply capabilities*

We do not currently have, nor have we ever had, commercial sales and marketing capabilities. If any of our product candidates become approved, we would have to build and establish these capabilities in order to commercialize our approved product candidates. The process of establishing commercial capabilities will be expensive and time consuming. Even if we are successful in building sales and marketing capabilities, we may not be successful in commercializing any of our product candidates. Any delays in commercialization or failure to successfully commercialize any product candidate may have material adverse impacts on our business and ability to continue operations.

**Risks Related to Regulation**

*The FDA or comparable foreign regulatory authorities may disagree with our regulatory plans and we may fail to obtain regulatory approval of our product candidates.*

Our products are subject to rigorous regulation by the FDA and numerous other federal, state and foreign governmental authorities. The process of seeking regulatory approval to market an antibody radiation-conjugate product is expensive and time-consuming, and, notwithstanding the effort and expense incurred, approval is never guaranteed. If we are not successful in obtaining timely approval of our products from the FDA, we may never be able to generate significant revenue and may be forced to cease operations. In particular, the FDA permits commercial distribution of a new antibody radiation-conjugate product only after a Biologics License Application (BLA) for the product has received FDA approval. The BLA process is costly, lengthy and inherently uncertain. Any BLA filed by us will have to be supported by extensive data, including, but not limited to, technical, preclinical, clinical trial, manufacturing and labeling data, to demonstrate to the FDA's satisfaction the safety and efficacy of the product for its intended use. The lengthy approval process as well as the unpredictability of future clinical trial results may result in our failing to obtain regulatory approval to market our product candidates, which would significantly harm our business, results of operations and prospects. In addition, even if we were to obtain approval, regulatory authorities may approve any of our product candidates for fewer or more limited indications than we request, may not approve the price we intend to charge for our products, may grant approval contingent on the performance of costly post-marketing clinical trials, or may approve a product candidate with a label that does not include the labeling claims necessary or desirable for the successful commercialization of that product candidate. Any of the foregoing scenarios could materially harm the commercial prospects for our product candidates.

The approval process in the United States and in other countries could result in unexpected and significant costs for us and consume management's time and other resources. The FDA and other foreign regulatory agencies could ask us to supplement our submissions, collect non-clinical data, conduct additional clinical trials or engage in other time-consuming actions, or it could simply deny our applications. In addition, even if we obtain approval to market

our products in the United States or in other countries, the approval could be revoked, or other restrictions imposed if post-market data demonstrates safety issues or lack of effectiveness. We cannot predict with certainty how, or when, the FDA or other regulatory authorities will act. If we are unable to obtain the necessary regulatory approvals, our financial condition and cash flow may be materially adversely affected, and our ability to grow domestically and internationally may be limited. Additionally, even if we obtain approval, regulatory authorities may approve any of our product candidates for fewer or more limited indications that we request. The Company's products may not be approved for the specific indications that are most necessary or desirable for successful commercialization or profitability.

***We have not demonstrated that any of our products are safe and effective for any indication.***

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

*We may encounter substantial delays in our clinical trials or may not be able to conduct our trials on the timelines we expect.*

We cannot predict whether we will encounter problems with any of our ongoing or planned clinical trials that will cause us or regulatory authorities to delay, suspend, or discontinue clinical trials or to delay the analysis of data from ongoing clinical trials. Any of the following could delay or disrupt the clinical development of our product candidates and potentially cause our product candidates to fail to receive regulatory approval:

conditions imposed on us by the FDA or comparable foreign authorities regarding the scope or design of our clinical trials;

delays in receiving, or the inability to obtain, required approvals from institutional review boards (IRBs) or other reviewing entities at clinical sites selected for participation in our clinical trials;

delays in enrolling patients into clinical trials;

a lower than anticipated retention rate of patients in clinical trials;

the need to repeat or discontinue clinical trials as a result of inconclusive or negative results or unforeseen complications in testing or because the results of later trials may not confirm positive results from earlier preclinical studies or clinical trials;

inadequate supply, delays in distribution, deficient quality of, or inability to purchase or manufacture drug product, comparator drugs or other materials necessary to conduct our clinical trials;

unfavorable FDA or other foreign regulatory inspection and review of a clinical trial site or records of any clinical or preclinical investigation;

serious and unexpected drug-related side effects experienced by participants in our clinical trials, which may occur even if they were not observed in earlier trials or only observed in a limited number of participants;

a finding that the trial participants are being exposed to unacceptable health risks;

the placement by the FDA or a foreign regulatory authority of a clinical hold on a trial; or

delays in obtaining regulatory agency authorization for the conduct of our clinical trials.

We may suspend, or the FDA or other applicable regulatory authorities may require us to suspend, clinical trials of a product candidate at any time if we or they believe the patients participating in such clinical trials, or in independent third-party clinical trials for drugs based on similar technologies, are being exposed to unacceptable health risks or for other reasons.

Further, individuals involved with our clinical trials may serve as consultants to us from time to time and receive stock options or cash compensation in connection with such services. If these relationships and any related compensation to the clinical investigator carrying out the study result in perceived or actual conflicts of interest, or the FDA concludes that the financial relationship may have affected interpretation of the study, the integrity of the data generated at the applicable clinical trial site may be questioned and the utility of the clinical trial itself may be jeopardized. The delay, suspension or discontinuation of any of our clinical trials, or a delay in the analysis of clinical data for our product candidates, for any of the foregoing reasons, could adversely affect our efforts to obtain regulatory approval for and to commercialize our product candidates, increase our operating expenses and have a material adverse effect on our financial results.

Clinical trials may also be delayed or terminated as a result of ambiguous or negative interim results. In addition, a clinical trial may be suspended or terminated by us, the FDA, the IRBs at the sites where the IRBs are overseeing a trial, or a data safety monitoring board, or DSMB (Data Safety Monitoring Board)/DMC (Data Monitoring Committee), overseeing the clinical trial at issue, or other regulatory authorities due to a number of factors, including:

failure to conduct the clinical trial in accordance with regulatory requirements or our clinical protocols;

inspection of the clinical trial operations or trial sites by the FDA or other regulatory authorities resulting in the imposition of a clinical hold;

varying interpretation of data by the FDA or similar foreign regulatory authorities;

failure to achieve primary or secondary endpoints or other failure to demonstrate efficacy;

unforeseen safety issues; or

lack of adequate funding to continue the clinical trial.

***Modifications to our product candidates may require federal approvals.***

The BLA application is the vehicle through which the company may formally propose that the FDA approve a new pharmaceutical for sale and marketing in the United States. Once a particular product candidate receives FDA approval, expanded uses or uses in new indications of our products may require additional human clinical trials and new regulatory approvals, including additional IND and BLA submissions and premarket approvals before we can begin clinical development, and/or prior to marketing and sales. If the FDA requires new approvals for a particular use or indication, we may be required to conduct additional clinical studies, which would require additional expenditures and harm our operating results. If the products are already being used for these new indications, we may also be subject to significant enforcement actions.

Conducting clinical trials and obtaining approvals is a time-consuming process, and delays in obtaining required future approvals could adversely affect our ability to introduce new or enhanced products in a timely manner, which in turn would have an adverse effect on our business prospects, financial condition and results of operation.

***The FDA or comparable foreign regulatory authorities may disagree with our regulatory plans, and we may fail to obtain regulatory approval of our product candidates.***

In June 2012, we acquired rights to BC8 (Iomab), a clinical stage monoclonal antibody with safety and efficacy data in more than 300 patients in need of a BMT. Iomab-B is our product candidate that links I-131 to the BC8 antibody that is being studied in an ongoing Phase 3 pivotal trial. Product candidates utilizing this antibody would require BLA approval before they can be marketed in the United States. We are also evaluating a lower dose of the BC8 antibody and I-131 for lymphodepletion prior to CAR-T or adoptive cell therapy. We are currently evaluating clinical trials that would use our construct for lymphodepletion. Our lintuzumab-Ac-225 product candidate is also being studied in several Phase 1 trials under our sponsorship and investigator-initiated trials in patients with AML, myelodysplastic syndrome and multiple myeloma. Product candidates utilizing the lintuzumab antibody would require BLA approval before they can be marketed in the United States. We are in the early stages of evaluating other product candidates consisting of conjugates of Ac-225 with human or humanized antibodies for pre-clinical and clinical development in other types of cancer. The FDA may not approve these products for the indications that are necessary or desirable for successful commercialization. The FDA may fail to approve any BLA we submit for new product candidates or for new intended uses or indications for approved products or future product candidates. Failure to obtain FDA approval for our products in the proposed indications would have a material adverse effect on our business prospects, financial condition and results of operations.



***Clinical trials necessary to support approval of our product candidates are time-consuming and expensive.***

Initiating and completing clinical trials necessary to support FDA approval of a BLA for Iomab-B, CD33 program candidates, and other product candidates, is a time-consuming and expensive process, and the outcome is inherently uncertain. Moreover, the results of early clinical trials are not necessarily predictive of future results, and any product candidate we advance into clinical trials may not have favorable results in later clinical trials. We have worked with the FDA to develop a clinical trial designed to test the safety and efficacy of Iomab-B in patients with relapsed or refractory AML who are age 55 and above prior to a BMT. This trial is designed to support a BLA filing for marketing approval by the FDA, pending results from the trial. We have also worked with the FDA to develop a regulatory pathway for our Actimab-MDS trial that consists of a dose-confirming Phase 1 trial that can be followed by a randomized, controlled pivotal trial that could support a BLA filing. In addition, there can be no assurance that the data generated during the trial will meet our chosen safety and effectiveness endpoints or otherwise produce results that will eventually support the filing or approval of a BLA. Even if the data from this trial are favorable, these data may not be predictive of the results of any future clinical trials.

***Our clinical trials may fail to demonstrate adequately the efficacy and safety of our product candidates, which would prevent or delay regulatory approval and commercialization.***

Even if our clinical trials are completed as planned, we cannot be certain that their results will support our product candidate claims or that the FDA or foreign authorities will agree with our conclusions regarding them. Success in pre-clinical studies and early clinical trials does not ensure that later clinical trials will be successful, and we cannot be sure that the later trials will replicate the results of prior trials and pre-clinical studies. The clinical trial process may fail to demonstrate that our product candidates are safe and effective for the proposed indicated uses. If FDA concludes that the clinical trials for Iomab-B, lintzumab-Ac-225, or any other product candidate for which we might seek approval, have failed to demonstrate safety and effectiveness, we would not receive FDA approval to market that product candidate in the United States for the indications sought. In addition, such an outcome could cause us to abandon the product candidate and might delay development of others. Any delay or termination of our clinical trials will delay or preclude the filing of any submissions with the FDA and, ultimately, our ability to commercialize our product candidates and generate revenues. It is also possible that patients enrolled in clinical trials will experience adverse side effects that are not currently part of a product candidate's profile.

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

The key patents related to the humanized antibody, lintuzumab, which we use in our CD33 program product candidates have expired. It is generally possible that others may be eventually able to use an antibody with the same sequence, and we will then need to rely on additional patent protection covering alpha particle drug products comprising Ac-225. Our final drug construct consists of the lintuzumab antibody labeled with the isotope Ac-225. We

have licensed issued patents that relate to the linker technology we use to conjugate the isotope to the antibody and own issued and pending patents related to isotope production methods and drug preparation methods. In addition, we possess trade secrets and know how related to the manufacturing and use of isotopes. Any competing product based on the lintuzumab antibody is likely to require several years of development before achieving our product candidate's current status and may be subject to significant regulatory hurdles but is nevertheless a possibility that could negatively impact our business in the future. Neither the antibody portion nor the composition of matter as a whole for the conjugated Iomab-B product candidate is covered by the claims of any issued patent. Accordingly, there are no patents that would prevent others from using an antibody with the same antibody sequence in any drug product. We have dedicated research and development activities towards improving the product's stability to enhance commercial usefulness of the product and now have a proprietary formulation for which IP is pending. We have and may continue to file patents related to Iomab-B that can provide barriers to entry but there is no certainty that these patents will be granted or such granting thereof will adequately prevent others from seeking to replicate and use the BC8 antibody or the construct. We have pending patents related to radioimmunoconjugate composition, formulation administration, and methods of use in solid or liquid cancers. This matter includes composition, administration, and methods of treatment for our products Actimab-A and Iomab-B. Any competing product based on the antibody used in Iomab-B is likely to require several years of development before achieving our product candidate's current status and may be subject to significant regulatory hurdles but is nevertheless a possibility that could negatively impact our business in the future.

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

***Our CD33 program clinical trials are testing the same drug construct***

Our CD33 program is comprised of several clinical trials including several investigator-initiated trials including AML, MDS and Multiple Myeloma that are studying the same drug construct consisting of lintuzumab-Ac-225. Negative results from any of these trials could negatively impact our ability to enroll or complete our other trials studying lintuzumab-Ac-225. Additionally, negative outcomes including safety concerns, may result in the FDA discontinuing other trials utilizing lintuzumab-Ac-225.

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

Iodine-131 is a key component of our Iomab-B drug candidate. We source medical grade I-131 from multiple suppliers including two leading global manufacturers. Currently, there is sufficient supply of I-131 to advance our ongoing SIERRA clinical trial, support additional trials we may undertake utilizing I-131 and for commercialization of Iomab-B. We continually evaluate I-131 manufacturers and suppliers and intend to have at a minimum of three qualified suppliers prior to the commercial launch of Iomab-B. While we consider I-131 to be commoditized and obtainable through several suppliers, there can be no guarantee that we will be able to secure a third I-131 supplier or obtain on terms that are acceptable to us.

Actinium-225 is a key component of our CD33 ARC program, AWE platform and other drug candidates that we might consider for development with the Ac-225 payload. There are adequate quantities of Ac-225 available today to meet our current needs via our present supplier, the Department of Energy, or DOE. The current Ac-225 currently supplied to Actinium’s clinical trials from the DOE is derived from the natural decay of thorium-229 from so-called ‘thorium-cows’ and is able to produce sufficient quantities that are several multiples of the amount of Ac-225 we require to supply our clinical programs through to early commercialization phase. The DOE is also producing Ac-225 from a recently developed alternative route for Ac-225 production via a linear accelerator that is currently being evaluated by Actinium. Initial preclinical and modelling results have indicated that the linear accelerator sourced Ac-225 does not impact labelling efficiency and expected distribution. Per representations made by the Department of

Energy, the capacity of Ac-225 from this route is expected to be sufficient to supply all of Actinium's pipeline and commercial Ac-225 needs and support new program expansion by not just Actinium but also other companies that are developing Ac-225 based products. Additional routes of Ac-225 production are being pursued by the DOE including the generation of new thorium cows and production via a cyclotron. The cyclotron production method for Ac-225 production leverages Actinium's proprietary technology and know-how and presents an additional path towards production of high-quality Ac-225 that would be able to satisfy commercial needs. In addition, we are aware of at least six other government and non-government entities globally including the U.S., Canada, Russia, Belgium, France and Japan that have, or expect to have ability to supply Ac-225 or equipment for its production within the timeframes relevant to first commercial approval of our Ac-225 ARC.

Our contract for supply of this isotope from the DOE must be renewed yearly, and the current contract extends through the end of 2019. While we expect this contract will be renewed at the end of its term as it has since 2009, there can be no assurance that the DOE will renew the contract or that change its policies that allow for the sale of isotope to us. Failure to acquire sufficient quantities of medical grade Ac-225 would make it impossible to effectively complete clinical trials and to commercialize any Ac-225 based drug candidates that we may develop and would materially harm our business.

Our ability to conduct clinical trials to advance our ARC drug candidates is dependent on our ability to obtain the radioisotopes I-131, Ac-225 and other isotopes we may choose to utilize in the future. Currently, we are dependent on third party manufacturers and suppliers for our isotopes. These suppliers may not perform their contracted services or may breach or terminate their agreements with us. Our suppliers are subject to regulations and standards that are overseen by regulatory and government agencies and we have no control over our suppliers' compliance to these standards. Failure to comply with regulations and standards may result in their inability to supply isotope could result in delays in our clinical trials, which could have a negative impact on our business. We have developed intellectual property, know-how and trade secrets related to the manufacturing process of Ac-225. While we have manufactured medical Ac-225 of a purity compared to the cyclotron sourced material in the past, this activity was terminated due to operating cost reasons and we currently do not have experience in manufacturing medical grade Ac-225 and may not obtain the resources necessary to establish our own manufacturing capabilities in future. Our inability to build out and establish our own manufacturing facilities would require us to continue to rely on third party suppliers as we currently do. However, based on our current third-party suppliers and potential future suppliers of Ac-225 we expect to have adequate isotope supply to support our current ongoing clinical trials, current AWE program activities and commercialization should our drug candidates receive approval.

*If we encounter difficulties enrolling patients in our clinical trials, our clinical development activities could be delayed or otherwise adversely affected.*

The timely completion of clinical trials in accordance with their protocols depends on our ability to enroll a sufficient number of patients who remain in the trial until its conclusion. We may experience difficulties in patient enrollment in our clinical trials for a variety of reasons, including:

the size and nature of the patient population;

the patient eligibility criteria defined in the protocol;

the size of the study population required for analysis of the trial's primary endpoints;

the proximity of patients to trial sites;

the design of the trial;

our ability to recruit clinical trial investigators with the appropriate competencies and expertise;

competing clinical trials for similar or alternate therapeutic treatments;

clinician's and patients' perceptions as to the potential advantages and side effects of the product candidate being studied in relation to other available therapies;

our ability to obtain and maintain patient consents; and

the risk that patients enrolled in clinical trials will not complete a clinical trial.

In addition, refractory patients, which several of our trials are enrolling, participating in clinical trials are seriously and often terminally ill and therefore may not complete the clinical trial due to reasons including comorbid conditions or occurrence of adverse medical events related or unrelated to the investigational products, or death. Even if we are able to enroll a sufficient number of patients in our clinical trials, delays in patient enrollment will result in increased costs or affect the timing of our planned trials, which could adversely affect our ability to advance the development of our product candidates.

***FDA may take actions that would prolong, delay, suspend, or terminate clinical trials of our product candidates, which may delay or prevent us from commercializing our product candidates on a timely basis.***

There can be no assurance that the data generated in our clinical trials will be acceptable to FDA or that if future modifications during the trial are necessary, that any such modifications will be acceptable to FDA. Certain modifications to a clinical trial protocol made during the course of the clinical trial have to be submitted to the FDA. This could result in the delay or halt of a clinical trial while the modification is evaluated. In addition, depending on the quantity and nature of the changes made, FDA could take the position that some or all of the data generated by the clinical trial is not usable because the same protocol was not used throughout the trial. This might require the enrollment of additional subjects, which could result in the extension of the clinical trial and the FDA delaying approval of a product candidate. If the FDA believes that its prior approval is required for a particular modification, it can delay or halt a clinical trial while it evaluates additional information regarding the change.

Any delay or termination of our current or future clinical trials as a result of the risks summarized above, including delays in obtaining or maintaining required approvals from IRBs, delays in patient enrollment, the failure of patients to continue to participate in a clinical trial, and delays or termination of clinical trials as a result of protocol modifications or adverse events during the trials, may cause an increase in costs and delays in the filing of any submissions with the FDA, delay the approval and commercialization of our product candidates or result in the failure of the clinical trial, which could adversely affect our business, operating results and prospects. Lengthy delays in the completion of our Actimab-A clinical trials would adversely affect our business and prospects and could cause us to cease operations.

### **Risks Related to Third Parties**

***We rely on third parties to conduct our clinical trials. If these third parties do not successfully carry out their contractual duties or meet expected deadlines or comply with regulatory requirements, we may not be able to obtain regulatory approval for or commercialize our product candidates.***

We do not have the ability to independently conduct our pre-clinical and clinical trials for our product candidates and we must rely on third parties, such as contract research organizations, medical institutions, clinical investigators and contract laboratories to conduct such trials. Our reliance on these third parties for clinical development activities results in reduced control over these activities. Moreover, the FDA requires us to comply with regulations and standards, commonly referred to as GCPs (good clinical practices), for conducting, recording and reporting the results of clinical trials to assure that data and reported results are credible and accurate and that the trial participants are adequately protected. Our reliance on third parties does not relieve us of these responsibilities and requirements. If we or any of our third-party contractors fail to comply with applicable GCPs, the clinical data generated in our clinical trials may be deemed unreliable and the FDA or comparable foreign regulatory authorities may require us to perform additional clinical trials before approving our marketing applications. We cannot assure you that upon inspection by a given regulatory authority, such regulatory authority will determine that any of our clinical trials complies with GCP regulations. In addition, our clinical trials must be conducted with product produced under current good manufacturing practice, or cGMP, regulations. Our failure to comply with these regulations may require us to repeat clinical trials, which would delay the regulatory approval process.

If our consultants, contract research organizations and other similar entities with which we are working do not successfully carry out their contractual duties, meet expected deadlines, or comply with applicable regulations, we may be required to replace them. Although we believe that there are a number of other third-party contractors, we could engage to continue these activities, we may not be able to enter into arrangements with alternative third-party contractors or to do so on commercially reasonable terms, which may result in a delay of our planned clinical trials and delayed development of our product candidates.

In addition, our third-party contractors are not our employees, and except for remedies available to us under our agreements with such third-party contractors, we cannot control whether or not they devote sufficient time and resources to our programs. If these third parties do not successfully carry out their contractual duties or regulatory obligations or meet expected deadlines, or if the quality or accuracy of the data they obtain is compromised due to the failure to adhere to our clinical protocols or regulatory requirements or for other reasons, our pre-clinical development activities or clinical trials may be extended, delayed, suspended or terminated, and we may not be able to obtain regulatory approval for, or successfully commercialize, our product candidates on a timely basis, if at all, and our business, operating results and prospects would be adversely affected.



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

Our product candidates are regulated by the FDA as biologic products and we intend to seek approval for these products pursuant to the BLA pathway. The Biologics Price Competition and Innovation Act of 2009, or BPCIA, created an abbreviated pathway for the approval of biosimilar and interchangeable biologic products. The abbreviated regulatory pathway establishes legal authority for the FDA to review and approve biosimilar biologics, including the possible designation of a biosimilar as “interchangeable” based on its similarity to an existing brand product. Under the BPCIA, an application for a biosimilar product cannot be approved by the FDA until 12 years after the original branded product was approved under a BLA. The law is complex and is still being interpreted and implemented by the FDA. As a result, its ultimate impact, implementation, and meaning are subject to uncertainty. While it is uncertain when such processes intended to implement BPCIA may be fully adopted by the FDA, any such processes could have a material adverse effect on the future commercial prospects for our biologic products.

***Our product candidates may never achieve market acceptance.***

Iomab-B, CD33 ARC program candidates and future product candidates that we may develop may never gain market acceptance among physicians, patients and the medical community. The degree of market acceptance of any of our products will depend on a number of factors, including the actual and perceived effectiveness and reliability of the product; the results of any long-term clinical trials relating to use of the product; the availability, relative cost and perceived advantages and disadvantages of alternative technologies; the degree to which treatments using the product are approved for reimbursement by public and private insurers; the strength of our marketing and distribution infrastructure; and the level of education and awareness among physicians and hospitals concerning the product.

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

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

***Even if we receive regulatory approval of our product candidates, we will be subject to ongoing regulatory obligations and continued regulatory review.***

Any regulatory approvals that we receive for our product candidates will require surveillance to monitor the safety and efficacy of the product candidate. The FDA may also require a risk evaluation and mitigation strategy in order to approve our product candidates, which could entail requirements for a medication guide, physician communication plans or additional elements to ensure safe use, such as restricted distribution methods, patient registries and other risk minimization tools. In addition, if the FDA or a comparable foreign regulatory authority approves our product candidates, the manufacturing processes, labeling, packaging, distribution, adverse event reporting, storage, advertising, promotion, import, export and recordkeeping for our product candidates will be subject to extensive and ongoing regulatory requirements. These requirements include submissions of safety and other post-marketing information and reports, registration, as well as continued compliance with cGMPs and cGCPs for any clinical trials that we conduct post-approval. In addition, the FDA could require us to conduct another study to obtain additional safety or biomarker information. Later discovery of previously unknown problems with our product candidates, including adverse events of unanticipated severity or frequency, or with our third-party suppliers or manufacturing processes, or failure to comply with regulatory requirements, may result in, among other things:

restrictions on the marketing or manufacturing of our product candidates, withdrawal of the product from the market, or voluntary or mandatory product recalls;

fines, warning letters or holds on clinical trials;

refusal by the FDA to approve pending applications or supplements to approved applications filed by us or suspension or revocation of license approvals;

product seizure or detention, or refusal to permit the import or export of our product candidates; and

injunctions or the imposition of civil or criminal penalties.

The FDA's and other regulatory authorities' policies may change, and additional government regulations may be enacted that could prevent, limit or delay regulatory approval of our product candidates. We cannot predict the likelihood, nature or extent of government regulation that may arise from future legislation or administrative action, either in the United States or abroad. If we are slow or unable to adapt to changes in existing requirements or the adoption of new requirements or policies, or if we are not able to maintain regulatory compliance, we may lose any marketing approval that we may have obtained, and we may not achieve or sustain profitability.

***Coverage and reimbursement may be limited or unavailable in certain market segments for our product candidates which could limit our sales of our product candidates, if approved.***

The commercial success of our product candidates in both domestic and international markets will be substantially dependent on whether third-party coverage and reimbursement is available for patients that use our products. However, the availability of insurance coverage and reimbursement for newly approved cancer therapies is uncertain, and therefore, third-party coverage may be particularly difficult to obtain even if our products are approved by the FDA as safe and efficacious. Patients using existing approved therapies are generally reimbursed all or part of the product cost by Medicare or other third-party payors. Medicare, Medicaid, health maintenance organizations and other third-party payors are increasingly attempting to contain healthcare costs by limiting both coverage and the level of reimbursement of new drugs, and, as a result, they may not cover or provide adequate payment for these products. Submission of applications for reimbursement approval generally does not occur prior to the filing of a BLA for that product and may not be granted until many months after BLA approval. In order to obtain coverage and reimbursement for these products, we or our commercialization partners may have to agree to a net sales price lower than the net sales price we might charge in other sales channels. The continuing efforts of government and third-party payors to contain or reduce the costs of healthcare may limit our revenue. Initial dependence on the commercial success of our products may make our revenues particularly susceptible to any cost containment or reduction efforts.

***We may be subject to claims that our third-party service providers, consultants or current or former employees have wrongfully used or disclosed confidential information of third parties.***

We have received confidential and proprietary information from third parties. In addition, we employ individuals who were previously employed at other biotechnology or pharmaceutical companies. We may be subject to claims that we or our employees, consultants or independent contractors have inadvertently or otherwise used or disclosed confidential information of these third parties or our employees' former employers. Litigation may be necessary to defend against these claims. Even if we are successful in defending against these claims, litigation could result in substantial cost and be a distraction to our management and employees.

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

We do not currently operate manufacturing facilities for pre-clinical or clinical production of any of our product candidates. We rely on third-party manufacturers to supply, store, and distribute pre-clinical and clinical supply of 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.

Our product candidates require precise, high-quality manufacturing. Failure by our contract manufacturer to achieve and maintain high manufacturing standards could result in patient injury or death, product recalls or withdrawals, delays or failures in testing or delivery, cost overruns, or other problems that could seriously hurt our business. Contract manufacturers may encounter difficulties involving production yields, quality control, and quality assurance. These manufacturers are subject to ongoing periodic and unannounced inspections by the FDA and corresponding state and foreign agencies to ensure strict compliance with cGMPs and other applicable government regulations and corresponding foreign standards; we do not have control over third-party manufacturers' compliance with these regulations and standards.

Furthermore, these third-party contractors, whether foreign or domestic, may experience regulatory compliance difficulty, mechanical shut downs, employee strikes, or any other unforeseeable acts that may delay or limit production. Our inability to adequately establish, supervise and conduct (either ourselves or through third parties) all aspects of the formulation and manufacturing processes, and the inability of third-party manufacturers to consistently supply quality product when required would have a material adverse effect on our ability to commercialize our products. We have faced delays and risks associated with reliance on key third party manufacturers in the past and may be faced with such delays and risks in the future. Any future manufacturing interruptions or related supply issues could have an adverse effect on our company, including delays in clinical trials.

***If we are successful in obtaining marketing approval from the FDA and/or other regulatory agencies for any of our product candidates, we anticipate continued reliance on third-party manufacturers.***

To date, our product candidates have been manufactured in small quantities for preclinical and clinical testing by third-party manufacturers. If the FDA or other regulatory agencies approve any of our product candidates for commercial sale, we expect that we would continue to rely, at least initially, on third-party specialized manufacturers to produce commercial quantities of approved products. These manufacturers may not be able to successfully increase the manufacturing capacity for any approved product in a timely or economic manner, or at all. Significant scale-up of manufacturing may require additional validation studies, which the FDA must review and approve. If third party manufacturers are unable to successfully increase the manufacturing capacity for a product candidate, or we are unable to establish our own manufacturing capabilities, the commercial launch of any approved products may be delayed or there may be a shortage in supply, which in turn could have a material adverse effect on our business.

In addition, the facilities used by our contract manufacturers to manufacture our product candidates must be approved by the FDA pursuant to inspections that will be conducted after we submit a BLA to the FDA. We do not control the manufacturing process of, and are completely dependent on, our contract manufacturing partners for compliance with cGMPs. If our contract manufacturers cannot successfully manufacture material that conforms to our specifications and the strict regulatory requirements of the FDA or other regulatory authorities, they will not be able to secure and/or maintain regulatory approval for their manufacturing facilities. If the FDA or a comparable foreign regulatory authority does not approve these facilities for the manufacture of our product candidates or if it withdraws any such approval in the future, we may need to find alternative manufacturing facilities, which would significantly impact our ability to develop, obtain regulatory approval for or market our product candidates, if approved.

***We may have conflicts with our partners that could delay or prevent the development or commercialization of our product candidates.***

We may have conflicts with our partners, such as conflicts concerning the interpretation of preclinical or clinical data, the achievement of milestones, the interpretation of contractual obligations, payments for services, development

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

***We face significant competition from other biotechnology and pharmaceutical companies.***

Our product candidates face, and will continue to face, intense competition from large pharmaceutical companies, as well as academic and research institutions. We compete in an industry that is characterized by (i) rapid technological change, (ii) evolving industry standards, (iii) emerging competition and (iv) new product introductions. Our competitors have existing products and technologies that will compete with our product candidates and technologies and may develop and commercialize additional products and technologies that will compete with our product candidates and technologies. Because several competing companies and institutions have greater financial resources than us, they may be able to (i) provide broader services and product lines, (ii) make greater investments in research and development, or R&D, and (iii) carry on broader R&D initiatives. Our competitors also have greater development capabilities than we do and have substantially greater experience in undertaking preclinical and clinical testing of product candidates, obtaining regulatory approvals, and manufacturing and marketing pharmaceutical products. They also have greater name recognition and better access to customers than us.

***Our product candidates may cause undesirable side effects or have other properties that could halt their clinical development, prevent their regulatory approval, limit their commercial potential, or result in significant negative consequences***

Undesirable side effects caused by our product candidates could cause us or regulatory authorities to interrupt, delay or halt clinical trials and could result in a more restrictive label or the delay or denial of regulatory approval by the FDA or other comparable foreign authorities. The drug-related side effects could affect patient recruitment or the ability of enrolled patients to complete the trial or result in potential product liability claims. Any of these occurrences may harm our business, financial condition and prospects significantly. Even if any of our product candidates receives marketing approval, as greater numbers of patients use a product following its approval, an increase in the incidence of side effects or the incidence of other post-approval problems that were not seen or anticipated during pre-approval clinical trials could result in a number of potentially significant negative consequences, including:

regulatory authorities may withdraw their approval of the product;

regulatory authorities may require the addition of labeling statements, such as warnings or contraindications;

we may be required to change the way the product is administered, conduct additional clinical trials or change the labeling of the product;

we may elect, or we may be required, to recall or withdraw product from the market;

we could be sued and held liable for harm caused to patients; and

our reputation may suffer.

Any of these events could substantially increase the costs and expenses of developing, commercializing and marketing any such product candidates or could harm or prevent sales of any approved products.

### **Risks Related to Our Intellectual Property**

#### ***We depend upon securing and protecting critical intellectual property.***

We are dependent on obtaining and maintaining patents, trade secrets, copyright and trademark protection of our technologies in the United States and other jurisdictions, as well as successfully enforcing this intellectual property and defending this intellectual property against third-party challenges. The degree of future protection of our proprietary rights is uncertain for product candidates that are currently in the early stages of development because we cannot predict which of these product candidates will ultimately reach the commercial market or whether the commercial versions of these product candidates will incorporate proprietary technologies.



*Our patent position is highly uncertain and involves complex legal and factual questions.*

Accordingly, we cannot predict the breadth of claims that may be allowed or enforced under our patents or in third-party patents. For example, we or our licensors might not have been the first to make the inventions covered by each of our pending patent applications and issued patents; we or our licensors might not have been the first to file patent applications for these inventions; others may independently develop similar or alternative technologies or duplicate any of our technologies; it is possible that none of our pending patent applications or the pending patent applications of our licensors will result in issued patents; our issued patents and issued patents of our licensors may not provide a basis for commercially viable technologies, or may not provide us with any competitive advantages, or may be challenged and invalidated by third parties; and, we may not develop additional proprietary technologies that are patentable.

As a result, our owned and licensed patents may not be valid, and we may not be able to obtain and enforce patents and to maintain trade secret protection for the full commercial extent of our technology. The extent to which we are unable to do so could materially harm our business.

We or our licensors have applied for and will continue to apply for patents for certain products. Such applications may not result in the issuance of any patents, and any patents now held or that may be issued may not provide us with adequate protection from competition. Furthermore, it is possible that patents issued or licensed to us may be challenged successfully. In that event, if we have a preferred competitive position because of such patents, such preferred position would be lost. If we are unable to secure or to continue to maintain a preferred position, we could become subject to competition from the sale of generic products. Failure to receive, inability to protect, or expiration of our patents for medical use, manufacture, conjugation and labeling of Ac-225, the antibodies that we license from third parties, or subsequent related filings, would adversely affect our business and operations.

Patents issued or licensed to us may be infringed by the products or processes of others. The cost of enforcing our patent rights against infringers, if such enforcement is required, could be significant, and we do not currently have the financial resources to fund such litigation. Further, such litigation can go on for years and the time demands could interfere with our normal operations. There has been substantial litigation and other proceedings regarding patent and other intellectual property rights in the pharmaceutical industry. We may become a party to patent litigation and other proceedings. The cost to us of any patent litigation, even if resolved in our favor, could be substantial. Some of our competitors may be able to sustain the costs of such litigation more effectively than we can because of their substantially greater financial resources. Litigation may also absorb significant management time.

Unpatented trade secrets, improvements, confidential know-how and continuing technological innovation are important to our scientific and commercial success. Although we attempt to and will continue to attempt to protect our proprietary information through reliance on trade secret laws and the use of confidentiality agreements with our

partners, collaborators, employees and consultants and other appropriate means, these measures may not effectively prevent disclosure of our proprietary information, and, in any event, others may develop independently, or obtain access to, the same or similar information.

Certain of our patent rights are licensed to us by third parties. If we fail to comply with the terms of these license agreements, our rights to those patents may be terminated, and we will be unable to conduct our business.

***If we are found to be infringing on patents or trade secrets owned by others, we may be forced to cease or alter our product development efforts, obtain a license to continue the development or sale of our products, and/or pay damages.***

Our manufacturing processes and potential products may violate proprietary rights of patents that have been or may be granted to competitors, universities or others, or the trade secrets of those persons and entities. As the pharmaceutical industry expands and more patents are issued, the risk increases that our processes and potential products may give rise to claims that they infringe the patents or trade secrets of others. These other persons could bring legal actions against us claiming damages and seeking to enjoin clinical testing, manufacturing and marketing of the affected product or process. If any of these actions are successful, in addition to any potential liability for damages, we could be required to obtain a license in order to continue to conduct clinical tests, manufacture or market the affected product or use the affected process. Required licenses may not be available on acceptable terms, if at all, and the results of litigation are uncertain. If we become involved in litigation or other proceedings, it could consume a substantial portion of our financial resources and the efforts of our personnel.

***Our ability to protect and enforce our patents does not guarantee that we will secure the right to commercialize our patents.***

A patent is a limited monopoly right conferred upon an inventor, and his successors in title, in return for the making and disclosing of a new and non-obvious invention. This monopoly is of limited duration but, while in force, allows the patent holder to prevent others from making and/or using its invention. While a patent gives the holder this right to exclude others, it is not a license to commercialize the invention where other permissions may be required for commercialization to occur. For example, a drug cannot be marketed without the appropriate authorization from the FDA, regardless of the existence of a patent covering the product. Further, the invention, even if patented itself, cannot be commercialized if it infringes the valid patent rights of another party.

***We rely on confidentiality agreements to protect our trade secrets. If these agreements are breached by our employees or other parties, our trade secrets may become known to our competitors.***

We rely on trade secrets that we seek to protect through confidentiality agreements with our employees and other parties. If these agreements are breached, our competitors may obtain and use our trade secrets to gain a competitive advantage over us. We may not have any remedies against our competitors and any remedies that may be available to us may not be adequate to protect our business or compensate us for the damaging disclosure. In addition, we may have to expend resources to protect our interests from possible infringement by others.

***The use of hazardous materials, including radioactive and biological materials, in our research and development efforts imposes certain compliance costs on us and may subject us to liability for claims arising from the use or misuse of these materials.***

Our research, development and manufacturing activities involve the controlled use of hazardous materials, including chemicals, radioactive and biological materials, such as radioactive isotopes. We are subject to federal, state, local and foreign environmental laws and regulations governing, among other matters, the handling, storage, use and disposal of these materials and some waste products. We cannot completely eliminate the risk of contamination or injury from these materials and we could be held liable for any damages that result, which could exceed our financial resources. We currently maintain insurance coverage for injuries resulting from the hazardous materials we use; however, future claims may exceed the amount of our coverage. Also, we do not have insurance coverage for pollution cleanup and removal. Currently the costs of complying with such federal, state, local and foreign environmental regulations are not significant, and consist primarily of waste disposal expenses. However, they could become expensive, and current or future environmental laws or regulations may impair our research, development, production and commercialization efforts.

***We may undertake international operations, which will subject us to risks inherent with operations outside of the United States.***

Although we do not have any international operations at this time, we intend to seek market clearances in foreign markets that we believe will generate significant opportunities. However, even with the cooperating of a commercialization partner, conducting drug development in foreign countries involves inherent risks, including, but not limited to difficulties in staffing, funding and managing foreign operations; unexpected changes in regulatory requirements; export restrictions; tariffs and other trade barriers; difficulties in protecting, acquiring, enforcing and litigating intellectual property rights; fluctuations in currency exchange rates; and potentially adverse tax consequences.

If we were to experience any of the difficulties listed above, or any other difficulties, any international development activities and our overall financial condition may suffer and cause us to reduce or discontinue our international development and registration efforts.

***We are highly dependent on our key personnel, and if we are not successful in attracting and retaining highly qualified personnel, we may not be able to successfully implement our business strategy.***

Our future operations and successes depend in large part upon the continued service of key members of our senior management team whom we are highly dependent upon to manage our business. If any member of our current senior management terminates his employment with us and we are unable to find a suitable replacement quickly, the departure could have a material adverse effect on our business.

Our future success also depends on our ability to identify, attract, hire or engage, retain and motivate other well-qualified managerial, technical, clinical and regulatory personnel. There can be no assurance that such professionals will be available in the market, or that we will be able to retain existing professionals or meet or continue to meet their compensation requirements. Furthermore, the cost base in relation to such compensation, which may include equity compensation, may increase significantly, which could have a material adverse effect on us. Failure to establish and maintain an effective management team and workforce could adversely affect our ability to operate, grow and manage our business.

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

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

the federal Anti-Kickback Statute, which prohibits, among other things, persons from knowingly and willfully soliciting, receiving, offering or paying remuneration, directly or indirectly, to induce, or in return for, the purchase or recommendation of an item or service reimbursable under a federal healthcare program, such as the Medicare and Medicaid programs;

federal civil and criminal false claims laws and civil monetary penalty laws, which prohibit, among other things, individuals or entities from knowingly presenting, or causing to be presented, claims for payment from Medicare, Medicaid, or other third-party payors that are false or fraudulent;

the federal Health Insurance Portability and Accountability Act of 1996, or HIPAA, which created federal criminal statutes that prohibit executing a scheme to defraud any healthcare benefit program and making false statements relating to healthcare matters;

HIPAA, as amended by the Health Information Technology and Clinical Health Act, or HITECH, and its implementing regulations, which imposes certain requirements relating to the privacy, security, and transmission of individually identifiable health information;

the federal physician sunshine requirements under PPACA, which require certain manufacturers of drugs, devices, biologics, and medical supplies to report annually to the U.S. Department of Health and Human Services information related to payments and other transfers of value to physicians, other healthcare providers, and teaching hospitals, and ownership and investment interests held by physicians and other healthcare providers and their immediate family members and applicable group purchasing organizations;

state law equivalents of each of the above federal laws, such as anti-kickback and false claims laws that may apply to items or services reimbursed by any third-party payor, including commercial insurers; state laws that require pharmaceutical companies to comply with the industry's voluntary compliance guidelines and the relevant compliance guidance promulgated by the federal government, or otherwise restrict payments that may be made to healthcare providers and other potential referral sources; state laws that require drug manufacturers to report information related to payments and other transfers of value to physicians and other healthcare providers or marketing expenditures; and state laws governing the privacy and security of health information in certain circumstances, many of which differ from each other in significant ways, thus complicating compliance efforts.

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

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

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

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

In March 2010, the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Affordability Reconciliation Act, or collectively, the PPACA, became law in the United States. The goal of the PPACA is to reduce the cost of healthcare and substantially change the way healthcare is financed by both governmental and private insurers. While we cannot predict what impact on federal reimbursement policies this legislation will have in general or on our business specifically, the PPACA may result in downward pressure on pharmaceutical reimbursement, which could negatively affect market acceptance of our drug candidates, if approved, or any of our future products. In 2012, members of the U.S. Congress and some state legislatures sought to overturn

certain provisions of the PPACA including those concerning the mandatory purchase of insurance. However, on June 28, 2012, the United States Supreme Court upheld the constitutionality of these provisions. Members of the U.S. Congress have since proposed a number of legislative initiatives, including possible repeal of the PPACA. We cannot predict the outcome or impact of current proposals or whether new proposals will be made or adopted, when they may be adopted or what impact they may have on us if they are adopted. These challenges add to the uncertainty of the legislative changes as part of ACA. Changes that may affect our business include those governing enrollment in federal healthcare programs, reimbursement changes, fraud and abuse and enforcement. These changes will impact existing government healthcare programs and will result in the development of new programs, including Medicare payment for performance initiatives and improvements to the physician quality reporting system and feedback program.

*Managing our growth as we expand operations may strain our resources.*

We expect to need to grow rapidly in order to support additional, larger, and potentially international, pivotal clinical trials of our product candidates, which will place a significant strain on our financial, managerial and operational resources. In order to achieve and manage growth effectively, we must continue to improve and expand our operational and financial management capabilities. Moreover, we will need to increase staffing and to train, motivate and manage our employees. All of these activities will increase our expenses and may require us to raise additional capital sooner than expected. Failure to manage growth effectively could materially harm our business, financial condition or results of operations.



***We may expand our business through the acquisition of rights to new product candidates that could disrupt our business, harm our financial condition and may also dilute current stockholders' ownership interests in our company.***

Our business strategy includes expanding our products and capabilities, and we may seek acquisitions of product candidates, antibodies or technologies to do so. Acquisitions involve numerous risks, including substantial cash expenditures; potentially dilutive issuance of equity securities; incurrence of debt and contingent liabilities, some of which may be difficult or impossible to identify at the time of acquisition; difficulties in assimilating acquired technologies or the operations of the acquired companies; diverting our management's attention away from other business concerns; risks of entering markets in which we have limited or no direct experience; and the potential loss of our key employees or key employees of the acquired companies.

We can make no assurances that any acquisition will result in short-term or long-term benefits to us. We may incorrectly judge the value or worth of an acquired product, company or business. In addition, our future success would depend in part on our ability to manage the rapid growth associated with some of these acquisitions. We cannot assure that we will be able to make the combination of our business with that of acquired products, businesses or companies work or be successful. Furthermore, the development or expansion of our business or any acquired products, business or companies may require a substantial capital investment by us. We may not have these necessary funds, or they might not be available to us on acceptable terms or at all. We may also seek to raise funds by selling shares of our preferred or common stock, which could dilute each current stockholder's ownership interest in the Company.

#### ***Risks Related to Ownership of Our Common Stock***

***The sale of securities by us in any equity or debt financing could result in dilution to our existing stockholders and have a material adverse effect on our earnings.***

We have financed our operations primarily through sales of stock and warrants. It is likely that during the next twelve months we will seek to raise additional capital through the sales of stock and warrants in order to expand our level of operations to continue our research and development efforts.

Any sale of common stock by us in a future offering could result in dilution to our existing stockholders as a direct result of our issuance of additional shares of our capital stock. In addition, our business strategy may include expansion through internal growth or by establishing strategic relationships with targeted customers and vendors. In order to do so, or to finance the cost of our other activities, we may issue additional equity securities that could dilute

our stockholders' stock ownership. We may also assume additional debt and incur impairment losses related to goodwill and other tangible assets if we acquire another company and this could negatively impact our earnings and results of operations.

***Our Common Stock has been considered a Penny Stock.***

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

*Our common stock is subject to price volatility which could lead to losses by stockholders and potential costly security litigation.*

The trading volume of our common stock has been and may continue to be extremely limited and sporadic. We expect the market price of our common stock to fluctuate substantially due to a variety of factors, including market perception of our ability to achieve our planned growth, quarterly operating results of other companies in the same industry, trading volume in our common stock, changes in general conditions in the economy and the financial markets or other developments affecting our competitors or us. This volatility has had a significant effect on the market price of securities issued by many companies for reasons unrelated to their operating performance and could have the same effect on our common stock.

The trading price of our Common Stock may be highly volatile and could fluctuate in response to factors such as:

actual or anticipated variations in our operating results;

announcements of developments by us or our competitors;

the timing of IND and/or BLA approval, the completion and/or results of our clinical trials;

regulatory actions regarding our products;

announcements by us or our competitors of significant acquisitions, strategic partnerships, joint ventures or capital commitments;

adoption of new accounting standards affecting our industry;

additions or departures of key personnel;

introduction of new products by us or our competitors;

sales of our Common Stock or other securities in the open market; and

other events or factors, many of which are beyond our control.

The stock market is subject to significant price and volume fluctuations. In the past, following periods of volatility in the market price of a company's securities, securities class action litigation has often been initiated against such a company. Litigation initiated against us, whether or not successful, could result in substantial costs and diversion of our management's attention and our resources, which could harm our business and financial condition.

***We do not intend to pay dividends on our common stock, so any returns will be determined by the value of our common stock.***

We have never declared or paid any cash dividends on our common stock. For the foreseeable future, it is expected that earnings, if any, generated from our operations will be used to finance the growth of our business, and that no dividends will be paid to holders of our common stock. As a result, the success of an investment in our common stock will depend upon any future appreciation in its value. There is no guarantee that our common stock will appreciate in value.

***Certain provisions of our Certificate of Incorporation and Bylaws and Delaware law make it more difficult for a third party to acquire us and make a takeover more difficult to complete, even if such a transaction were in our stockholders' interest.***

Provisions of our certificate of incorporation and bylaws may delay or discourage transactions involving an actual or potential change in our control or change in our management, including transactions in which stockholders might otherwise receive a premium for their shares, or transactions that our stockholders might otherwise deem to be in their best interests. Therefore, these provisions could adversely affect the price of our stock. Among other things, the certificate of incorporation and bylaws:

provide that the authorized number of directors may be changed by resolution of the board of directors;

provide that all vacancies, including newly-created directorships, may, except as otherwise required by law, be filled by the affirmative vote of a majority of directors then in office, even if less than a quorum;

divide the board of directors into three classes;

provide that stockholders seeking to present proposals before a meeting of stockholders or to nominate candidates for election as directors at a meeting of stockholders must provide notice in writing in a timely manner, and meet specific requirements as to the form and content of a stockholder's notice;

In addition, we are governed by Section 203 of the Delaware General Corporation Law. In general, Section 203 prohibits a public Delaware corporation from engaging in a "business combination" with an "interested stockholder" for a period of three years after the date of the transaction in which the person became an interested stockholder, unless the business combination is approved in a prescribed manner. A "business combination" includes mergers, asset sales or other transactions resulting in a financial benefit to the stockholder. An "interested stockholder" is a person who, together with affiliates and associates, owns, or within three years, did own, 15% or more of the corporation's outstanding voting stock. These provisions may have the effect of delaying, deferring or preventing a change in our control.

***Compliance with the reporting requirements of federal securities laws can be expensive.***

We are subject to the information and reporting requirements of the Exchange Act and other federal securities laws, and the compliance obligations of the Sarbanes-Oxley Act. The costs of preparing and filing annual and quarterly reports and other information with the Securities and Exchange Commission and furnishing audited reports to stockholders are substantial. In addition, we will incur substantial expenses in connection with the preparation of registration statements and related documents with respect any offerings of our common stock.

***Our ability to utilize our net operating loss carryforwards and certain other tax attributes may be limited.***

Our ability to utilize our federal net operating loss and tax credit carryforwards may be limited under Sections 382 and 383 of the Internal Revenue Code of 1986, as amended, or the Code. The limitations apply if we experience an “ownership change”, generally defined as a greater than 50 percentage point change in the ownership of our equity by certain stockholders over a rolling three-year period. Similar provisions of state tax law may also apply. We have not assessed whether such an ownership change has previously occurred. If we have experienced an ownership change at any time since our formation, we may already be subject to limitations on our ability to utilize our existing net operating losses and other tax attributes to offset taxable income. In addition, future changes in our stock ownership, which may be outside of our control, may trigger an ownership change and, consequently, the limitations under Sections 382 and 383 of the Code. As a result, if or when we earn net taxable income, our ability to use our pre-change net operating loss carryforwards and other tax attributes to offset such taxable income may be subject to limitations, which could adversely affect our future cash flows.

***Failure to establish and maintain adequate finance infrastructure and accounting systems and controls could impair our ability to comply with the financial reporting and internal controls requirements for publicly traded companies.***

As a public company, we operate in an increasingly demanding regulatory environment, including with respect to more complex accounting rules. Company responsibilities required by the Sarbanes-Oxley Act of 2002, as amended, or the Sarbanes-Oxley Act, include establishing and maintaining corporate oversight and adequate internal control over financial reporting and disclosure controls and procedures. Effective internal controls are necessary for us to produce reliable financial reports and are important to help prevent financial fraud.

Our compliance with Section 404 of the Sarbanes-Oxley Act requires that we incur substantial accounting expense and expend significant management efforts. We complied with Section 404 at December 31, 2018 and 2017 and while our testing did not reveal any material weaknesses in our internal controls, subsequent testing by our independent registered public accounting firm may reveal material weaknesses in our internal controls that we would be required to remediate in a timely manner so as to be able to comply with the requirements of Section 404 of the Sarbanes-Oxley Act each year. If we are not able to comply with the requirements of Section 404 of the Sarbanes-Oxley Act in a timely manner each year, we could be subject to sanctions or investigations by the SEC, NYSE American or other regulatory authorities which would require additional financial and management resources and could adversely affect the market price of our common stock. Furthermore, if we cannot provide reliable financial reports or prevent fraud, our business and results of operations could be harmed, and investors could lose confidence in our reported financial information.

**ITEM 1B. UNRESOLVED STAFF COMMENTS.**

None.

**ITEM 2. PROPERTIES.**

We do not own any real property. We lease offices at 275 Madison Avenue, New York, NY. The lease is for 5,790 square feet and has a term of seven years and three months, with an expiration date of September 6, 2022, with a current annual rate of \$312,660 until June 8, 2019 and \$341,610 for the remaining life of the lease. We are also responsible for certain other costs, such as insurance, taxes, utilities and maintenance. We issued a letter of credit of \$390,825 in connection with the lease and maintained a \$391,131 certified deposit as collateral for the letter of credit.

**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 AMERICAN under the symbol "ATNM".

#### **Holder**

As of March 15, 2019, there were 119,136,036 shares of common stock issued and outstanding, which were held by approximately 97 holders of record. There are no shares of preferred stock outstanding. On March 14, 2019, the closing price of our common stock as reported on the NYSE AMERICAN was \$0.57 per share.

#### **Securities Authorized for Issuance under Equity Compensation Plans**

We currently have two equity compensation plans defined as follows:

The Company's 2013 Stock Plan has an expiration date of September 9, 2023 and the total number of shares of our common stock available for grant to employees, directors and consultants under the plan is currently 22,750,000 shares. At our Annual Meeting of Stockholders held in December 2018, our stockholders increased the number of shares available to be granted under the 2013 Stock Plan from 17,750,000 shares to 22,750,000 shares.

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



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

The following table indicates shares of common stock authorized for issuance under our equity compensation plans as of December 31, 2018:

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	7,236,101	\$ 1.74	15,912,235
Equity compensation plans not approved by security holders	-	-	-
Total	7,236,101	\$ 1.74	15,912,235

**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,				
	2018	2017	2016	2015	2014
<b>Statements of Operations Data:</b>					
Revenues	\$-	\$-	\$-	\$-	\$-
Loss from operations	\$(23,827,322 )	\$(26,910,788 )	\$(26,847,481 )	\$(24,829,764 )	\$(22,480,544 )
Net loss	\$(23,653,963 )	\$(26,601,235 )	\$(24,321,724 )	\$(21,025,314 )	\$(24,687,509 )
<b>Net loss per common share:</b>					
Basic and diluted	\$(0.22 )	\$(0.40 )	\$(0.50 )	\$(0.55 )	\$(0.90 )
<b>Weighted-average common shares outstanding:</b>					
Basic and diluted	106,041,809	66,746,389	48,463,268	38,158,480	27,363,748

	As of December 31,				
	2018	2017	2016	2015	2014
<b>Balance Sheet Data:</b>					
Cash and cash equivalents	\$13,673,308	\$17,399,636	\$20,519,294	\$25,643,273	\$6,706,802
Total assets	\$14,889,394	\$18,337,107	\$22,528,886	\$26,587,581	\$7,569,086
Total liabilities	\$6,076,597	\$4,666,004	\$4,520,557	\$4,613,533	\$9,491,616
Stockholders’ equity (deficit)	\$8,812,797	\$13,671,103	\$18,008,329	\$21,974,048	\$(1,922,530)

## 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, 2018, 2017 and 2016. 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.*

Actinium Pharmaceuticals Inc. is a clinical-stage, biopharmaceutical company focused on developing and potentially commercializing therapies for targeted conditioning prior to cell therapies such as a BMT or Bone Marrow Transplant or CAR-T, a type of cellular therapy that genetically alters a patient's own T cells to target and kill their cancer cells, and for other adoptive cell therapies. In addition, we are also developing potential therapies for targeting and killing of cancer cells either as single agents or in combination with other drugs. Our targeted therapies are Antibody Radiation-Conjugates or ARCs, that combine the targeting ability of a monoclonal antibody (mAb) with the cell-killing ability of a radioisotope to deliver radiation internally in a precise manner to potentially generate more potent efficacy and with less toxicity than radiation that is delivered externally. We are developing two clinical stage ARC programs that target the antigens CD45 and CD33, respectively, that are currently being studied in several hematologic indications. We employ our ARCs at higher doses of radioisotope intensity for targeted conditioning prior to a BMT and at lower doses for targeted conditioning which is also known as lymphodepletion prior to CAR-T and other adoptive cell therapies. In addition, we are pursuing development of our ARC's at low doses in combination with other therapeutic modalities such as chemotherapy, targeted agents or immunotherapy and as a monotherapy. Our ARC based clinical programs are underpinned by our AWE or Antibody Warhead Enabling technology platform where we have data in both liquid and solid tumors, intellectual property and know-how that we intend to use to create additional ARCs targeting new antigens with multiple radioisotopes such as actinium-225 or Ac-225 or and iodine-131 or I-131. Our AWE technology platform is currently being utilized in a research collaboration with Astellas Pharma, Inc. centered around our technology for Ac-225.

We have never generated revenue. Currently we do not have a recurring source of revenues to cover our operating costs. We have incurred net losses and negative operating cash flows since inception. As of December 31, 2018 and 2017, our accumulated deficit was \$186.9 million and \$163.2 million, respectively. Our net loss was \$23.7 million, \$26.6 million, and \$24.3 million for the years ended December 31, 2018, 2017 and 2016, respectively. These conditions raise substantial doubt as to our ability to continue as a going concern. As of December 31, 2018, we had \$13.7 million in cash and cash equivalents. Our consolidated financial statements are prepared using Generally Accepted Accounting Principles in the United States of America applicable to a going concern, which contemplates

the realization of assets and the satisfaction of liabilities in the normal course of business. The accompanying consolidated financial statements do not include any adjustments relating to the recoverability and classification of recorded asset amounts and classification of liabilities should we be unable to continue as a going concern. As of the date of filing this report, we expect that our existing resources will be sufficient to fund our planned operations into the fourth quarter of 2019; however, additional capital resources will be needed to fund operations longer-term. If we are unsuccessful in accomplishing our plans, we may have to delay or terminate existing and/or planned clinical trials and other related activity, which could have a material adverse impact on our business. Our plan to continue as a going concern is includes obtaining capital from the sale of our equity securities, potential exercise of outstanding warrants, fees from licensing one or more of our product candidates, additional collaborations with our Iomab-ACT program and AWE technology platform, and short-term borrowings from banks, stockholders or other related parties, if needed. However, we cannot provide any assurance that we will be successful in accomplishing any of our plans. Our ability to continue as a going concern is dependent upon our ability to successfully accomplish the plans described above and eventually to secure other sources of financing and attain profitable operations.

**Results of Operations – Year Ended December 31, 2018 Compared to the Year Ended December 31, 2017**

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

	For the year ended December 31,		<b>Increase (Decrease)</b>
	2018	2017	
Revenues	\$-	\$-	\$-
Operating expenses:			
Research and development, net of reimbursements	17,094,778	17,719,855	(625,077 )
General and administrative	6,732,544	9,190,933	(2,453,389)
Total operating expenses	23,827,322	26,910,788	(3,083,466)
Other income			
Interest income	173,359	5,430	167,929
Gain on change in fair value of derivative liabilities	-	304,123	(304,123 )
Total other income	173,359	309,553	(136,194 )
Net loss	\$ (23,653,963)	\$ (26,601,235)	\$ (2,947,272)

**Revenues**

We recorded no commercial revenues for the years ended December 31, 2018 and 2017, respectively.

**Research and Development Expense**

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

Research and development expenses declined by \$0.7 million to \$17.0 million for the year ended December 31, 2018 compared to \$17.7 million for the year ended December 31, 2017. The decrease was primarily attributable to the recognition of payments received from Astellas, with such payments accounted for as a reduction in research and development expenses, as well as lower expenses related to Actimab-A and lower non-cash stock-based compensation expense.

### **General and Administrative Expenses**

General and administrative expenses declined by \$2.5 million to \$6.7 million for the year ended December 31, 2018 compared to \$9.2 million for the year ended December 31, 2017, primarily due to lower compensation expense, resulting from lower non-cash stock-based compensation expense during 2018 and one-time charges paid to certain former employees in 2017.

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

Other income of \$0.2 million for the year ended December 31, 2018 was attributable to interest income.

Historically, we accounted for certain instruments which do not have fixed settlement provisions as derivative instruments in accordance with FASB ASC 815-40, *Derivative and Hedging – Contracts in Entity’s Own Equity*. This was due to an anti-dilution provision for certain warrants that provide for a reduction to the exercise price if we issued equity or equity-linked instruments at an effective price per share less than the exercise price then in effect for the warrant, or a “down round provision”. As such, the warrants were re-measured at each balance sheet date based on estimated fair value. Changes in estimated fair value were recorded as non-cash adjustments within other income in our accompanying Consolidated Statements of Operations. We recorded a gain on the change in the estimated fair value of warrants of \$0.3 million for the year ended December 31, 2017.

As of April 1, 2018, we early adopted Accounting Standard Update, or ASU, 2017-11, which revised the guidance for instruments with down-round provisions. As such, we treated outstanding warrants as free-standing equity-linked instruments that are recorded to equity in the Consolidated Balance Sheet as of January 1, 2018. As a result, there was no gain or loss from the valuation of the derivative liability recorded for the year ended December 31, 2018.

**Net Loss**

Net loss decreased by \$2.9 million to \$23.7 million for the year ended December 31, 2018 compared to \$26.6 million for the year ended December 31, 2017. The decrease was primarily due to lower general and administrative expenses and research and development expenses.

**Results of Operations – Year Ended December 31, 2017 Compared to the Year Ended December 31, 2016**

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

	For the year ended December 31,		Increase
	2017	2016	(Decrease)
Revenues	\$-	\$-	\$-
Operating expenses:			
Research and development, net of reimbursements	17,719,855	17,828,287	(108,432 )
General and administrative	9,190,933	9,019,194	171,739
Total operating expenses	26,910,788	26,847,481	63,307
Other income (expense)			
Interest income (expense)	5,430	(5,007 )	10,437
Gain on change in fair value of derivative liabilities	304,123	2,530,764	(2,226,641)
Total other income (expense)	309,553	2,525,757	(2,216,204)
Net loss	\$(26,601,235)	\$(24,321,724)	\$(2,279,511)

**Revenues**

We recorded no commercial revenues for the years ended December 31, 2017 and 2016, respectively.

**Research and Development Expense**

Research and development expenses declined \$0.1 million to \$17.7 million for the year ended December 31, 2017 compared to \$17.8 million for the year ended December 31, 2016. The decrease was primarily attributable to the higher expenses in 2016 resulting from start-up costs for a Phase 2 trial for Actimab-A and closing costs associated with a Phase 1 trial of Actimab A, mostly offset by higher expenses related to Iomab-B.

### **General and Administrative Expenses**

General and administrative expenses increased by \$0.2 million to \$9.2 million for the year ended December 31, 2017 compared to \$9.0 million for the year ended December 31, 2016, primarily as a result of one-time charges paid to certain former employees and higher professional fees.

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

Other income (expense) was \$0.3 million and \$2.5 million for the years ended December 31, 2017 and 2016, respectively. The decline is attributable to the fluctuation of our stock price and its impact on the derivative value of certain warrants we issued in connection with a financing in December 2012.

### **Net Loss**

Net loss increased by \$2.3 million to \$26.6 million for the year ended December 31, 2017 compared to \$24.3 million for the year ended December 31, 2016. The increase was primarily due to one-time charges paid to certain former employees and the decrease in noncash other income, resulting from the lower gain on the change in fair value of our derivative warrant liabilities.



## Liquidity and Capital Resources

We have financed our operations primarily through sales of our stock and warrants.

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

	For the year ended		
	December 31,		
	2018	2017	2016
Cash used in operating activities	\$(20,571,056)	\$(21,553,346)	\$(20,789,237)
Cash used in investing activities	(96,092 )	(24,739 )	(109,819 )
Cash provided by financing activities	16,981,086	18,814,634	15,775,077
Net change in cash, cash equivalents and restricted cash	\$(3,686,062 )	\$(2,763,451 )	\$(5,123,979 )

### For the years ended December 31, 2018 and 2017

Net cash used in operating activities was \$20.6 million for the year ended December 31, 2018, a decline of \$1.0 million compared to \$21.6 million used in operations for the year ended December 31, 2017. The decrease reflects our lower research and development expenses, our receipt of payments from Astellas and lower compensation.

Net cash used in investing activities of \$96 thousand and \$25 thousand for the years ended December 31, 2018 and December 31, 2017, respectively, was for the purchase of equipment.

Net cash provided by financing activities was mainly generated by the sale of shares of common stock and warrants.

On October 18, 2018, we entered into a purchase agreement and a registration rights agreement with Lincoln Park Capital Fund, LLC or Lincoln Park, whereby we have the right to sell to Lincoln Park shares of common stock having an aggregate value of up to \$32.5 million, subject to certain limitations and conditions set forth in the agreements. As consideration for entering into the agreements, we issued to Lincoln Park 852,537 shares of common stock.

Pursuant to the purchase agreement, Lincoln Park initially purchased 3.4 million shares of common stock, at a price of \$0.74 per share, for a total gross purchase price of \$2.5 million. We have the right, from time to time, subject to certain daily limitations, to direct Lincoln Park to purchase up to an additional \$30.0 million. We control the timing and amount of any sales of common stock to Lincoln Park. In all instances, we may not sell shares of common stock to Lincoln Park if it would result in Lincoln Park beneficially owning more than 9.99% of its common stock.

The purchase agreement does not limit our ability to raise capital from other sources, except that (subject to certain exceptions) we may not enter into any variable-rate transaction, including the issuance of any floating conversion rate or variable priced equity-like securities) during the 30 months after the date of the purchase agreement. We have the right to terminate the purchase agreement at any time, at no cost to us.

Through December 31, 2018, we elected to sell to Lincoln Park an additional 1.0 million shares and received \$0.7 million.

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

**For the years ended December 31, 2017 and 2016**

Net cash used in operating activities was \$21.6 million for the year ended December 31, 2017 compared to \$20.8 million used in operations for the year ended December 31, 2016, the increase was due to increased activity from our clinical trials and one-time charges paid to certain former employees.

Net cash used in investing activities was \$25 thousand and \$110 thousand for the years ended December 31, 2017 and 2016, respectively.

Net cash provided by financing activities was \$18.8 million and \$15.8 million for the years ended December 31, 2017 and 2016, respectively.

During 2017, we issued 2.7 million shares of common stock for gross proceeds of approximately \$4.0 million as part of an at-the-market sales agreement with an investment bank. We paid expenses of approximately \$0.2 million resulting in net proceeds of \$3.8 million.

In August 2017, we completed an underwritten public offering of 21.5 million shares of common stock and warrants to purchase 18.3 million shares of common stock at an offering price of \$0.75 per share and related warrant. The warrants have an exercise price of \$1.05 per share and have a term of five years. The gross proceeds from this offering were approximately \$16.1 million, before deducting underwriting discounts and commissions and other estimated offering expenses payable by the Company resulting in net proceeds of approximately \$15.0 million.

In October 2016, we sold 8.0 million shares of common stock at a price of \$1.25 per share through an underwritten public offering.

During 2016, we issued 3.5 million shares of common stock for net proceeds of \$6.8 million as part of an at-the-market sales agreement with an investment bank.

As of the date of filing this report, we expect that our existing resources will be sufficient to fund our planned operations into the fourth quarter of 2019; however, additional capital resources will be needed to fund operations longer-term. If we are unsuccessful in accomplishing our plans, we may have to delay or terminate existing and/or

planned clinical trials and other related activity, which could have a material adverse impact on our business. Our plan to continue as a going concern includes obtaining capital from the sale of our equity securities, potential exercise of outstanding warrants, fees from licensing one or more of our product candidates, additional collaborations with our Iomab-ACT program and AWE technology platform, and short-term borrowings from banks, stockholders or other related parties, if needed. However, we cannot provide any assurance that we will be successful in accomplishing any of our plans. Our ability to continue as a going concern is dependent upon our ability to successfully accomplish the plans described above and eventually to secure other sources of financing and attain profitable operations.

### **Off-Balance Sheet Arrangements**

We do not have any off-balance sheet arrangements.

### **Critical Accounting Policies**

Our management's discussion and analysis of financial condition and results of operations is based on our consolidated financial statements, which have been prepared in accordance with accounting principles generally accepted in the United States, or GAAP. The preparation of these financial statements requires us to make estimates and judgments that affect the reported amounts of assets, liabilities and expenses and the disclosure of contingent assets and liabilities in our consolidated financial statements during the reporting periods. These items are monitored and analyzed by us for changes in facts and circumstances, and material changes in these estimates could occur in the future. We base our estimates on historical experience, known trends and events, and on various other factors that we believe are reasonable under the circumstances, the results of which form the basis for making judgments about the carrying value of assets and liabilities that are not readily apparent from other sources. Changes in estimates are reflected in reported results for the period in which they become known. Actual results may differ materially from these estimates under different assumptions or conditions.

### **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.

### **Research and Development Costs**

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

### **Share-Based Payments**

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

### **Income Taxes**

We use the asset and liability method to calculate deferred taxes. Deferred taxes are recognized based on the differences between the financial reporting and income tax bases of assets and liabilities using the enacted tax rates and laws that will be in effect when the differences are expected to reverse. We review 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 our assessment as to their realization.

We recognize tax when the positions meet a “more-likely-than-not” recognition threshold. There were no tax positions for which it is considered reasonably possible that the total amounts of unrecognized tax benefits will significantly increase or decrease within the next year. We recognize interest related to unrecognized tax benefits in interest

expense and penalties in operating expenses.

### Accounting Standards Recently Adopted

In November 2016, the Financial Accounting Standards Board (“FASB”) issued an Accounting Standards Update (“ASU”) amending the presentation of restricted cash within the consolidated statements of cash flows. The new guidance requires that restricted cash be added to cash and cash equivalents on the consolidated statements of cash flows. We adopted this ASU on January 1, 2018 on a retrospective basis with the following impact to our consolidated statements of cash flows for the year ended December 31, 2017:

	Previously Reported	Adjustment	As Revised
Net cash used in investing activities	\$(380,946)	\$ 356,207	\$(24,739)

As of December 31, 2018 and December 31, 2017, we had a certified deposit of \$391,131 and \$390,940, respectively, as collateral for a letter of credit issued in connection with a lease agreement and as of December 31, 2018, we had restricted cash of \$40,075 related to credit card accounts.

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

In July 2017, the FASB issued ASU No. 2017-11, *Earnings Per Share (Topic 260); Distinguishing Liabilities from Equity (Topic 480); Derivatives and Hedging (Topic 815): (Part I) Accounting for Certain Financial Instruments with Down Round Features*. These amendments simplify the accounting for certain financial instruments with down round features. The amendments require companies to disregard the down round feature when assessing whether the instrument is indexed to its own stock, for purposes of determining liability or equity classification. The guidance was adopted as of April 1, 2018.

### **Recent Accounting Standards**

From time to time, new accounting standards are issued by the FASB or other standard setting bodies. Unless otherwise discussed, we believe that the impact of recently issued standards that are not yet effective will not have a material impact on our consolidated financial position or results of operations upon adoption.

In February 2016, FASB issued ASU No. 2016-02 *Leases* (Topic 842), which creates new accounting and reporting guidelines for leasing arrangements. The standard requires that a lessee recognize the assets and liabilities that arise from operating leases. A lessee should recognize on its balance sheet a liability to make lease payments (the lease liability) and a right-of-use asset representing its right to use the underlying asset for the lease term. For leases with a term of 12 months or less, a lessee is permitted to make an accounting policy election by class of underlying asset not to recognize lease assets and lease liabilities. In transition, lessees and lessors are required to recognize and measure leases at the beginning of the earliest period presented using a modified retrospective approach. The guidance in ASU 2016-02 is effective for annual and interim reporting periods beginning after December 15, 2018. Our initial evaluation of our current leases does not indicate that the adoption of this standard will have a material impact on our consolidated statements of operations. We do expect that the adoption of the standard will have an impact on our consolidated balance sheets for the recognition of certain operating leases as right-of-use assets and lease liabilities

In June 2018, the FASB issued ASU 2018-07 to expand the scope of ASC Topic 718, *Compensation - Stock Compensation*, to include share-based payment transactions for acquiring goods and services from nonemployees. The standard is effective for fiscal years, and for interim periods within those fiscal years, beginning after December 15, 2018, with early adoption permitted. We are currently evaluating the impact of the new standard on our financial statements and related disclosures, but this is not expected to have an impact on our financial statements.



In August 2018, the FASB issued ASU 2018-13, *Fair Value Measurement - Disclosure Framework (Topic 820)*. The updated guidance improves the disclosure requirements on fair value measurements and is effective for fiscal years, and interim periods within those fiscal years, beginning after December 15, 2019. Early adoption is permitted upon issuance of the standard for disclosures modified or removed with a delay of adoption of the additional disclosures until their effective date. We are in the process of evaluating the provisions of the ASU but do not expect it to have a material effect on our consolidated financial statements.

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

### **Subsequent Events**

In January 2019, we sold 924,500 common shares through our at-the-market program and realized net proceeds of \$0.4 million.

Since December 31, 2018, holders of our March 2018 Series A warrants exercised 2.5 million shares, resulting in proceeds to us of \$1.5 million.

Since December 31, 2018, we granted stock options to our employees to purchase a total of 530,000 common shares at a price range from \$0.43 to \$0.58 per share related to new hires.

On March 6, 2019, the Company executed an amendment to the Company's 2013 Amended and Restated Stock Plan, as amended (the "Plan Amendment"). The Plan Amendment increases the number of shares of common stock that the Company is authorized to issue under the plan to 22,750,000 shares.

On March 6, 2019, the Company filed a Certificate of Amendment to our Certificate of Incorporation, as amended, with the Secretary of State of the State of Delaware to increase the number of authorized shares of Actinium's common stock from 400,000,000 to 600,000,000 shares.



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

We are not currently exposed to significant market risk related to changes in interest rates. As of December 31, 2018, our cash equivalents consisted of primarily of short-term money market funds. Our primary exposure to market risk is interest rate sensitivity, which is affected by changes in the general level of U.S. interest rates. Due to the short-term nature of the cash equivalents in our portfolio and the low risk profile of our cash equivalents, an immediate 10% change in interest rates would not have a material effect on the fair market value of our financial position or results of operations.

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

Inflation generally affects us by increasing our cost of labor and clinical trial costs. We do not believe that inflation had a material effect on our business, financial condition or results of operations during the years ended December 31, 2018, 2017 and 2016, respectively.

**ITEM 8. FINANCIAL STATEMENTS AND SUPPLEMENTARY DATA.**

**REPORT OF MANAGEMENT ON INTERNAL CONTROL OVER FINANCIAL REPORTING**

The management of Actinium Pharmaceuticals, 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, 2018. 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, 2018, the Company’s internal control over financial reporting is effective based on those criteria.

Marcum, LLP, 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/ Sandesh Seth

Sandesh Seth  
Chairman and Chief Executive Officer  
March 15, 2019

F-1

REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

To the Board of Directors and Stockholders of

Actinium Pharmaceuticals, Inc.

New York, New York

**Opinion on Internal Control over Financial Reporting**

We have audited Actinium Pharmaceutical, Inc.’s (the “Company”) internal control over financial reporting as of December 31, 2018, based on criteria established in *Internal Control-Integrated Framework (2013)* issued by the Committee of Sponsoring Organizations of the Treadway Commission. In our opinion, the Company maintained, in all material respects, effective internal control over financial reporting as of December 31, 2018, based on criteria established in *Internal Control—Integrated Framework (2013)* issued by the Committee of Sponsoring Organizations of the Treadway Commission.

We have also audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States) (“PCAOB”), the consolidated balance sheet as of December 31, 2018 and the related consolidated statements of operations, changes in shareholders’ equity, and cash flows for the year then ended of the Company and our report dated March 15, 2019 expressed an unqualified opinion with an explanatory paragraph related to the substantial doubt about the Company’s ability to continue as a going concern on those financial statements.

**Basis for Opinion**

The Company’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 Report of Management on Internal Control over Financial Reporting. Our responsibility is to express an opinion on the Company’s internal control over financial reporting based on our audit. We are a public accounting firm registered with the PCAOB and are required to be independent with respect to the Company in accordance with the U.S. federal securities laws and the applicable rules and regulations of the Securities and Exchange Commission and the PCAOB.

We conducted our audit in accordance with the standards of the PCAOB. 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.

### **Definition and Limitations of Internal Control over Financial Reporting**

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.

Because of the 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 degree of compliance with the policies or procedures may deteriorate.

/s/ Marcum LLP

Marcum LLP  
Houston, Texas  
March 15, 2019

F-2

REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

To the Board of Directors and Stockholders of

Actinium Pharmaceuticals, Inc.

New York, New York

**Opinion on the Financial Statements**

We have audited the accompanying consolidated balance sheet of Actinium Pharmaceutical, Inc. (the “Company”) as of December 31, 2018, the related consolidated statements of operations, changes in stockholders’ equity and cash flows for the year then ended, and the related notes (collectively referred to as the “financial statements”). In our opinion, the financial statements present fairly, in all material respects, the financial position of the Company as of December 31, 2018, and the results of its operations and its cash flows for the year then ended, 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) (“PCAOB”), the Company’s internal control over financial reporting as of December 31, 2018, based on the criteria established in Internal Control—Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission (COSO) in 2013 and our report dated March 15, 2019, expressed an unqualified opinion on the effectiveness of the Company’s internal control over financial reporting.

**Explanatory Paragraph – Going Concern**

The accompanying financial statements have been prepared assuming that the Company will continue as a going concern. As discussed in Note 1 to the financial statements, the Company has suffered recurring losses from operations, negative cash flows and has an accumulated deficit that raise substantial doubt about its ability to continue as a going concern. Management’s plans in regard to these matters are also described in Note 1. The financial statements do not include any adjustments that might result from the outcome of this uncertainty.

**Basis for Opinion**

These financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on the Company's financial statements based on our audits. We are a public accounting firm registered with the PCAOB and are required to be independent with respect to the Company in accordance with the U.S. federal securities laws and the applicable rules and regulations of the Securities and Exchange Commission and the PCAOB.

We conducted our audit in accordance with the standards of the PCAOB. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement, whether due to error or fraud. Our audit included performing procedures to assess the risks of material misstatement of the financial statements, whether due to error or fraud, and performing procedures that respond to those risks. Such procedures included examining, on a test basis, evidence regarding the amounts and disclosures in the financial statements. Our audit also included evaluating the accounting principles used and significant estimates made by management, as well as evaluating the overall presentation of the financial statements. We believe that our audit provides a reasonable basis for our opinion.

/s/ Marcum LLP

We have served  
as the Company's  
auditor since  
2012.

Marcum LLP  
Houston, Texas  
March 15, 2019

F-3



REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

To the Board of Directors and Stockholders of

Actinium Pharmaceuticals, Inc.

New York, New York

**Opinion on the Financial Statements**

We have audited the accompanying consolidated balance sheet of Actinium Pharmaceuticals, Inc. (the “Company”) as of December 31, 2017, the related consolidated statements of operations, changes in stockholders’ equity and cash flows for the years ended December 31, 2017 and 2016, including the related notes (collectively referred to as the “financial statements”).

In our opinion, the financial statements present fairly, in all material respects, the financial position of the Company as of December 31, 2017, and the results of its operations and its cash flows for the years ended December 31, 2017 and 2016, in conformity with accounting principles generally accepted in the United States of America.

**Basis for Opinion**

These financial statements are the responsibility of the Company’s management. Our responsibility is to express an opinion on the Company’s financial statements based on our audits. We are a public accounting firm registered with the PCAOB and are required to be independent with respect to the Company in accordance with the U.S. federal securities laws and the applicable rules and regulations of the Securities and Exchange Commission and the PCAOB.

We conducted our audits in accordance with the standards of the PCAOB. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement, whether due to error or fraud. Our audits included performing procedures to assess the risks of material misstatement of the financial statements, whether due to error or fraud, and performing procedures that respond to those risks. Such procedures included examining, on a test basis, evidence regarding the amounts and disclosures in the financial statements. Our audits also included evaluating the accounting principles used and significant estimates made by management, as well as evaluating the overall presentation of the financial statements. We believe that our

audits provide a reasonable basis for our opinion.

/s/ GBH CPAs, PC

We have served as  
the Company's  
auditor since 2012.

GBH CPAs, PC  
[www.gbhcpas.com](http://www.gbhcpas.com)  
Houston, Texas  
March 16, 2018

F-4

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

	December 31, 2018	December 31, 2017
<b>Assets</b>		
<b>Current Assets:</b>		
Cash and cash equivalents	\$ 13,673,308	\$ 17,399,636
Restricted cash – current	40,075	-
Prepaid expenses and other current assets	616,222	439,322
<b>Total Current Assets</b>	<b>14,329,605</b>	<b>17,838,958</b>
Property and equipment, net of accumulated depreciation of \$266,381 and \$215,660	118,799	57,350
Security deposit	49,859	49,859
Restricted cash	391,131	390,940
<b>Total Assets</b>	<b>\$ 14,889,394</b>	<b>\$ 18,337,107</b>
<b>Liabilities and Stockholders' Equity</b>		
<b>Current Liabilities:</b>		
Accounts payable and accrued expenses	\$5,814,004	\$4,650,088
Note payable	249,239	-
Derivative liabilities	-	15,916
<b>Total Current Liabilities</b>	<b>6,063,243</b>	<b>4,666,004</b>
Long-term capital lease obligation	13,354	-
<b>Total Liabilities</b>	<b>6,076,597</b>	<b>4,666,004</b>
<b>Commitments and contingencies</b>		
<b>Stockholders' Equity:</b>		
Preferred stock, \$0.001 par value; 50,000,000 shares authorized, 0 shares issued and outstanding	-	-
Common stock, \$0.001 par value; 600,000,000 and 400,000,000 shares authorized; 115,703,044 and 80,072,334 shares issued and outstanding	115,703	80,072
Additional paid-in capital	195,554,332	176,744,068
Accumulated deficit	(186,857,238)	(163,153,037)
<b>Total Stockholders' Equity</b>	<b>8,812,797</b>	<b>13,671,103</b>
<b>Total Liabilities and Stockholders' Equity</b>	<b>\$ 14,889,394</b>	<b>\$ 18,337,107</b>

See accompanying notes to the consolidated financial statements.

F-5

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

	For the Year Ended		
	December 31,		
	2018	2017	2016
Revenue	\$-	\$-	\$-
Operating expenses:			
Research and development, net of reimbursements	17,094,778	17,719,855	17,828,287
General and administrative	6,732,544	9,190,933	9,019,194
Total operating expenses	23,827,322	26,910,788	26,847,481
Loss from operations	(23,827,322 )	(26,910,788 )	(26,847,481 )
Other income (expense):			
Interest income (expense)	173,359	5,430	(5,007 )
Gain on change in fair value of derivative liabilities	-	304,123	2,530,764
Total other income (expense)	173,359	309,553	2,525,757
Net loss	\$(23,653,963 )	\$(26,601,235 )	\$(24,321,724 )
Net loss per common share - basic and diluted	\$(0.22 )	\$(0.40 )	\$(0.50 )
Weighted average common shares outstanding - basic and diluted	106,041,809	66,746,389	48,463,268

See accompanying notes to the consolidated financial statements.

**Actinium Pharmaceuticals, Inc.****Consolidated Statement of Changes in Stockholders' Equity****For the Years Ended December 31, 2018, 2017 and 2016**

	Common Stock		Additional Paid-In Capital	Accumulated Deficit	Stockholders' Equity
	Shares	Amount			
Balance, January 1, 2016	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
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
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
Stock-based compensation	93,385	93	3,474,282	-	3,474,375
Sale of common stock and warrants, net of offering costs	24,172,973	24,173	18,765,461	-	18,789,634
Issuance of common stock from exercise of warrants	4,234	4	(4)	-	-
Net loss	-	-	-	(26,601,235)	(26,601,235)
Balance, December 31, 2017	80,072,334	80,072	176,744,068	(163,153,037)	13,671,103
Modified retroactive adjustment for derivative liability	-	-	66,154	(50,238)	15,916
Stock-based compensation	156,393	157	1,798,498	-	1,798,655
Sale of common stock and warrants, net of offering costs	34,614,448	34,614	16,941,623	-	16,976,237
Issuance of commitment shares to Lincoln Park	852,537	853	(853)	-	-
Issuance of common stock from exercise of warrants	7,332	7	4,842	-	4,849
Net loss	-	-	-	(23,653,963)	(23,653,963)
Balance, December 31, 2018	115,703,044	\$115,703	\$195,554,332	\$(186,857,238)	\$8,812,797

See accompanying notes to the consolidated financial statements.

F-7

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

	For the Year Ended December 31,		
	2018	2017	2016
<b>Cash Flows from Operating Activities:</b>			
Net loss	\$(23,653,963)	\$(26,601,235)	\$(24,321,724)
Adjustments to reconcile net loss to net cash used in operating activities:			
Stock-based compensation expense	1,798,655	3,493,731	4,297,778
Depreciation expense	50,721	55,938	77,523
Gain on change in fair value of derivative liabilities	-	(304,123 )	(2,530,764 )
Changes in operating assets and liabilities:			
(Increase) decrease in:			
Prepaid expenses and other current assets	100,032	1,397,129	(1,032,988 )
Increase in:			
Accounts payable and accrued expenses	1,133,499	405,214	2,720,938
Net Cash Used In Operating Activities	(20,571,056)	(21,553,346)	(20,789,237)
<b>Cash Flows from Investing Activities:</b>			
Payment of security deposit	-	-	(49,859 )
Purchase of property and equipment	(96,092 )	(24,739 )	(59,960 )
Net Cash Used In Investing Activities	(96,092 )	(24,739 )	(109,819 )
<b>Cash Flows from Financing Activities:</b>			
Payments on note payable	-	-	(265,695 )
Proceeds from sales of shares of common stock and warrants, net of offering costs	16,976,237	18,814,634	16,022,667
Proceeds from the exercise of stock options	-	-	18,105
Proceeds from the exercise of warrants	4,849	-	-
Net Cash Provided By Financing Activities	16,981,086	18,814,634	15,775,077
Net change in cash, cash equivalents and restricted cash	(3,686,062 )	(2,763,451 )	(5,123,979 )
Cash, cash equivalents and restricted cash at beginning of year	17,790,576	20,554,027	25,678,006
Cash, cash equivalents and restricted cash at end of year	\$14,104,514	\$17,790,576	\$20,554,027
<b>Supplemental disclosures of cash flow information:</b>			
Cash paid for interest	\$-	\$-	\$5,007
Cash paid for taxes	\$-	\$-	\$-
<b>Supplemental disclosure of non-cash investing and financing activities:</b>			
Stock issuance costs included in accounts payable and accrued expenses	\$-	\$25,000	\$-



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

Prepaid expenses financed by accounts payable and notes payable	\$276,932	\$-	\$-
Capital lease of office equipment	\$16,078	\$-	\$-
Transfer from derivative liability classification to equity classification	\$-	\$-	\$17,455

See accompanying notes to the consolidated financial statements.

F-8

**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”, “Actinium”, or “We”) is a clinical-stage, biopharmaceutical company focused on developing and potentially commercializing therapies for targeted conditioning prior to cell therapies such as a BMT or Bone Marrow Transplant or CAR-T, a type of cellular therapy that genetically alters a patient’s own T cells to target and kill their cancer cells, and for other adoptive cell therapies. In addition, the Company is also developing potential therapies for targeting and killing of cancer cells either as single agents or in combination with other drugs.

**Going concern** - The Company has never generated revenue. Currently it does not have a recurring source of revenue to cover its operating costs. The Company has incurred net losses and negative operating cash flows since inception. As of December 31, 2018 and 2017, the Company’s accumulated deficit was \$186.9 million and \$163.2 million, respectively. The Company’s net loss was \$23.7 million, \$26.6 million, and \$24.3 million for the years ended December 31, 2018, 2017 and 2016, respectively. These conditions raise substantial doubt as to our ability to continue as a going concern. As of December 31, 2018, in the Company had a balance of its cash and cash equivalents of \$13.7 million. The Company’s consolidated financial statements are prepared using Generally Accepted Accounting Principles in the United States of America applicable to a going concern, which contemplates the realization of assets and the satisfaction of liabilities in the normal course of business. The accompanying consolidated financial statements do not include any adjustments relating to the recoverability and classification of recorded asset amounts and classification of liabilities should the Company be unable to continue as a going concern. As of the date of filing this report, the Company expects that its existing resources will be sufficient to fund its planned operations into the fourth quarter of 2019; however, additional capital resources will be needed to fund operations longer-term. If the Company is unsuccessful in accomplishing its plans, it may have to delay or terminate existing and/or planned clinical trials and other related activity, which could have a material adverse impact on its business. The Company plans to continue as a going concern include obtaining capital from the sale of its equity securities, potential exercise of outstanding warrants, fees from licensing one or more of our product candidates, additional collaborations with our Iomab-ACT program and AWE technology platform, and short-term borrowings from banks, stockholders or other related parties, if needed. However, the Company cannot provide any assurance that we will be successful in accomplishing any of our plans.

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

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

**Cash and Cash Equivalents** - The Company considers all highly liquid accounts with original maturities of three months or less to be cash equivalents. Balances held by the Company are typically in excess of Federal Deposit Insurance Corporation insured limits.

**Property and Equipment** - Machinery and equipment are recorded at cost and depreciated on a straight-line basis over estimated useful lives of three to five years. Furniture and fixtures are recorded at cost and depreciated on a straight-line basis over estimated useful lives of seven years. When assets are retired, 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. Capitalized lease assets are recorded at the lesser of the present value of minimum lease payments or fair value and amortized over the estimated useful life of the related property or term of the lease.

**Fair Value of Financial Instruments** - Fair value is defined as the price that would be received to sell an asset, or paid to transfer a liability, in an orderly transaction between market participants. A fair value hierarchy has been established for valuation inputs that gives the highest priority to quoted prices in active markets for identical assets or liabilities and the lowest priority to unobservable inputs. As required by ASC 820 “*Fair Value Measurements and Disclosures*”, financial assets and liabilities are classified in their entirety based on the lowest level of input that is significant to the fair value measurement. The Company’s assessment of the significance of a particular input to the fair value measurement requires judgment and may affect the valuation of fair value assets and liabilities and their placement within the fair value hierarchy levels.

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 provides for income taxes using the liability method. Under this method, deferred income tax assets and liabilities are determined based on the differences between the financial statement carrying amounts of existing assets and liabilities at each year-end and their respective tax bases, and are measured using enacted tax rates in effect for the year in which the differences are expected to affect taxable income. Significant judgment is required by management to determine the Company’s provision for income taxes, deferred tax assets and liabilities, and the valuation allowance to record against net deferred tax assets, which are based on complex and evolving tax regulations throughout the world.

Deferred tax assets and other tax benefits are recorded when it is more likely than not that the position will be sustained upon audit. There were no tax positions for which it is considered reasonably possible that the total amounts of unrecognized tax benefits will significantly increase or decrease within the next year. The Company recognizes interest related to unrecognized tax benefits in interest expense and penalties in operating expenses.

The Tax Cuts and Jobs Act, or the Act, was enacted in December 2017. The Act reduces the U.S. federal corporate tax rate from 35% to 21%. As a result, the Company evaluated and adjusted its deferred tax assets to reflect the new corporate tax rates as of December 31, 2017. As of December 31, 2018, upon completing its analysis of the Act, the Company believes that its disclosures in its financial statements as of December 31, 2017 remain accurate.

**Revenue Recognition** - The Company adopted new accounting guidance for revenue recognition, effective January 1, 2018, which did not have a significant impact on the Company's financial statements. Beginning January 1, 2018, revenues are recognized when control of the promised goods or services is transferred to customers in an amount that reflects the consideration expected to be entitled to in exchange for those goods or services.

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

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

**Net Loss Per Common Share** - Basic loss per common share is computed by dividing the net loss available to common stockholders by the weighted average number of common shares outstanding during the reporting period. For the years ended December 31, 2018, 2017 and 2016, the Company's potentially dilutive shares, which include outstanding common stock options and warrants have not been included in the computation of diluted net loss per share as the result would have been anti-dilutive.

	December 31, 2018	December 31, 2017	December 31, 2016
Options	7,236,101	5,174,592	5,906,886
Warrants	55,820,876	25,662,340	8,964,752
Total	63,056,977	30,836,932	14,871,638

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

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

**Accounting Standards Recently Adopted** - In November 2016, the Financial Accounting Standards Board ("FASB") issued an Accounting Standards Update ("ASU") amending the presentation of restricted cash within the consolidated statements of cash flows. The new guidance requires that restricted cash be added to cash and cash equivalents on the consolidated statements of cash flows. The Company adopted this ASU on January 1, 2018 on a retrospective basis with the impact to its consolidated statements of cash flows for the year ended December 31, 2017:

	Previously Reported	Adjustment	As Revised
Net cash used in investing activities	\$(380,946)	\$ 356,207	\$(24,739)

There was no impact to the cash flows from operating, investing and financing activities for the year ended December 31, 2016 as the amount of restricted cash did not change during 2016.

Following is a summary of cash and cash equivalents and restricted cash at December 31, 2018, 2017 and 2016, respectively:

	December 31, 2018	December 31, 2017	December 31, 2016
Cash and cash equivalents	\$13,673,308	\$17,399,636	\$20,519,294
Restricted cash – current	40,075	-	34,733
Restricted cash – long term	391,131	390,940	-
Cash and cash equivalent and restricted cash	\$14,104,514	\$17,790,576	\$20,554,027

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

In July 2017, the FASB issued ASU No. 2017-11, *Earnings Per Share (Topic 260); Distinguishing Liabilities from Equity (Topic 480); Derivatives and Hedging (Topic 815): (Part I) Accounting for Certain Financial Instruments with Down Round Features*. These amendments simplify the accounting for certain financial instruments with down round features. The amendments require companies to disregard the down round feature when assessing whether the instrument is indexed to its own stock, for purposes of determining liability or equity classification. The guidance was adopted as of April 1, 2018. See Note 2 for further discussion.

### Recent Accounting Standards –

In February 2016, FASB issued ASU No. 2016-02 *Leases (Topic 842)*, which creates new accounting and reporting guidelines for leasing arrangements. The standard requires that a lessee recognize the assets and liabilities that arise from operating leases. A lessee should recognize on its balance sheet a liability to make lease payments (the lease liability) and a right-of-use asset representing its right to use the underlying asset for the lease term. For leases with a term of 12 months or less, a lessee is permitted to make an accounting policy election by class of underlying asset not to recognize lease assets and lease liabilities. In transition, lessees and lessors are required to recognize and measure leases at the beginning of the earliest period presented using a modified retrospective approach. The guidance in ASU 2016-02 is effective for annual and interim reporting periods beginning after December 15, 2018. The Company's initial evaluation of its current leases does not indicate that the adoption of this standard will have a material impact on its consolidated statements of operations. However, the Company does expect that the adoption of the standard will have an impact on its consolidated balance sheets for the recognition of certain operating leases as right-of-use assets and lease liabilities.

In June 2018, the FASB issued ASU 2018-07 to expand the scope of ASC Topic 718, *Compensation - Stock Compensation*, to include share-based payment transactions for acquiring goods and services from nonemployees. The standard is effective for fiscal years, and for interim periods within those fiscal years, beginning after December 15, 2018, with early adoption permitted. The Company is currently evaluating the impact of the new standard on its financial statements and related disclosures, but does not expect this ASU to have a material impact on its financial statements.

In August 2018, the FASB issued ASU 2018-13, *Fair Value Measurement - Disclosure Framework (Topic 820)*. The updated guidance improves the disclosure requirements on fair value measurements and is effective for fiscal years, and interim periods within those fiscal years, beginning after December 15, 2019. Early adoption is permitted upon issuance of the standard for disclosures modified or removed with a delay of adoption of the additional disclosures until their effective date. The Company is in the process of evaluating the provisions of the ASU but does not expect it to have a material effect on its consolidated financial statements.

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

In August 2018, the SEC adopted the final rule under SEC Release No. 33-10532, *Disclosure Update and Simplification*, amending certain disclosure requirements that were redundant, duplicative, overlapping, outdated or superseded. In addition, the amendments expanded the disclosure requirements on the analysis of stockholders' equity for interim financial statements. Under the amendments, an analysis of changes in each caption of stockholders' equity presented in the balance sheet must be provided in a note or separate statement. The analysis should present a reconciliation of the beginning balance to the ending balance of each period for which a statement of comprehensive income is required to be filed. The Company anticipates its first presentation of changes in stockholders' equity will be included in its Form 10-Q for the three months ended March 31, 2019.

## **Note 2 - Derivative Liabilities**

Historically, the Company accounted for certain instruments, which do not have fixed settlement provisions, as derivative instruments in accordance with FASB ASC 815-40, *Derivative and Hedging – Contracts in Entity's Own Equity*. This was due to an anti-dilution provision for the warrants that provides for a reduction to the exercise price if



the Company issues equity or equity-linked instruments in the future at an effective price per share less than the exercise price then in effect for the warrant (“down round provision”). As such, the warrants were re-measured at each balance sheet date based on estimated fair value. Changes in estimated fair value were recorded as non-cash adjustments within other income (expense), net, in the Company’s accompanying Consolidated Statements of Operations. The Company recorded a gain on the change in the estimated fair value of warrants of \$0.3 million and \$2.5 million for the years ended December 31, 2017 and 2016, respectively.

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

F-12

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

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

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

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

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

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

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

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

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

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

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

As a result of an agreement with Lincoln Park Capital Fund, LLC (See Note 7) the exercise price was further reset to \$1.23 per share, with an immaterial change in the fair value of the warrants before and after the price reset.

### Note 3 - Prepaid Expenses and Other Current Assets

Prepaid expenses and other current assets consisted of the following at December 31, 2018 and 2017:

	<b>December 31, 2018</b>	<b>December 31, 2017</b>
Prepaid insurance	\$ 339,336	\$ 72,371
Prepaid clinical trial expenses	171,128	226,997
Other prepaid expenses	105,758	139,954
Total prepaid expenses and other current assets	\$ 616,222	\$ 439,322

In December 2018, the Company issued a note payable of \$249,239 for its insurance premiums; payments are scheduled during 2019.

**Note 4 - Property and Equipment**

Property and equipment consisted of the following at December 31, 2018 and 2017:

	<b>Lives</b>	<b>December 31, 2018</b>	<b>December 31, 2017</b>
Lab equipment	5 years	\$ 176,500	\$ 116,070
Office equipment & furniture	3 - 7 years	208,680	156,940
Less: accumulated depreciation		(266,381 )	(215,660 )
Property and equipment, net		\$ 118,799	\$ 57,350

In December 2018, the Company entered into a five-year capital lease agreement for office equipment and services for \$906 per month. At December 31, 2018, the capitalized value associated with the lease agreement was \$16,078.

Depreciation expense consisted of the following for the years ended December 31, 2018, 2017 and 2016, respectively:

	<b>December 31, 2018</b>	<b>December 31, 2017</b>	<b>December 31, 2016</b>
Research & development	\$ 20,170	\$ 20,352	\$ 41,632
General administrative	30,551	35,586	35,891
Depreciation expense	\$ 50,721	\$ 55,938	\$ 77,523

**Note 6 - Commitments and Contingencies****License and Research Agreements**

The Company has entered into agreements with third parties for the rights to certain intellectual property, manufacturing and clinical trial services under which the Company may incur obligations to make payments including upfront payments as well as milestone and royalty payments. Notable inclusions in this category are:

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, 2018, 2017 and 2016, the Company purchased material from ORNL of approximately \$0.3 million, \$0.6 million and \$1.0 million, respectively. On December 19, 2018, the Company signed a contract with ORNL to purchase \$0.2 million of radioactive material during calendar year 2019.

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.

- b. The Company has been granted exclusive rights to the BC8 antibody and related master cell bank developed by FHCRC. A milestone payment of \$1 million will be due to FHCRC upon FDA approval of the first drug utilizing the licensed BC 8 antibody. Upon commercial sale of the drug, royalty payments of 2% of net sales will be due to FHCRC.

On February 27, 2014, the Company entered into a manufacturing agreement with Goodwin Biotechnology Inc. (“Goodwin”). Goodwin oversees the current Good Manufacturing Practices (“cGMP”) production of a monoclonal antibody used in the Phase 3 clinical trial of Iomab-B. As of December 31, 2018, the remaining cost of the service agreement is \$1.0 million. During the years ended December 31, 2018, 2017 and 2016, the Company paid Goodwin \$1.2 million, \$1.4 million and \$0.7 million, respectively.

On February 16, 2016, the Company entered into an agreement with Medpace, Inc. (“Medpace”), a Contract Research Organization, (“CRO”). Medpace provides project management services for the Iomab-B study. The total project is currently estimated to cost approximately \$10.2 million. As of December 31, 2018, the remaining cost of the agreement is approximately \$3.3 million. Medpace bills the Company when services are rendered and the Company records the related expense to research and development costs. During the years ended December 31, 2018, 2017 and 2016, the Company paid Medpace \$3.1 million, \$2.8 million and \$2.6 million, respectively.

On August 4, 2016, the Company entered into a CRO agreement with George Clinical Services, (“George”). George provides project management services for the study of Actimab-A used for a Phase 2 clinical trial. The total project is estimated to cost approximately \$4.6 million. As of December 31, 2018, the remaining cost of the agreement is approximately \$0.5 million. George bills the Company when services are rendered and the Company records the related expense to research and development costs. During the years ended December 31, 2018, 2017 and 2016, the Company paid George \$1.9 million, \$0.7 million and \$0.1 million, respectively.

## Lease Agreements

The Company does not own any real property. It currently leases office space located at 275 Madison Avenue, New York, NY. The lease is for 5,790 square feet and has a term of seven years and three months, with an expiration date of September 6, 2022, with a current annual rate of \$312,660 until June 8, 2019 and \$341,610 for the remaining life of the lease. The Company is also responsible for certain other costs, such as insurance, taxes, utilities, and maintenance. The Company issued a letter of credit of \$390,825 in connection with the lease and maintained a \$391,131 certified deposit as collateral for the letter of credit.

In 2017, the Company also entered into a license agreement for furniture and fixtures located at its office space. Pursuant to the terms of the agreement, the Company leases the furniture and fixtures and tenant improvements located in the office space for the same term as the office space for \$7,529 per month. At any time during the term of this amended agreement, the Company has the right to purchase the furniture, and fixtures.

In December 2018, the Company entered into a five-year lease agreement for office equipment and services for \$906 per month and the capitalized value associated with the lease agreement was \$16,078.

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

Future minimum obligations on all of the Company's operating leases with a term over one year are:

For the year ending December 31:

2019	\$419,896
2020	431,958
2021	431,958
2022	287,972
Total	\$1,571,784

F-15

## Note 7 - Equity

On October 18, 2018, the Company and Lincoln Park Capital Fund, LLC (“Lincoln Park”) entered into a purchase agreement and a registration rights agreement, pursuant to which the Company has the right to sell to Lincoln Park shares of the Company’s common stock having an aggregate value of up to \$32,500,000, subject to certain limitations and conditions set forth in the agreement. As consideration for entering into the purchase agreement, the Company issued to Lincoln Park 852,537 shares of common stock, determined to be offering costs as part of the financing. These shares had a fair value of \$0.6 million based on the market price on the issuance date.

Pursuant to the purchase agreement, Lincoln Park initially purchased 3,376,554 shares of common stock, at a price of \$0.74 per share, for a total gross purchase price of \$2,500,000. As often as every business day from and after one business day following the date of the initial purchase and over the 30-month term of the agreement, and up to an aggregate amount of an additional \$30,000,000 (subject to certain limitations) of shares of common stock, the Company has the right, from time to time, at its sole discretion and subject to certain conditions, to direct Lincoln Park to purchase up to 400,000 shares of common stock, with such amount increasing as the closing sale price of the common stock increases; provided Lincoln Park’s obligation under any single such purchase will not exceed \$1,500,000, unless the Company and Lincoln Park mutually agree to increase the maximum amount of such single purchase (each, a “Regular Purchase”). If the Company directs Lincoln Park to purchase the maximum number of shares of common stock it then may sell in a Regular Purchase, then in addition to such Regular Purchase, and subject to certain conditions and limitations in the agreement, the Company may direct Lincoln Park in an “accelerated purchase” to purchase an additional amount of common stock that may not exceed the lesser of (i) 300% the number of shares purchased pursuant to the corresponding Regular Purchase or (ii) 30% of the total number of shares of the Company’s common stock traded during a specified period on the applicable purchase date as set forth in the agreement. Under certain circumstances and in accordance with the agreement, the Company may direct Lincoln Park to purchase shares in multiple accelerated purchases on the same trading day.

The Company controls the timing and amount of any sales of its common stock to Lincoln Park. There is no upper limit on the price per share that Lincoln Park must pay for its common stock under the agreement, but in no event will shares be sold to Lincoln Park on a day the closing price is less than the floor price specified in the agreement. In all instances, the Company may not sell shares of its common stock to Lincoln Park under the purchase agreement if it would result in Lincoln Park beneficially owning more than 9.99% of its common stock.

The agreement does not limit the Company’s ability to raise capital from other sources at the Company’s sole discretion, except that (subject to certain exceptions) the Company may not enter into any variable rate transaction (as defined in the agreement, including the issuance of any floating conversion rate or variable priced equity-like securities) during the 30 months after the date of the Purchase Agreement. The Company has the right to terminate the agreement at any time, at no cost to the Company.



Through December 31, 2018, the Company elected to sell to Lincoln Park an additional 1.0 million shares and received \$0.7 million.

In March 2018, the Company sold an aggregate of 30,237,894 units consisting of an aggregate of 30,237,894 shares of common stock, 7,559,445 series A warrants and 22,678,393 series B warrants, with each series A warrant exercisable for one share of common stock at an exercise price of \$0.60 per share and each series B warrant exercisable for one share of common stock at an exercise price of \$0.70 per share, resulting in gross proceeds to Actinium of approximately \$15.1 million (each unit was sold at \$0.50 per unit), and net proceeds of approximately \$13.8 million after deducting expenses relating to dealer-manager fees and other offering expenses.

During the year ended December 31, 2017, the Company issued 2,672,973 shares of common stock for gross proceeds of approximately \$4.0 million as part of its At-The-Market sales agreement with an investment bank. The Company paid expenses of approximately \$0.2 million resulting in net proceeds of \$3.8 million.

On August 2, 2017, the Company completed an underwritten public offering of 21,500,000 shares of its common stock and warrants to purchase 18,275,000 shares of the Company's common stock at an offering price to the public of \$0.75 per share and related warrant. The warrants have an exercise price of \$1.05 per share and have a term of five years. The gross proceeds from this offering were approximately \$16.1 million, before deducting underwriting discounts and commissions and other estimated offering expenses payable by the Company resulting in net proceeds of approximately \$15.0 million.

During the year ended December 31, 2017, the Company issued 67,385 common shares for consulting services. The shares have a total value of \$99 thousand based on the Company's stock price on the grant date at \$1.47 per share. During the year ended December 31, 2017, the Company also issued 4,234 common shares for the cashless exercise of warrants.

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, for net proceeds of \$9.3 million.

During 2016, the Company also issued 3,500,000 shares of common stock for net proceeds of \$6.8 million as part of an at-the-market (ATM) sales agreement with an investment bank.

During the year ended December 31, 2016, the Company issued 125,862 common shares for the cashless exercise of warrants.

### **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 was 2,750,000 shares. In December 2015, 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, 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. In December 2017, shareholders of the Company approved the sixth amendment to the plan and increased the number of shares authorized under the plan to 17,750,000 shares. In December 2018, shareholders of the Company approved the seventh amendment to the plan and increased the number of shares authorized under the plan to 22,750,000 shares.

### **2013 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 was 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 2018, the Company granted 107,911 restricted common shares for consulting services, which all vested during 2018. The shares had a total value of \$72,825. During the year ended December 31, 2018, the Company issued 156,393 common shares for restricted shares that became fully vested, of which 81,393 shares were granted prior to 2018.

As of December 31, 2018, the Company has yet to issue 254,819 common shares for restricted shares that have vested. As of December 31, 2018, all restricted shares granted were vested with no unamortized compensation expenses.

During the year ended December 31, 2017, the Company issued 26,000 common shares for restricted shares that became fully vested. The Company also granted 59,393 common shares for consulting services. The shares have a total value of \$65,813 based on the services provided.

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. 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 years ended December 31, 2018, 2017 and 2016, the Company recorded stock-based compensation expense of \$0.1 million, \$0.2 million and \$0.6 million, respectively, for the restricted shares granted.

**Stock Options**

Following is a summary of option activities for the years ended December 31, 2018, 2017 and 2016:

	<b>Number of Options</b>	<b>Weighted Average Exercise Price</b>	<b>Weighted Average Remaining Contractual Term (in years)</b>	<b>Aggregate Intrinsic Value</b>
Outstanding, January 1, 2016	3,971,583	\$ 4.34	8.01	2,964,146
Granted	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
Granted	2,597,500	1.32		
Cancelled	(3,329,794)	2.85		
Outstanding, December 31, 2017	5,174,592	2.83	7.95	2,648
Granted	3,577,159	0.69		
Cancelled	(1,515,650)	2.96		
Outstanding, December 31, 2018	7,236,101	1.74	7.97	6,400
Exercisable, December 31, 2018	3,021,818	2.88	6.55	-

During the year ended December 31, 2018, the Company granted its employees and members of the Board of Directors 3,577,159 options to purchase Company common stock with an exercise price ranging from \$0.344 to \$0.7829 per share, a term of 10 years, and a vesting period from 4 to 4.2 years. The options have an aggregated fair value of \$1.7 million that was calculated using the Black-Scholes option-pricing model. Variables used in the Black-Scholes option-pricing model include: (1) discount rate range from 2.34% to 2.99% (2) expected life of 6 years, (3) expected volatility range from 78.8% to 80.4%, and (4) zero expected dividends.

During the year ended December 31, 2017, the Company granted its employees and members of the Board of Directors 2,597,500 options to purchase Company common stock with an exercise price ranging from \$0.57 to \$1.58 per share, a term of 10 years, and a vesting period from 4 to 4.2 years. The options have an aggregated fair value of \$2.4 million that was calculated using the Black-Scholes option-pricing model. Variables used in the Black-Scholes option-pricing model include: (1) discount rate range from 1.84% to 2.28% (2) expected life of 6 years, (3) expected volatility range from 80.83% to 82.37%, and (4) zero expected dividends.

On June 6, 2017, a director, resigned from the Company and the Company entered into an agreement with the director. Pursuant to the agreement, all the outstanding vested options, (which originally were to expire 90 days from termination date), as well as 68,200 unvested options granted prior to December 31, 2016, shall be exercisable until the end of the term of each option grant agreement. As a result of the modification, the Company recorded an additional expense of approximately \$174,000 for the incremental fair value of the options, calculated using the Black-Scholes option-pricing model. Variables used in the Black-Scholes option-pricing model include: (1) discount rate range from 0.97% to 1.39% (2) expected life of 3 months to 8.9 years, (3) expected volatility range from 45.72% to 79.81%, 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, 2018, 2017 and 2016, options to purchase 1,515,650, 3,329,794 and 266,485 common shares were cancelled, respectively, upon the termination of employment.

There were no exercises of options during the years ended December 31, 2018 and 2017. During the year ended December 31, 2016, the Company received gross proceeds of \$18,105 for the exercise of stock options for 23,212 shares.

The fair values of all options issued and outstanding are being amortized over their respective vesting periods. The unrecognized compensation expense at December 31, 2018 was approximately \$2.6 million. During each of the years ended December 31, 2018, 2017 and 2016, the Company recorded total option expense of approximately \$1.7 million, \$3.1 million and \$3.6 million, respectively.

## Warrants

Following is a summary of warrant activities for the years ended December 31, 2018, 2017 and 2016, respectively:

	Number of Units	Weighted Average Exercise Price	Weighted Average Remaining Contractual Term (in years)	Aggregate Intrinsic Value
Outstanding, January 1, 2016	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
Granted	18,496,575	1.05		
Exercised	(9,364 )	0.78		
Cancelled	(1,789,623 )	2.22		
Outstanding, December 31, 2017	25,662,340	1.89	3.62	995,373
Granted	30,360,466	0.67		
Exercised	(7,332 )	0.66		
Cancelled	(194,598 )	9.00		
Outstanding, December 31, 2018	55,820,876	1.20	2.04	569,038
Exercisable, December 31, 2018	55,613,377	1.19	2.03	566,676

On November 8, 2018, the Company amended certain warrants, originally dated December 17, 2012, that had been issued to three entities affiliated with the family of the Mr. Sandesh Seth, Chairman and CEO, Amrosan LLC, Carnegie Hill Partners, and Bioche Asset Management, LCC, in the amount of 375,556, 353,023 and 721,068 shares, respectively and extended their date of expiration from December 17, 2019 to February 21, 2022. The warrants had originally been issued in 2012 as part of investment banking and advisory services provided by Mr. Seth. The incremental fair value for the warrants due to the amendment was immaterial.

In March 2018, the Company sold an aggregate of 30,237,894 units consisting of an aggregate of 30,237,894 shares of common stock, 7,559,445 series A warrants and 22,678,393 series B warrants, with each series A warrant exercisable for one share of common stock at an exercise price of \$0.60 per share and each series B warrant exercisable for one share of common stock at an exercise price of \$0.70 per share.

During the year ended December 31, 2018, the Company granted 122,628 warrants to consultants. The warrants are exercisable for periods ranging from 4 to 5 years at exercise prices ranging from \$0.36 to \$0.80 per share. The fair value of the warrants was approximately \$27 thousand at the grant date and was determined utilizing the Black-Scholes option pricing model. Variables used in the Black-Scholes option-pricing model include (1) discount rate range of 2.34% to 2.99%, (2) expected term of 4-5 years, (3) expected volatility range of 77.01% to 79.00%, and (4) zero expected dividends.

On August 2, 2017, the Company completed an underwritten offering of 21,500,000 shares of its common stock and warrants to purchase an aggregate of 18,275,000 shares of its common stock at a price of \$0.75 per share and related warrant. The warrants are exercisable for a period of 5 years at an exercise price of \$1.05 per share. The transaction date relative fair value of the warrants of \$4.9 million was determined utilizing the Black-Scholes option pricing model. Variables used in the Black-Scholes option-pricing model include (1) discount rate of 1.83%, (2) expected term of 5 years, (3) expected volatility of 82%, and (4) zero expected dividends.

Certain warrants were issued to the Company's Executive Chairman (now Chairman and CEO) as part of investment banking and advisory services either prior to and outside of his role as a Board Member and subsequently Chairman and CEO. On March 14, 2017, the Company canceled a warrant to purchase 57,212 shares of common stock of the Company, dated December 19, 2012 and issued a new warrant to its Chairman and CEO to purchase 57,212 common shares with the term of the warrant expiring on February 11, 2022. 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 Chairman and CEO and an entity affiliated with its Chairman and CEO to purchase 64,746 and 99,617 common shares, respectively. Pursuant to the terms of the warrant amendments, the term of the warrants was extended to February 11, 2022 from January 31, 2019. As a result of the replacement and modification, the Company recorded an additional non-cash expense of \$64 thousand for the incremental fair value of the new warrants.

During the year ended December 31, 2016, the Company granted 130,000 warrants to consultants. The warrants are exercisable for periods ranging from 5 to 10 years at exercise prices ranging from \$0.98 to \$1.77 per share. The fair value of the warrants was approximately \$116,000 at the grant date and was determined utilizing the Black-Scholes option pricing model. Variables used in the Black-Scholes option-pricing model include (1) discount rate range of 1.13% to 1.20%, (2) expected term of 5-10 years, (3) expected volatility range of 79.79% to 84.84%, and (4) zero expected dividends.

During the years ended December 31, 2018, 2017 and 2016, the Company recorded stock-based compensation expense related to warrants of \$33 thousand, \$0.1 million and \$0.1 million respectively.

## **Note 8 - Income Taxes**

The Tax Cuts and Jobs Act, or the "Act," was enacted in December 2017. The Act reduces the U.S. federal corporate tax rate from 35% to 21%. As of December 31, 2017, the Company remeasured its existing deferred tax balance by recording a provisional charge of \$17.9 million, which was fully offset by a change in the valuation allowance. As of December 31, 2018, upon completing its analysis of the Act, the Company believes that the disclosures in its financial statements as of December 31, 2017 are still accurate.



Deferred income taxes reflect the net tax effects of temporary differences between the carrying amounts of assets and liabilities for financial reporting purposes and the amounts used for income tax purposes. Significant components of the Company's deferred tax assets and liabilities at December 31, 2018 and 2017 are as follows:

	<b>2018</b>	<b>2017</b>
Deferred tax assets:		
Net operating losses carry forward	\$ 34,531,577	\$ 30,826,534
Share-based compensation	2,950,963	3,731,413
Research and development/orphan drug credits	8,896,703	6,324,998
Others	15,285	11,369
Less: valuation allowance	(46,394,528)	(40,894,314)
Deferred tax assets, net	\$-	\$-

F-20

The Company has recorded a valuation allowance of \$46.4 million and \$40.9 million against its deferred tax assets at December 31, 2018 and 2017, respectively, because management determined that it is not more-likely-than not that those assets will be realized.

For federal income tax purposes, the Company has approximately \$144.5 million of unused net operating losses (“NOLs”) at December 31, 2018 available for carry forward to future years. Prior NOLs have begun to expire as they are unused.

For state income tax purposes, the Company has approximately \$66.8 million of unused NOLs available for carry forward to future years. These NOLs will begin to expire in 2035 if unused.

The Company has federal research and development tax credits of approximately \$1.4 million at December 31, 2018 which will begin to expire in 2033 if unused and orphan drug credits of \$7.5 million which will begin to expire in 2037 if unused.

Pursuant to Internal Revenue Code Section 382, the annual use of the net operating loss carryforwards and research and development tax credits could be limited by any greater than 50% ownership change during any three-year testing period. As a result of any such ownership change, portions of the Company’s net operating loss carryforwards and research and development tax credits are subject to annual limitations. Accordingly, the Company’s ability to utilize these carryforwards may be limited as a result of an ownership change which may have already happened or may happen in the future. Such an ownership change could result in a limitation in the use of the net operating losses in future years and possibly a reduction of the net operating losses available.

The difference between the income tax provision and the amount that would result if the U.S. Federal statutory rates were applied to pre-tax losses for the year ended December 31, 2018, 2017 and 2016 are as follows:

	For the year ended		December 31,		December 31,		December 31,	
	December 31,		2017		2016		2016	
	2018							
Federal statutory income taxes	\$(4,967,332)	(21.0)%	\$(9,044,420)	(34.0)%	\$(8,269,386)	(34.0)%		
State income taxes	1,413,678	6.0 %	(1,940,945)	(7.3 )%	973,547	4.0 %		
Change in federal statutory rate	-	- %	17,939,714	67.4 %	-	- %		
Deferred true-up	-	- %	3,090,816	11.8 %	(10,511,380)	(43.3)%		
	(1,986,609)	(8.4 )%	(3,029,074)	(11.4)%	(141,769)	(0.6 )%		

Research and Development/Orphan Drug  
Tax Credit

Unrealized derivative gain/loss	-	-	%	(120,870 )	(0.5 )%	(956,840 )	(3.9 )%
Other	40,049	0.2	%	12,845	0.0	13,632	0.1
Change in valuation allowance	5,500,214	23.2	%	(6,908,066 )	(26.0)%	18,892,196	77.7
Provision for income tax	\$-	-		\$-	-	\$-	-

**Note 9 - Subsequent Event**

In January 2019, the Company sold 924,500 common shares through its at-the-market program and realized net proceeds of \$0.4 million.

Since December 31, 2018, holders of the Company's March 2018 Series A warrants exercised approximately 2.5 million shares, resulting in proceeds to the Company of \$1.5 million.

Since December 31, 2018, the Company granted stock options to its employees to purchase a total of 530,000 common shares at a price range from \$0.43 to \$0.58 per share related to new hires.

On March 6, 2019, the Company executed an amendment to the Company's 2013 Amended and Restated Stock Plan, as amended (the "Plan Amendment"). The Plan Amendment increased the number of shares of common stock that the Company is authorized to issue under the plan to 22,750,000 shares.

On March 6, 2019, the Company filed a Certificate of Amendment to its Certificate of Incorporation, as amended, with the Secretary of State of the State of Delaware to increase the number of authorized shares of Actinium's common stock from 400,000,000 to 600,000,000 shares.

**ITEM 9. CHANGES IN AND DISAGREEMENTS WITH ACCOUNTANTS ON ACCOUNTING AND FINANCIAL DISCLOSURE.**

None.

**ITEM 9A. CONTROLS AND PROCEDURES.**

***Disclosure controls and procedures.*** The Company, under the supervision and with the participation of its management, including the Company's principal executive officer and principal financial and accounting officer, evaluated the effectiveness of the Company's "disclosure controls and procedures," as such term is defined in Rule 13a-15(e) under the Securities Act of 1934, as amended (the "Exchange Act"), as of the end of the period covered by this Annual Report on Form 10-K. Based on that evaluation, the Company's principal executive officer and principal financial and accounting officer have concluded that the Company's disclosure controls and procedures are effective as of December 31, 2018 to ensure that information required to be disclosed by the Company in reports that it files or submits under the Exchange Act is recorded, processed, summarized and reported within the time periods specified in Securities and Exchange Commission rules and forms, and includes controls and procedures designed to ensure that information required to be disclosed by the Company in such reports is accumulated and communicated to the Company's management, including the Company's principal executive officer and principal financial and accounting officer, as appropriate, to allow timely decisions regarding required disclosure.

***Management's Annual Report on Internal Control Over Financial Reporting.*** The Company's management is responsible for establishing and maintaining adequate internal control over financial reporting. The 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.

The Company's internal control over financial reporting includes policies and procedures that (1) pertain to the maintenance of records that, in reasonable detail, accurately and fairly reflect transactions and dispositions of assets; (2) provide reasonable assurances that transactions are recorded as necessary to permit preparation of financial statements in accordance with generally accepted accounting principles, and that receipts and expenditures are being made only in accordance with authorizations of management and the 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 our financial statements.

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.

Management assessed the effectiveness of the Company's internal control over financial reporting as of December 31, 2018. In making this assessment, management used the criteria set forth by the Committee of Sponsoring Organizations of the Treadway Commission (COSO) in Internal Control-Integrated Framework (2013). Based on our assessment and those criteria, management concluded that as of December 31, 2018, the Company's internal control over financial reporting was effective.

***Changes in internal controls over financial reporting.*** There were no changes in the Company's internal controls over financial reporting that occurred during the fourth quarter of the fiscal year covered by this Annual Report on Form 10-K that have materially affected, or are reasonably likely to materially affect, the Company's internal control over financial reporting.

**ITEM 9B. OTHER INFORMATION.**

**None.**

45

## PART III

### ITEM 10. DIRECTORS, EXECUTIVE OFFICERS AND CORPORATE GOVERNANCE.

#### Directors and Executive Officers

The names, positions and ages of our directors and executive officers as of March 15, 2019, are as follows:

<b>Name</b>	<b>Age</b>	<b>Position</b>
Sandesh Seth	54	Chairman and Chief Executive Officer
Mark S. Berger, M.D.	64	Chief Medical Officer
Anil Kapur	50	Chief Commercial Officer
Dale L. Ludwig, Ph.D.	57	Chief Scientific Officer
Steve O'Loughlin	34	Principal Financial Officer (Principal Financial and Accounting Officer)
Jeffrey W. Chell M.D.	64	Director
David Nicholson, Ph.D.	63	Lead Independent Director
Richard I. Steinhart	61	Director
Ajit S. Shetty, Ph.D.	72	Director

Subject to the classified board provisions of our charter, all directors hold office until the next annual meeting of stockholders and the election and qualification of their successors. Officers are elected annually by the board of directors and serve at the discretion of the board.

There are no other arrangements or understanding between any of our directors and any other persons pursuant to which they were selected as a director.

## **Background of Executive Officers and Directors**

The principal occupations for the past five years (and, in some instances, for prior years) of each of our directors and executive officers are as follows:

### **Sandesh Seth, Chairman and Chief Executive Officer**

Mr. Sandesh Seth has been our Chief Executive Officer since June 2017. Mr. Seth has been a Director since March 2012, our Chairman of the Board since October 2013, and served as Executive Chairman from August 2014 to June 2017.

Mr. Seth has 25+ years of experience in investment banking (Laidlaw & Co (UK) Ltd., Cowen & Co.), equity research (Bear Stearns, Commonwealth Associates) and in the pharma industry (Pfizer, Warner-Lambert, SmithKline in strategic planning, business development and R&D project management). Mr. Seth has an MBA in Finance from New York University; an M.S. in the Pharmaceutical Sciences from the University of Oklahoma Health Center and a B.Sc. in Chemistry from Bombay University. He has published several scientific articles and was awarded the University Regents Award for Research Excellence at the University of Oklahoma. Mr. Seth was designated as Regulatory Affairs Certified (R.A.C.) by the Regulatory Affairs Professionals Society which signifies proficiency with U.S. FDA regulations.



That Mr. Seth has served in various business executive-level positions over the course of his career, has significant investment banking experience, has developed significant management, operational and leadership skills and is well accustomed to interfacing with investors, analysts, auditors, C-level executives, and outside advisors, led us to conclude that Mr. Seth should serve as a director.

**Mark S. Berger, MD., Chief Medical Officer**

Dr. Berger has been our Chief Medical Officer since January 2017. From September 2013 to January 2017 Dr. Berger worked for Kadmon Corporation where he was Senior Vice President, Clinical Research. In this role he was responsible for all clinical aspects of new drug development including designing and managing clinical trials in oncology indications (non-small cell lung cancer and glioblastoma) and non-oncology indications (chronic graft versus host disease and polycystic kidney disease). Dr. Berger joined Kadmon after serving as Chief Medical Officer of Deciphera Pharmaceuticals from June 2011 to September 2013. Prior to Deciphera, Dr. Berger was Vice President for Clinical Development at Gemin X Pharmaceuticals where he led the clinical strategy, design and management of clinical trials for two novel oncology agents including obatoclax, a pan Bcl-2 inhibitor. Based on the results of a randomized Phase 2 clinical trial of obatoclax, Gemin X was acquired by Cephalon in March of 2011 for a total consideration of \$525 million including \$225 million in an upfront cash payment.

Before his work with biotechnology companies, Dr. Berger held key positions in two global pharmaceutical companies. Dr. Berger previously served as Group Director, Medicine Development Centre-Oncology for GlaxoSmithKline. In this position Dr. Berger managed the development of Tykerb (lapatinib) in lung and breast cancer where he designed and led two Phase 2 clinical trials before planning and leading a 399 patient pivotal Phase 3 trial that resulted in the FDA approval of Tykerb in breast cancer. In addition, he managed the Lapatinib Expanded Access Program (LEAP) that enrolled over 4000 patients on a global basis. Dr. Berger began his career in drug development at Wyeth Research where he led the planning and execution of the pivotal Phase 2 trial for Mylotarg, which was the first antibody targeted chemotherapy agent and targeted CD33, similar to Actimab-A. He presented the Mylotarg clinical data at the FDA's Oncology Drug Advisory Committee meeting, after which Mylotarg received accelerated FDA approval for patients with relapsed AML.

Dr. Berger has a B.A. in biology from Wesleyan University and received his M.D. from the University of Virginia School of Medicine. He did his Hematology-Oncology fellowship at the University of Pennsylvania where he was an Assistant Professor of Medicine, and also was a Research Fellow at the Ludwig Institute for Cancer Research and the Imperial Cancer Research Fund, both in London. Dr. Berger is board certified in internal medicine, hematology and medical oncology.

**Anil Kapur, Chief Commercial Officer**

Mr. Kapur joined Actinium in February 2018 from Bristol-Myers Squibb, where he was the Vice President, Head of Early Assets, Biomarkers & External Innovation within the Worldwide Oncology Commercialization organization and helped advance the company's leading Immuno-Oncology portfolio. Prior to this position, he was the Vice President & Global Head, Oncology Commercial Portfolio & Product Strategy at Baxalta and a member of the Oncology Leadership Team. In this role, Mr. Kapur also led the Joint Strategic Committees responsible for advancing the early Immuno-Oncology partnerships with Symphogen and the allogeneic CAR-T partnership with Precision Bio-Sciences.

Mr. Kapur built a distinguished career spanning 15 years at Johnson & Johnson where in his last role, he served as the Vice President, Commercial Leader for the Hematology Franchise with responsibility for the development and execution of global commercial strategy and launch plans for all Hematology in-market, late-stage development, and early pipeline assets. He is credited with significantly shaping the clinical development plans and successful launch and growth of multiple Oncology blockbuster products including IMBRUVICA®, DARZALEX®, and VELCADE®.

At J&J, he led the IMBRUVICA® Joint Commercial Committee (JCC), established between J&J and Pharmacyclics, and built and led the global team that launched DARZALEX®, the first biologic for Multiple Myeloma. Anil also held leadership roles of increasing complexity and responsibility in US Marketing, US Regional Sales, and within the Asia-Pacific Regional Oncology organization covering 14 markets including Japan, China, Australia and Korea.

Mr. Kapur has an MBA from the Fuqua School of Business at Duke University, a MS in Industrial Engineering from Louisiana Tech University, and a Bachelor of Engineering from the Birla Institute of Technology, India.

**Dale L. Ludwig, Ph.D., Chief Scientific Officer**

Dr. Ludwig joined Actinium in January 2018. Dr. Ludwig has worked for 20 years in oncology antibody drug discovery and development at Eli Lilly and Company and at ImClone Systems, Inc., until its acquisition by Eli Lilly where he supported the development and successful launch of several biologic oncology drugs including Erbitux®, Cyramza™, Portrazza®, and Lartruvo™ as well as the clinical advancement of 10 additional therapeutic antibodies. Most recently, Dr. Ludwig served Chief Scientific Officer/Vice President of Oncology Discovery Research - Biologics Technology. In this role he was responsible for directing antibody discovery and development for oncology biologics and contributed to key strategic and project advancement efforts. Dr. Ludwig was a member of the Oncology Research Senior Leadership Team and directed the empowered antibody drug discovery programs that included collaborations with Immunogen and Zymeworks.

Prior to the acquisition of Imclone by Eli Lilly and Company, Dr. Ludwig served as Head of Molecular & Cellular Engineering at IMClone Systems Incorporated. In this capacity, Dr. Ludwig served as core team leader for several IND filings and phase 1 advancements for novel antibodies. In addition, he directed and oversaw the full spectrum of drug development including antibody discovery, screening, selection, engineering, optimization, cloning and expression. He was also tasked with establishing meaningful preclinical collaborations with key academic investigators and industry leaders. Post-acquisition he was the research representative to the ImClone-Lilly Transition Team.

Before his work in the biotechnology industry, Dr. Ludwig trained as a postdoctoral associate in the DNA Damage and Repair Group of the Los Alamos National Laboratory and as a postdoctoral fellow in the Department of Molecular Genetics, Biochemistry and Microbiology at the University of Cincinnati College of Medicine. Dr. Ludwig has a B.S. in biology with a concentration in microbiology from James Madison University and received his Ph.D. in Microbiology from East Carolina University.

**Steve O’Loughlin, Principal Financial Officer**

Steve O’Loughlin has been our Principal Financial Officer since May 2017. Mr. O’Loughlin joined Actinium in October 2015 as Vice President, Finance and Corporate Development, with almost a decade of life sciences industry experience gained from previous positions in investment banking and publicly traded life sciences companies. Prior to Actinium, from June 2015 to October 2015, Mr. O’Loughlin worked at J. Streicher LLC as an investment banker, from

August 2012 to June 2015 Mr. O'Loughlin held the position of Vice President, Corporate Finance and Development and was a corporate officer at Protea Biosciences, Inc., a publicly traded life sciences tools company. Previously, From June 2010 to June 2012, Mr. O'Loughlin held corporate development positions with Caliber I.D., a publicly traded diagnostics company. Mr. O'Loughlin previously worked in investment banking at Jesup & Lamont where he focused on the biotechnology and life sciences industries. Mr. O'Loughlin has a B.S. in Business Administration with a concentration in finance from Ramapo College of New Jersey.

**Jeffrey W. Chell, M.D., Director**

Dr. Chell has been a director of the Company since April 2018. Dr. Chell is also a member of our Audit Committee and Compensation Committee. He has been the Chief Executive Officer Emeritus of the National Marrow Donor Program (NMDP) since 2017 having served as its CEO since 2000. Dr. Chell has led the NMDP through transformational growth as its Be The Match Registry tripled to more than 12 million donors, the number of transplants facilitated has grown five fold to over 6,400 annually, and revenue more than tripled to nearly \$400 million per year. He is also the co-founder and has served as Executive Director of the Center For International Blood & Marrow Transplant Research since 2004, a leading research program in the field contributing over 70 research publications per year in peer-reviewed journals. Dr. Chell also currently serves as chair of CLR Insurance, a captive insurance company domiciled in the Cayman Islands. From 2014 to 2016, Dr. Chell served as co-chair of Bone Marrow Donors Worldwide (BMDW) during its IT transformation project, improving revenues and reducing costs.

Prior to joining the NMDP, he served as President, Allina Medical Clinics, a 450 physician multi-specialty medical group from 1994 to 1999. Prior to that he practiced Internal Medicine in Minneapolis and in the U.S. Air Force Medical Corps.

Dr. Chell received his M.D. from the University of Minnesota and his training in Internal Medicine at the University of Wisconsin, Madison. Dr. Chell is a diplomate of the American Board of Internal Medicine, a member of the American Society of Hematology and a member of the American Society of Blood and Marrow Transplantation.

He has received multiple honors including the 2018 Public Service award of the American Society For Blood and Marrow Transplantation, 2017 Most Admired CEO by the Minneapolis/St. Paul Business Journal, 2010 Healthcare Executive of the Year by the Minneapolis/St. Paul Business Journal, and the 2017 Bone Marrow Foundation Service Award.

#### **David Nicholson, Ph.D., Director**

David Nicholson has been a Director of the Company since 2008. Dr. Nicholson is also a member of our Compensation Committee and Corporate Governance Committee. In August 2014, Dr. Nicholson joined Actavis plc and Forest Laboratories, Inc. as Senior Vice President, Actavis Global Brands R&D. From March 2012 to August 2014, Dr. Nicholson was on the Executive Committee of Bayer CropScience as Head of Research & Development responsible for the integration of the company's R&D activities into one global organization. Dr. Nicholson graduated in pharmacology, earning his B.Sc. from the University of Manchester (1975) and his Ph.D. from the University of Wales (1980). Between 1978 and 1988, Dr. Nicholson worked in the pharmaceutical industry for the British company Beecham-Wülfing in Gronau, Germany. The main emphasis of his activities as group leader in a multidisciplinary project group was the development of cardiovascular drugs.

From 1988-2007, Dr. Nicholson held various positions of increasing seniority in the UK, the Netherlands and the USA with Organon, a Business Unit of Akzo Nobel. Ultimately, he became Executive Vice President, Research & Development, and member of the Organon Executive Management Committee. He implemented change programs, leading to maximizing effectiveness in research & development, ensuring customer focus and the establishment of a competitive pipeline of innovative drugs. In 2007, Dr. Nicholson transferred to Schering-Plough, Kenilworth, New Jersey as Senior Vice President, responsible for Global Project Management and Drug Safety. From 2009 to December 2011, he was Vice President Licensing and Knowledge Management at Merck in Rahway, New Jersey, reporting to the President of Merck R&D. As an integration team member, Dr. Nicholson played a role in the strategic mergers of Organon BioSciences, the human and animal health business of Dutch chemical giant Akzo-Nobel, and Schering-Plough in 2007 as well as of Schering-Plough and Merck in 2009.

That Dr. Nicholson brings over 25 years of pharmaceutical experience to our Board, having served in various pharmaceutical research and development executive-level positions over the course of his career, and that Dr. Nicholson has developed significant management and leadership skills relating to the pharmaceutical industry, and is well accustomed to interfacing with investors, analysts, auditors, outside advisors and governmental officials, led us to conclude that Dr. Nicholson should serve as a director.

**Ajit S. Shetty, Ph.D., Director**

Dr. Shetty has been a Director of the Company since March, 2017. Dr. Shetty is also a member of our, Audit Committee, Compensation Committee, and Chairman of our Corporate Governance Committee. Dr. Shetty joined Janssen Pharmaceutica, Inc. in 1976 ultimately rising to the position of President in 1986 where he led the establishment of Janssen's business in the U.S. From 1999 to 2008 he was Managing Director of Janssen Pharmaceutica, during this time the Janssen Group of companies' global sales grew from \$1 billion to \$8 billion, and from 2004 until 2012 he was Chairman of the Board of Directors. In Dr. Shetty's most recent role at Johnson & Johnson he was head of Enterprise Supply Chain, where he reported to the CEO and was responsible for the transformation and optimization of Johnson & Johnson's supply chain. Dr. Shetty earned a Ph.D. in Metallurgy and B.A. Natural Sciences from Trinity College, Cambridge University and a Master of Business Administration from Carnegie Mellon University. Dr. Shetty has served as a member of Agile Therapeutics, Inc.'s board of directors since February 2016. In 2007, Dr. Shetty was bestowed the title of Baron by King Albert II of Belgium for his exceptional merits. He is a member of the Board of Trustees of Carnegie Mellon University, serves on the Board of Governors for GS1 (Global Standards) in Belgium and formerly served on the Corporate Advisory Board of the John Hopkins Carey Business School. In 2016, Dr. Shetty was named as Chairperson of the Vlaams Instituut voor Biotechnologie (VIB), a Belgium based life sciences research institute focused on translating scientific results into pharmaceutical, agricultural and industrial applications. In addition, he was elected Manager of the Year in 2004 in Flanders and received a Life-Time Achievement Award in India in 2010. We believe Dr. Shetty's qualifications to sit on our Board include his extensive pharmaceutical experience leading commercial and supply chain operations and his significant education background.

That Dr. Shetty has 37 years of leadership and executive experience in the pharmaceutical industry, that he has significant supply chain knowledge and that he has experience conducting business in the U.S. and Europe, led us to conclude that Dr. Shetty should serve as a director.

### **Richard I. Steinhart, Director**

Mr. Steinhart has served as our Director and Chairman of the Audit Committee since November 2013. Mr. Steinhart is also a member of our Corporate Governance Committee. Since October 2017 Mr. Steinhart has been the Chief Financial Officer of BioXcel Therapeutics, Inc. Since March 2014, Mr. Steinhart has been a Member of the Board of Directors of Atossa Genetics, Inc. where he is Chairman of the Audit Committee and a member of the Compensation Committee. From October 2015 to April 2017, Mr. Steinhart was Vice President and CFO at Remedy Pharmaceuticals, a privately-held, clinical stage pharmaceutical company. From January 2014 through September 2015 Mr. Steinhart had been a financial and strategic consultant to the biotechnology and medical device industries. From April 2006 through December 2013, Mr. Steinhart was employed by MELA Sciences, Inc., as their Vice President, Finance and Chief Financial Officer, Treasurer and Secretary. In April 2012, Mr. Steinhart received a promotion to Sr. Vice President, Finance and Chief Financial Officer. From May 1992 until joining MELA Sciences, Mr. Steinhart was a Managing Director of Forest Street Capital/SAE Ventures, a boutique investment banking, venture capital, and management consulting firm focused on healthcare and technology companies. Prior to Forest Street Capital/SAE Ventures, he was Vice President and Chief Financial Officer of Emisphere Technologies, Inc. Mr. Steinhart's other experience includes seven years at CW Group, Inc., a venture capital firm focused on medical technology and biopharmaceutical companies, where he was a General Partner and Chief Financial Officer. Mr. Steinhart began his career at Price Waterhouse, now known as PricewaterhouseCoopers. He holds BBA and MBA degrees from Pace University and is a Certified Public Accountant (inactive).

That Mr. Steinhart brings nearly 30 years of financial experience to our Board, having served in various financial executive-level positions over the course of his career, and that Mr. Steinhart is a certified public accountant led us to conclude that Mr. Steinhart should serve as a director and chair the audit committee.

### **Corporate Governance**

The Board of Directors oversees our business affairs and monitors the performance of management. In accordance with our corporate governance principles, the Board of Directors does not involve itself in day-to-day operations. The directors keep themselves informed through discussions with the Chairman and Chief Executive Officer and other key executives and by reading the reports and other materials that we send them and by participating in Board of Directors and committee meetings.

*Term of Office*

Our directors are divided into three classes, designated Class I, Class II and Class III. Class I shall consists of two directors, Class II shall consist of one director, and Class III consists of one director.



The term of each director is set forth below or until their successors are duly elected:

<b>Director</b>	<b>Class</b>	<b>Term (from 2018 Annual Meeting)</b>
David Nicholson	Class I	2 years
Richard Steinhart	Class I	2 years
Sandesh Seth	Class II	3 years
Jeffrey W. Chell	Class II	3 years
Ajit Shetty	Class III	1 year

Notwithstanding the foregoing, each director shall serve until his successor is duly elected and qualified, or until his or her retirement, death, resignation or removal. In order to implement a classified board of directors, Class I shall serve a two-year term from the date of the 2018 Annual Shareholders Meeting; Class II shall serve a three-year term from the date of the 2018 Annual Shareholders Meeting; and Class III shall serve a one-year term from the date of the 2018 Annual Shareholders Meeting. Directors elected at each annual meeting are elected for a three-year term.

### ***Director Independence***

We use the definition of “independence” of the NYSE American stock exchange to make this determination. We are listed on the NYSE American under the symbol “ATNM”. NYSE MKT corporate governance rule Sec. 803(A)(2) provides that an “independent director” means a person other than an executive officer or employee of the company. No director qualifies as independent unless the issuer’s board of directors affirmatively determines that the director does not have a relationship that would interfere with the exercise of independent judgment in carrying out the responsibilities of a director. Under the NYSE American director independence rules, Jeffrey W. Chell, David Nicholson, Ajit S. Shetty, and Richard I. Steinhart are independent directors of the Company.

### **Chief Executive Officer’s Compensation**

In August 2018, we amended and restated Mr. Seth’s, our Chairman and Chief Executive Officer, August 6, 2015 Executive Chairman Agreement (the “Prior CEO Agreement”), as amended. This new agreement sets forth the terms related to his position as Chief Executive Officer and Chairman of the Board of the Company while retaining and adapting material provisions of the Prior CEO Agreement to that of his role of Chief Executive Officer. Mr. Seth is currently paid an annual salary of \$545,000. The Board reviews the amount of his base salary and performance bonus and determines the appropriate adjustments to each component of his compensation each calendar year, and he may be entitled to a cash bonus in an amount to be determined by the board with a target of 50% of the base salary.

The Chairman and CEO shall also be awarded stock options and/or restricted stock grants at our Board's discretion. Mr. Seth's agreement includes severance benefits, including in the event of a change of control of the Company, and to provide for immediate vesting of options in accordance with our Amended and Restated 2013 Stock Plan. The term of the agreement is until February 21, 2021.

### **Chief Medical Officer Agreement**

In December 2016, the Company and Dr. Mark S. Berger entered into an agreement (the “Berger Employment Agreement”), to employ Dr. Berger as our Chief Medical Officer. Dr. Berger’s employment with the Company is on an “at will” basis, meaning that either Dr. Berger or the Company may terminate his employment at any time for any reason or no reason, without further obligation or liability, except as provided in his employment agreement.

Pursuant to the Berger Employment Agreement, Dr. Berger is entitled to the following compensation and benefits:

Dr. Berger’s current annual base salary is \$400,000 per year. Dr. Berger may be entitled to a cash bonus in an amount to be determined by the Board with a target of 30% of the base salary.

Dr. Berger is also eligible to participate in the Company’s benefit plans that are generally provided for executive employees.

### **Principal Financial Officer Compensation**

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

Mr. O’Loughlin’s employment with the Company is on an “at will” basis, meaning that either Mr. O’Loughlin or the Company may terminate his employment at any time for any reason or no reason, without further obligation or liability, except as provided in his employment agreement. Mr. O’Loughlin is entitled to the following compensation and benefits:

Mr. O’Loughlin’s current annual base salary is \$285,000 per year, and Mr. O’Loughlin may be entitled to a cash bonus in an amount to be determined by the Board with a target of 30% of the base salary.

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

Mr. O'Loughlin is eligible to receive all standard benefits that Company employees are eligible to receive.

### **Chief Scientific Officer Compensation**

The Company and Dr. Dale Ludwig, effective January 2018, entered into an Offer Letter pursuant to which Dr. Ludwig is the Company's Chief Scientific Officer. Dr. Ludwig's employment with the Company is on an "at will" basis, meaning that either Dr. Ludwig or the Company may terminate his employment at any time for any reason or no reason, without further obligation or liability, except as provided in his employment agreement. Pursuant to the employment agreement, Dr. Ludwig is entitled to the following compensation and benefits:

Dr. Ludwig's current annual base salary is \$325,000 per year, and Dr. Ludwig may be entitled to a cash bonus in an amount to be determined by the Board with a target of 30% of the base salary.

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

Dr. Ludwig is eligible to receive all standard benefits that Company employees are eligible to receive.

### **Chief Commercial Officer Compensation**

In January 2018 the Company and Anil Kapur entered into an Offer Letter pursuant to which Mr. Kapur is the Company's Chief Commercial Officer. Mr. Kapur's employment with the Company is on an "at will" basis, meaning that either Dr. Kapur or the Company may terminate his employment at any time for any reason or no reason, without further obligation or liability, except as provided in his employment agreement. Pursuant to the employment agreement, Mr. Kapur is entitled to the following compensation and benefits:

Mr. Kapur's current annual base salary is \$325,000 per year, and he may be entitled to a cash bonus in an amount to be determined by the board with a target of 35% of the base salary.

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

Mr. Kapur is eligible to receive all standard benefits that Company employees are eligible to receive.

## Board of Directors Meetings and Attendance

During the fiscal year 2018, our Board held nine meetings and did not act by unanimous written consent. Each director attended all of the meetings of our Board and of any committees of which he was a member during the year ended December 31, 2018. It is our policy that directors should make every effort to attend the annual meeting of stockholders, and each of our directors attended the annual meeting of stockholders in 2018.

## Committees of the Board of Directors

Our board of directors has formed three standing committees: audit, compensation and corporate governance. Actions taken by our committees are reported to the full board. Each of our committees has a charter and each charter is posted on our website.

<b>Audit Committee</b>	<b>Compensation Committee</b>	<b>Corporate Governance Committee</b>
Richard I. Steinhart*	David Nicholson*	Ajit S. Shetty*
Jeffrey W. Chell	Jeffrey W. Chell	David Nicholson
Ajit S. Shetty	Ajit S. Shetty	Richard I. Steinhart

\*Indicates committee chair

### *Audit Committee*

Our audit committee, which currently consists of three directors, provides assistance to our board in fulfilling its legal and fiduciary obligations with respect to matters involving the accounting, financial reporting, internal control and compliance functions of the company. The board of directors has determined that Mr. Steinhart is an “audit committee financial expert” as defined in Item 407(d)(5)(ii) of Regulation S-K. Our audit committee employs an independent registered public accounting firm to audit the financial statements of the company and perform other assigned duties. Further, our audit committee provides general oversight with respect to the accounting principles employed in financial reporting and the adequacy of our internal controls. In discharging its responsibilities, our audit committee may rely on the reports, findings and representations of the company’s auditors, legal counsel, and responsible officers. Our board has determined that all members of the audit committee are financially literate within the meaning of SEC rules and under the current listing standards of the NYSE AMERICAN. Richard I. Steinhart is the chairman of the audit committee. The Audit Committee met four times during 2018. Each member of the Audit Committee was present at all of the Audit Committee meetings held during such director’s tenure as a member of the Audit Committee.

### *Compensation Committee*

Our compensation committee, which currently consists of three directors, establishes executive compensation policies consistent with the company’s objectives and stockholder interests. The compensation committee met one time during 2018. Our compensation committee also reviews the performance of our executive officers and establishes, adjusts and awards compensation, including incentive-based compensation, as more fully discussed below. In addition, our compensation committee generally is responsible for:

establishing and periodically reviewing our compensation philosophy and the adequacy of compensation plans and programs for our directors, executive officers and other employees;

overseeing our compensation plans, including the establishment of performance goals under the company’s incentive compensation arrangements and the review of performance against those goals in determining incentive award payouts;

overseeing our executive employment contracts, special retirement benefits, severance, change in control arrangements and/or similar plans;

acting as administrator of any company stock option plans; and

overseeing outside compensation consultants when engaged.

Our compensation committee periodically reviews the compensation paid to our non-employee directors and the principles upon which their compensation is determined. The compensation committee also periodically reports to the board on how our non-employee director compensation practices compare with those of other similarly situated public corporations and, if the compensation committee deems it appropriate, recommends changes to our director compensation practices to our board for approval.

Outside consulting firms retained by our compensation committee and management also will, if requested, provide assistance to the compensation committee in making its compensation-related decisions.

### *Corporate Governance Committee*

Corporate Governance Committee, which currently consists of three directors, monitors our corporate governance system. The Corporate Governance Committee met one time during 2018.

### *Nomination of Directors*

Board of Director nominations are selected, or recommended for the Board's selection, by a majority of the independent directors. Our independent directors include Jeffrey W. Chell, David Nicholson, Richard I. Steinhart and Ajit S. Shetty. These directors are charged with the responsibility of proposing potential director nominees to the board of directors for consideration. All of our independent directors are independent directors as defined by the rules of the NYSE AMERICAN. Our independent directors use criteria by which it will seek to evaluate candidates to serve on our board of directors. The evaluation methodology includes items such as experience in the biotechnology sector, experience with public companies, executive managerial experience, operations and commercial experience, fundraising experience and contacts in the investment banking industry, personal and skill set compatibility with current board members, industry reputation, knowledge of our company generally, and independence.



### ***Lead Director***

In September 2017, our board of directors created the position of Lead Director. Our board of directors designated David Nicholson, an existing independent director, as our Lead Director. Pursuant to the charter of the Lead Director, the Lead Director shall be an independent, non-employee director designated by our board of directors who shall serve in a lead capacity to coordinate the activities of the other non-employee directors, interface with and advise management, and perform such other duties as are specified in the charter or as our board of directors may determine.

### **Family Relationships**

There are no family relationships among any of our officers or directors.

### **Involvement in Certain Legal Proceedings**

To our knowledge, none of our current directors or executive officers has, during the past ten years:

been convicted in a criminal proceeding or been subject to a pending criminal proceeding (excluding traffic violations and other minor offenses);

had any bankruptcy petition filed by or against the business or property of the person, or of any partnership, corporation or business association of which he was a general partner or executive officer, either at the time of the bankruptcy filing or within two years prior to that time;

been subject to any order, judgment, or decree, not subsequently reversed, suspended or vacated, of any court of competent jurisdiction or federal or state authority, permanently or temporarily enjoining, barring, suspending or otherwise limiting, his involvement in any type of business, securities, futures, commodities, investment, banking, savings and loan, or insurance activities, or to be associated with persons engaged in any such activity;

been found by a court of competent jurisdiction in a civil action or by the SEC or the Commodity Futures Trading Commission to have violated a federal or state securities or commodities law, and the judgment has not been reversed, suspended, or vacated;

been the subject of, or a party to, any federal or state judicial or administrative order, judgment, decree, or finding, not subsequently reversed, suspended or vacated (not including any settlement of a civil proceeding among private litigants), relating to an alleged violation of any federal or state securities or commodities law or regulation, any law or regulation respecting financial institutions or insurance companies including, but not limited to, a temporary or permanent injunction, order of disgorgement or restitution, civil money penalty or temporary or permanent cease-and-desist order, or removal or prohibition order, or any law or regulation prohibiting mail or wire fraud or fraud in connection with any business entity; or

been the subject of, or a party to, any sanction or order, not subsequently reversed, suspended or vacated, of any self-regulatory organization (as defined in Section 3(a)(26) of the Exchange Act), any registered entity (as defined in Section 1(a)(29) of the Commodity Exchange Act), or any equivalent exchange, association, entity or organization that has disciplinary authority over its members or persons associated with a member.

Except as set forth in our discussion below in “Certain Relationships and Related Transactions,” none of our directors or executive officers has been involved in any transactions with us or any of our directors, executive officers, affiliates or associates which are required to be disclosed pursuant to the rules and regulations of the SEC.

## **Code of Ethics**

The Company has adopted a code of ethics, a copy of which is attached as Exhibit 14.1 to the Form 8-K filed on January 2, 2013.

## **Compliance with Section 16 (a) of the Exchange Act**

Under Section 16(a) of the Exchange Act, our directors and certain of our officers, and persons holding more than 10 percent of our common stock are required to file forms reporting their beneficial ownership of our common stock and subsequent changes in that ownership with the United States Securities and Exchange Commission.

Based solely upon a review of copies of such forms filed on Forms 3, 4, and 5, and amendments thereto furnished to us, we believe that as of December 31, 2018, our executive officers and directors have complied on a timely basis with all Section 16(a) filing requirements, except for a Form 4 filing on March 19, 2018 by Dr. Berger for the purchase of warrants and common stock on March 6, 2019.

## **Compensation Discussion and Analysis**

Our Compensation Committee of our Board of Directors has the responsibility to review, determine and approve the compensation for our executive officers. Further, our Compensation Committee oversees our overall compensation strategy, including compensation policies, plans and programs that cover all employees. In 2016, our Stockholders voted on an advisory basis with respect to our compensation program for named executive officers. Of the votes cast (excluding abstentions and broker non-votes), 69.0% were cast in support of the program. In light of this, in reviewing the executive compensation program for 2016, our Compensation Committee decided to retain the general overall program design, which ties a significant portion of the executives' pay closely with our performance. In the future, our Compensation Committee will continue to consider the executive compensation program in light of changing circumstances and stockholder feedback.

We currently employ five executive officers, each of whom serves as a "Named Executive Officer" (or NEO) for purposes of SEC reporting: (1) Sandesh Seth, our Chairman and Chief Executive Officer (who we refer to in this Compensation Discussion and Analysis as our CEO); (2) Steve O'Loughlin, our Principal Financial Officer, (3) Mark Berger, our Chief Medical Officer; (4) Dale Ludwig, our Chief Scientific Officer, and (5) Anil Kapur, our Chief Commercial Officer.

This Compensation Discussion and Analysis sets forth a discussion of the compensation for our NEOs as well as a discussion of our philosophies underlying the compensation for our NEOs and our employees generally.

### **Objectives of Our Compensation Program**

The Compensation Committee's philosophy seeks to align the interests of our stockholders, officers and employees by tying compensation to individual and company performance, both directly in the form of salary or annual cash incentive payments, and indirectly in the form of equity awards. The objectives of our compensation program enhance our ability to:

attract and retain qualified and talented individuals; and

provide reasonable and appropriate incentives and rewards to our team for building long-term value within our company, in each case in a manner comparable to companies similar to ours.

In addition, we strive to be competitive with other similarly situated companies in our industry. The process of developing pharmaceutical products and bringing those products to market is a long-term proposition and outcomes may not be measurable for several years. Therefore, in order to build long-term value for our company and its stockholders, and in order to achieve our business objectives, we believe that we must compensate our officers and employees in a competitive and fair manner that reflects current company activities but also reflects contributions to building long-term value.

We utilize the services of StreeterWyatt Governance LLC to review compensation programs of peer companies in order to assist the Compensation Committee in determining the compensation levels for our NEOs, as well as for other employees of our company. StreeterWyatt is a recognized independent consulting company and services clients throughout the United States.

## **Elements of Our Compensation Program and Why We Chose Each**

### *Main Compensation Components*

Our company-wide compensation program, including for our NEOs, is broken down into three main components: base salary, performance cash bonuses and potential long-term compensation in the form of stock options or restricted stock awards. We believe these three components constitute the minimum essential elements of a competitive compensation package in our industry.

### *Salary*

Base salary is used to recognize the experience, skills, knowledge and responsibilities required of our NEOs as well as recognizing the competitive nature of the biopharmaceutical industry. This is determined partially by evaluating our peer companies as well as the degree of responsibility and experience levels of our NEOs and their overall contributions to our company. Base salary is one component of the compensation package for NEOs; the other components being cash bonuses, annual equity grants, and company benefit programs. Base salary is determined in advance whereas the other components of compensation are awarded in varying degrees following an assessment of the performance of a NEO. This approach to compensation reflects the philosophy of our board of directors and its Compensation Committee to emphasize and reward, on an annual basis, performance levels achieved by our NEOs.

### *Performance Bonus Plan*

We have a performance bonus plan under which bonuses are paid to our NEOs based on achievement of company performance goals and objectives established by the Compensation Committee and/or our board of directors as well as on individual performance. The bonus program is discretionary and is intended to: (i) strengthen the connection between individual compensation and our company's achievements; (ii) encourage teamwork among all disciplines within our company; (iii) reinforce our pay-for-performance philosophy by awarding higher bonuses to higher performing employees; and (iv) help ensure that our cash compensation is competitive. Depending on the cash

position of the company, the Compensation Committee and our board of directors have the discretion to not pay cash bonuses in order that we may conserve cash and support ongoing development programs and commercialization efforts. Regardless of our cash position, we consistently grant annual merit-based stock options to continue incentivizing both our senior management and our employees.

Based on their employment agreements, each NEO is assigned a target payout under the performance bonus plan, expressed as a percentage of base salary for the year. Actual payouts under the performance bonus plan are based on the achievement of corporate performance goals and an assessment of individual performance, each of which is separately weighted as a component of such officer's target payout. For the NEOs, the corporate goals receive the highest weighting in order to ensure that the bonus system for our management team is closely tied to our corporate performance. Each employee also has specific individual goals and objectives as well that are tied to the overall corporate goals. For employees, mid-year and end-of-year progress is reviewed with the employees' managers.

#### *Equity Incentive Compensation*

We view long-term compensation, currently in the form of stock options and restricted stock generally vesting in annual increments over four years, as a tool to align the interests of our NEOs and employees generally with the creation of stockholder value, to motivate our employees to achieve and exceed corporate and individual objectives and to encourage them to remain employed by the company. While cash compensation is a significant component of employees' overall compensation, the Compensation Committee and our board of directors (as well as our NEOs) believe that the driving force of any employee working in a small biotechnology company should be strong equity participation. We believe that this not only creates the potential for substantial longer term corporate value but also serves to motivate employees and retain their loyalty and commitment with appropriate personal compensation.

### *Other Compensation*

In addition to the main components of compensation outlined above, we also have provided contractual severance and/or change in control benefits to several employees including our Executive Chairman and CEO. The change in control benefits for all applicable persons have a “double trigger.” A double-trigger means that the executive officers will receive the change in control benefits described in the agreements only if there is both (1) a Change in Control of our company (as defined in the agreements) and (2) a termination by us of the applicable person’s employment “without cause” or a resignation by the applicable persons for “good reason” (as defined in the agreements) within a specified time period prior to or following the Change in Control. We believe this double trigger requirement creates the potential to maximize stockholder value because it prevents an unintended windfall to management as no benefits are triggered solely in the event of a Change in Control while providing appropriate incentives to act in furtherance of a change in control that may be in the best interests of the stockholders. We believe these severances or change in control benefits are important elements of our compensation program that assist us in retaining talented individuals at the executive and senior managerial levels and that these arrangements help to promote stability and continuity of our executives and senior management team. Further, we believe that the interests of our stockholders will be best served if the interests of these members of our management are aligned with theirs. We believe that providing change in control benefits lessens or eliminates any potential reluctance of members of our management to pursue potential change in control transactions that may be in the best interests of the stockholders. We also believe that it is important to provide severance benefits to members of our management, to promote stability and focus on the job at hand.

We also provide benefits to the executive officers that are generally available to all regular full-time employees of our company, including our medical and dental insurance, and a 401(k) plan. Further, we do not have deferred compensation plans, pension arrangements or post-retirement health coverage for our executive officers or employees. All of our employees not specifically under contract are “at-will” employees, which means that their employment can be terminated at any time for any reason by either us or the employee.

### *Determination of Compensation Amounts*

A number of factors impact the determination of compensation amounts for our NEOs, including the individual’s role in the company and individual performance, length of service with the company, competition for talent, individual compensation package, assessments of internal pay equity and industry data. Stock price performance has generally not been a factor in determining annual compensation because the price of our common stock is subject to a variety of factors outside of our control.

### *Industry Survey Data*

In collaboration with StreeterWyatt, we establish and maintain a list of peer companies to best assure ourselves that we are compensating our executives on a fair and reasonable basis, as set forth above under the heading “Objectives of our Compensation Program.” We also utilize StreeterWyatt-prepared data for below-executive level personnel, which data focuses on biotechnology companies that can be considered peers in terms of numerous variables including phase of development, size, therapeutic and technological focus among others. The availability of peer data is used by the Compensation Committee strictly as a guide in determining compensation levels with regard to salaries, cash bonuses and performance related annual equity grants to all employees. However, the availability of this data does not imply that the Compensation Committee is under any obligation to exactly follow peer companies in compensation matters.

#### *Determination of Base Salaries*

As a guideline for NEO base salary, we perform formal benchmarks against respective comparable positions in our established peer group. We adjust salaries based on our assessment of our NEOs’ levels of responsibility, experience, overall compensation structure and individual performance. The Compensation Committee is not obliged to raise salaries purely on the availability of data. Merit-based increases to salaries of executive officers are based on our assessment of individual performance and the relationship to applicable salary ranges. Cost of living adjustments may also be a part of that assessment.



### *Performance Bonus Plan*

Concurrently with the beginning of each calendar year, preliminary corporate goals that reflect our business priorities for the coming year are prepared by the CEO with input from the other executive officers. These goals are weighted by relative importance. The draft goals and proposed weightings are presented to the Compensation Committee and the Board and discussed, revised as necessary, and then approved by our board of directors. The Compensation Committee then reviews the final goals and their weightings to determine and confirm their appropriateness for use as performance measurements for purposes of the bonus program. The goals and/or weightings may be re-visited during the year and potentially restated in the event of significant changes in corporate strategy or the occurrence of significant corporate events. Following the agreement of our board of directors on the corporate objectives, the goals are then shared with all employees in a formal meeting(s), and are reviewed periodically throughout the year.

### *Determination of Equity Incentive Compensation*

To assist us in assessing the reasonableness of our equity grant amounts, we have reviewed StreeterWyatt supplied information. Such information included equity data from a cross-section of similar companies in our industry.

### *Equity Grant Practices*

All stock options and/or restricted stock granted to the NEOs and other executives are approved by the Compensation Committee. Exercise prices for options are set at the closing price of our common stock on the date of grant. Grants are generally made: (i) on the employee's start date and (ii) at board of director meetings held each February and following annual performance reviews. However, grants have been made at other times during the year. The size of year-end grants for each NEO is assessed against our internal equity guidelines. Current market conditions for grants for comparable positions and internal equity may also be assessed. Also, grants may be made in connection with promotions or job-related changes in responsibilities. In addition, on occasion, the Compensation Committee may make additional special awards for extraordinary individual or company performance.

### *Compensation Setting Process*

Annually, at a meeting of our board of directors and the Compensation Committee, overall corporate performance and relative achievement of the corporate goals for the prior year are assessed. The relative achievement of each goal is assessed and quantified and the summation of the individual components results in a corporate goal rating, expressed

as percentages. The Compensation Committee then approves the final disbursement of salary increases, cash bonuses and option or restricted stock grants.

The Compensation Committee looks to the CEO's performance assessments of the other NEOs and his recommendations regarding a performance rating for each, as well as input from the other members of our board of directors. These recommendations may be adjusted by the Compensation Committee prior to finalization. For the CEO, the Compensation Committee evaluates his performance, taking into consideration input from the other members of our board of directors, and considers the achievement of overall corporate objectives by both the CEO specifically and the company generally. The CEO is not present during the Compensation Committee's deliberations regarding his compensation.

The Compensation Committee has the authority to directly engage, at our company's expense, any compensation consultants or other advisors (such as StreeterWyatt) that it deems necessary to determine the amount and form of employee, executive and director compensation. In determining the amount and form of employee, executive and director compensation, the Compensation Committee has reviewed and discussed historical salary information as well as salaries for similar positions at comparable companies. However, the availability of this data does not imply that the Compensation Committee is under any obligation to exactly follow peer companies' compensation practices.

We paid consultant fees to StreeterWyatt of \$10,000 during the year ended December 31, 2018. NEOs may have indirect input in the compensation results for other executive officers by virtue of their participation in the performance review and feedback process for the other executive officers.

**ITEM 11. EXECUTIVE COMPENSATION****Summary Compensation Table**

The following table provides information regarding the compensation earned during the fiscal years ended December 31, 2018 and 2017 for our named executive officers.

Name/Position	Year	Salary	Bonus (1)	Option Awards	All Other Compensation	Total
Sandesh Seth (2)	2018	\$545,000	\$280,000	\$549,253	\$ -	\$1,374,253
	2017	\$306,250	\$-	\$-	\$ -	\$306,250
Kaushik J. Dave, Former CEO (3)	2018					
	2017	\$577,942	\$110,000	\$244,766	\$ -	\$932,708
Mark Berger	2018	\$400,000	\$75,000	\$137,313	\$ -	\$612,313
	2017	\$343,750	\$-	\$234,695	\$ -	\$578,445
Dragan Cicic, Former COO (4)	2018					
	2017	\$389,125	\$45,000	\$73,430	\$ -	\$507,555
Anil Kapur	2018	\$294,402	\$-	\$211,261	\$ -	\$505,663
Dale Ludwig	2018	\$323,769	\$-	\$100,926	\$ -	\$424,695
Nitya Ray Former Executive Vice President (5)	2018	\$323,331	\$35,000	\$41,194	\$ -	\$399,525
	2017	\$177,273	\$-	\$198,896	\$ -	\$376,169
Steve O'Loughlin	2018	\$285,000	\$75,000	\$145,552	\$ -	\$505,552
	2017	\$235,152	\$50,000	\$97,907	\$ -	\$383,059

(1) The bonus disclosed in this column relates to performance in the prior year, but was contingent upon board approval, and was paid in the year disclosed.

(2) Mr. Seth was appointed Chief Executive Officer on June 5, 2017. Prior to this, Mr. Seth was Executive Chairman and was paid an annual consulting fee and bonus. In March 2017, Mr. Seth was awarded stock options to purchase 750,000 shares for \$1.39, having an option award value of \$734,301 and in April 2017, Mr. Seth received a bonus as Executive Chairman of \$215,000.

(3)Dr. Dave resigned from the company on May 12, 2017. His 2017 salary includes a severance of \$410,000.

(4)Dr. Cacic resigned from the company on May 12, 2017. His 2017 salary includes a severance of \$283,000.

(5)Dr. Ray resigned from the company on December 21, 2018.

**Director Compensation**

The following table sets forth the compensation of our non-employee directors for the 2018 fiscal year:

Name	Fees Earned or Paid in Cash	Stock Awards	Option Awards (1)	All Other Compensation	Total
Jeffrey W. Chell (2)	\$34,607	-	\$59,366	-	\$93,973
David Nicholson	\$63,500	-	\$41,194	-	\$104,694
Ajit J. Shetty	\$58,500	-	\$41,194	-	\$99,694
Richard Steinhart	\$66,091	-	\$41,194	-	\$107,285

At the end of December 31, 2018, the aggregate number of option awards outstanding for each director was as (1) follows: (i) for Dr. Chell, 150,000, (ii) for Dr. Nicholson, 349,900, (iii) for Dr. Shetty, 150,000, and (iv) for Mr. Steinhart, 299,950.

(2) Mr. Chell was appointed a director on April 27, 2018.

In accordance with SEC rules, the amounts shown reflect the aggregate grant date fair value of option awards granted to Non-Employee Directors during 2018, computed in accordance with Financial Accounting Standards Board Accounting Standards Codification Topic 718.

Our non-employee directors are paid an annual fee of \$40,000 and receive annual option grants. Dr. Nicholson as Lead Director receives an additional annual fee of \$10,000. Board committee members receive the following compensation:

BOD Committee	Chairman	Member
Audit	\$ 20,000	\$ 6,000
Compensation	\$ 10,000	\$ 5,000
Corporate Governance	\$ 7,500	\$ 3,000



**Outstanding Equity Awards at Fiscal Year-End Table**

**OUTSTANDING EQUITY AWARDS AT FISCAL YEAR-END - 2018**

The following table sets forth all unexercised options that have been awarded to our named executives by the Company that were outstanding as of December 31, 2018.

Name (a)	Option Awards				Stock Awards				
	Number of Securities Underlying Unexercised Options (#) (b)	Number of Securities Underlying Unexercised Options (Unexercisable) (#) (c)	Equity Incentive Plan Awards: Number of Securities Underlying Unexercised Options (#) (d)	Option Exercise Price (\$) (e)	Option Expiration Date (f)	Number of Shares or Units of Stock That Have Not Vested (#) (g)	Market Value of Shares or Units of Stock That Have Not Vested (\$) (h)	Equity Incentive Plan Awards: Number of Unearned Shares, Units or Rights That Have Not Vested (#) (i)	Equity Incentive Plan Awards: Market Payout Value of Unearned Shares, Units or Rights That Have Not Vested (\$) (j)
Sandesh Seth	24,975	-	-	1.50	8/30/2022	-	-	-	-
	24,975	-	-	1.50	12/19/2022	-	-	-	-
	280,000	-	-	6.13	9/23/2024	-	-	-	-
	138,000	12,000	-	3.58	2/15/2025	-	-	-	-
	320,000	180,000	-	1.99	4/15/2026	-	-	-	-
	373,000	377,000	-	1.39	3/14/2027	-	-	-	-
	100,000	900,000	-	0.7829	7/13/2028	-	-	-	-
Mark Berger	162,500	162,500	-	1.04	1/17/2027	-	-	-	-
	25,000	225,000	-	0.7829	7/13/2028	-	-	-	-
Anil Kapur	-	475,000	-	0.6369	2/06/2028	-	-	-	-
Dale Ludwig	-	200,000	-	0.723	1/08/2028	-	-	-	-

Nitya Ray	100,000	-	-	1.15	3/21/2019	-	-	-	-
	7,500	-	-	0.7829	3/21/2019	-	-	-	-
Steve O'Loughlin	80,000	20,000	-	1.79	9/28/2025	-	-	-	-
	32,000	18,000	-	1.99	4/15/2026	-	-	-	-
	56,500	43,500	-	1.39	3/14/2027	-	-	-	-
	26,500	238,500	-	0.7829	7/13/2028	-	-	-	-

### Indemnification of Directors and Officers

Section 102(b)(7) of the Delaware General Corporation Law allows a corporation to provide in its certificate of incorporation that a director of the corporation will not be personally liable to the corporation or its stockholders for monetary damages for breach of fiduciary duty as a director, except where the directors breached the duty of loyalty, failed to act in good faith, engaged in intentional misconduct or knowingly violated a law, authorized the payment of a dividend or approved a stock repurchase in violation of Delaware corporate law or obtained an improper personal benefit. Our certificate of incorporation provides for this limitation of liability.



Section 145 of the General Corporation Law of the State of Delaware provides that a Delaware corporation may indemnify any person who was, is or is threatened to be made, party to any threatened, pending or completed action, suit or proceeding, whether civil, criminal, administrative or investigative (other than an action by or in the right of such corporation), by reason of the fact that such person is or was an officer, director, employee or agent of such corporation or is or was serving at the request of such corporation as a director, officer employee or agent of another corporation or enterprise. The indemnity may include expenses (including attorneys' fees), judgments, fines and amounts paid in settlement actually and reasonably incurred by such person in connection with such action, suit or proceeding, provided such person acted in good faith and in a manner he reasonably believed to be in or not opposed to the corporation's best interests and, with respect to any criminal action or proceeding, had no reasonable cause to believe that his conduct was illegal. A Delaware corporation may indemnify any persons who are, or were, a party to any threatened, pending or completed action or suit by or in the right of the corporation by reason of the fact that such person is or was a director, officer, employee or agent of another corporation or enterprise. The indemnity may include expenses (including attorneys' fees) actually and reasonably incurred by such person in connection with the defense or settlement of such action or suit, provided such person acted in good faith and in a manner he reasonably believed to be in or not opposed to the corporation's best interests, provided that no indemnification is permitted without judicial approval if the officer, director, employee or agent is adjudged to be liable to the corporation. Where an officer or director is successful on the merits or otherwise in the defense of any action referred to above, the corporation must indemnify him against the expenses which such officer or directors has actually and reasonably incurred.

Section 145 further authorizes a corporation to purchase and maintain insurance on behalf of any person who is or was a director, officer, employee or agent of the corporation or is or was serving at the request of the corporation as a director, officer, employee or agent of another corporation or enterprise, against any liability asserted against him and incurred by him in any such capacity, or arising out of his status as such, whether or not the corporation would otherwise have the power to indemnify him under Section 145.

Our bylaws provide that we will indemnify our directors and officers to the fullest extent authorized by the General Corporation Law of the State of Delaware. Expenses (including attorneys' fees) incurred by an officer or director of the Corporation in defending any civil, criminal, administrative or investigative action, suit or proceeding may be paid by the Company in advance of the final disposition of such action, suit or proceeding upon receipt of an undertaking by or on behalf of such director or officer to repay such amount if it shall ultimately be determined that such person is not entitled to be indemnified by the Company as authorized under Delaware law. Such expenses (including attorneys' fees) incurred by former directors and officers or other employees and agents of the Company or by persons serving at the request of the Company as directors, officers, employees or agents of another corporation, partnership, joint venture, trust or other enterprise may be so paid upon such terms and conditions, if any, as the Company deems appropriate.

The indemnification rights set forth above shall not be exclusive of any other right which an indemnified person may have or hereafter acquire under any bylaw, agreement, vote of stockholders or disinterested directors or otherwise, both as to action in such person's official capacity and as to action in another capacity while holding such office, and shall continue as to a person who has ceased to be a director, officer, employee, or agent and shall inure to the benefit

of the heirs, executors, and administrators of such person.

We maintain a general liability insurance policy that covers liabilities of directors and officers of our corporation arising out of claims based on acts or omissions in their capacities as directors or officers. We have also entered in to Indemnification Agreements with our executive officers and directors.

At the present time, there is no pending litigation or proceeding involving a director, officer, employee, or other agent of ours in which indemnification would be required or permitted. We are not aware of any threatened litigation or proceeding that may result in a claim for such indemnification.

## **ITEM 12. SECURITY OWNERSHIP OF CERTAIN BENEFICIAL OWNERS AND MANAGEMENT**

The following table shows the beneficial ownership of our Common Stock as of March 5, 2019 held by (i) each person known to us to be the beneficial owner of more than five percent (5%) of any class of our shares; (ii) each director; (iii) each executive officer; and (iv) all directors and executive officers as a group.

Beneficial ownership is determined in accordance with the rules of the SEC, and generally includes voting power and/or investment power with respect to the securities held. Shares of Common Stock subject to options and warrants currently exercisable or which may become exercisable within 60 days of March 5, 2019, are deemed outstanding and beneficially owned by the person holding such options or warrants for purposes of computing the number of shares and percentage beneficially owned by such person, but are not deemed outstanding for purposes of computing the percentage beneficially owned by any other person. Except as indicated in the footnotes to this table, the persons or entities named have sole voting and investment power with respect to all shares of our Common Stock shown as beneficially owned by them.

The percentages below are based on fully diluted shares of our Common Stock equivalents as of March 5, 2019. Unless otherwise indicated, the principal address of each of the persons below is c/o Actinium Pharmaceuticals, Inc., 275 Madison Ave, 7th floor, New York, NY 10016.

Unless otherwise indicated, the principal address of each of the persons below is c/o Actinium Pharmaceuticals, Inc., 275 Madison Ave, 7<sup>th</sup> floor, New York, NY 10016.

Executive Officers and Directors	Number of Shares of Common Stock and Preferred Stock Beneficially Owned		Percentage of Ownership <sup>(a)</sup>	
Sandesh Seth	1,830,147	(1)	1.6	%
Steve O'Loughlin	282,500	(2)	*%	
Mark Berger, M.D.	268,000	(3)	*%	
Anil Kapur	201,500	(4)	*%	
Dale Ludwig, Ph.D.	82,000	(5)	*%	
Jeffrey W. Chell, M.D.	82,000	(6)	*%	
David Nicholson, Ph.D.	241,400	(7)	*%	
Ajit S. Shetty, Ph.D.	78,230	(8)	*%	
Richard I. Steinhart	200,196	(9)	*%	
<b>All Directors and Officers as a Group (9 persons)</b>	3,219,973	(10)	<b>2.7</b>	<b>%</b>
<b>All other 5% holders</b>				

\*less than 1%

(a) Based on 117,337,447 shares of Common Stock outstanding as of March 5, 2019

(1) Warrants to purchase an aggregate of 64,747 shares of Common Stock of the Company at an exercise price of \$0.784 per share, exercisable on a cashless basis, warrants to purchase an aggregate of 99,617 of Common Stock of the Company at an exercise price of \$0.784 per share, exercisable on a cashless basis issued to Amrosan, LLC, a partnership in which the majority member interest is owned by the family of Mr. Seth, and warrants to purchase 57,212 shares of Common Stock at an exercise price of \$1.23 per share. Excludes warrants to purchase an aggregate of 375,556 shares of Common Stock of the Company at par value per share, exercisable on a cashless basis issued to Amrosan, LLC as the warrants are not exercisable upon less than 90 days' notice. The holder may waive the 90-day exercise notice requirement by giving 65 days prior notice of such waiver. Excludes 353,023 warrants issued to Carnegie Hill Asset Partners and irrevocable trust linked to Mr. Seth's family and 721,068 warrants issued to Bioche Asset Management, LLC, a partnership in which the majority member interest is owned by the family of Mr. Seth whose terms are the same as those issued to Amrosan LLC. On August 30, 2012 and December 12, 2012, Mr. Seth was granted options to purchase an aggregate of 49,950 shares of Common Stock at an exercise price of \$1.50 per share. On September 13, 2014, Mr. Seth was granted an option to purchase 280,000

shares with an exercise price of \$6.13 per share. On February 18, 2015, Mr. Seth was granted an option to purchase 150,000 shares with an exercise price of \$3.58 per share. On April 15, 2016, Mr. Seth was granted an option to purchase 500,000 shares at an exercise price of \$1.99 per share. On March 14, 2017, Mr. Seth was granted options to purchase an aggregate of 750,000 shares of Common Stock at an exercise price of \$1.39 per share. On July 13, 2018, Mr. Seth was granted an option to purchase 1,000,000 shares at an exercise price of \$0.7829 per share. All options are subject to vesting. Within 60 days of March 5, 2019, 1,464,950 options will have vested. Includes 161,458 shares of Common Stock and 39,375 March 2018 Series B Warrants.

On October 1, 2015, Mr. O'Loughlin was granted 100,000 options with an exercise price of \$1.79 per share. On April 14, 2016, Mr. O'Loughlin was granted options to purchase of 50,000 shares of Common Stock at an exercise price of \$1.99 per share. On March 14, 2017, Mr. O'Loughlin was granted options to purchase 100,000 shares (2) of Common Stock at an exercise price of \$1.39 per share. On July 13, 2018, Mr. O'Loughlin was granted an option to purchase 265,000 shares of Common Stock at an exercise price of \$0.7829 per share. All options are subject to vesting. Within 60 days of March 5, 2019, 239,500 options will have vested. Includes 35,500 shares of Common Stock and 7,500 March 2018 Series B Warrants.

On January 17, 2017, Dr. Berger was granted an option to purchase 325,000 shares with an exercise price of \$1.04 (3) per share. On July 13, 2018, Dr. Berger was granted an option to purchase 250,000 shares at an exercise price of \$0.7829 per share. All options are subject to vesting. Within 60 days of March 5, 2019, 238,500 options will have vested. Includes 19,000 shares of Common Stock and 10,500 March 2018 Series B Warrants.

On February 6, 2018, Mr. Kapur was granted an option to purchase 475,000 shares with an exercise price of \$0.64 (4) per share. This option is subject to vesting. Within 60 days of March 5, 2019, 161,500 options will have vested. Includes 40,000 shares of Common Stock.

On January 8, 2018, Dr. Ludwig was granted an option to purchase 200,000 shares with an exercise price of \$0.72 (5) per share. This option is subject to vesting. Within 60 days of March 5, 2019, 72,000 options will have vested. Includes 10,000 shares of Common Stock.

On April 27, 2018, Dr. Chell was granted an option to purchase 75,000 shares with an exercise price of \$0.347 per (6) share. On July 13, 2018, Dr. Chell was granted an option to purchase 75,000 shares at an exercise price of \$0.7829 per share. All options are subject to vesting. Within 60 days of March 5, 2019, 36,000 options will have vested.

On February 12, 2012, Dr. Nicholson was granted an option to purchase 49,950 shares of Common Stock at an exercise price of \$0.784 per share and on August 12, 2012 and December 19, 2012, Dr. Nicholson was granted options to purchase an aggregate of 49,950 shares at an exercise price of \$1.50 per share. On February 18, 2015, Dr. Nicholson was granted an option to purchase 25,000 shares with an exercise price of \$3.58 per share. On April (7) 15, 2016, Dr. Nicholson was granted an option to purchase 75,000 shares at an exercise price of \$1.99 per share. On March 14, 2017, Dr. Nicholson was granted an option to purchase 75,000 shares at an exercise price of \$1.39 per share. On July 13, 2018, Dr. Nicholson was granted an option to purchase 75,000 shares at an exercise price of \$0.7829 per share. All options are subject to vesting. Within 60 days of March 5, 2019 231,400 options will have vested. Includes 10,000 shares of Common Stock.

On March 28, 2017, Dr. Shetty was granted an option to purchase 75,000 shares of Common Stock with an (8) exercise price of \$1.58 per share. On July 13, 2018, Dr. Shetty was granted an option to purchase 75,000 shares at an exercise price of \$0.7829 per share. All options are subject to vesting. Within 60 days of March 5, 2019, 55,500 shares will have vested. Includes 22,730 shares of Common Stock.

On December 16, 2013 Mr. Steinhart was granted an option to purchase 49,950 shares of Common Stock at an exercise price of \$6.70 per share. On February 18, 2015, Mr. Steinhart was granted an option to purchase 25,000 shares at an exercise price of \$3.58 per share. On April 15, 2016, Mr. Steinhart was granted an option to purchase 75,000 shares at an exercise price of \$1.99 per share. On March 14, 2017, Mr. Steinhart was granted an option to purchase 75,000 shares at an exercise price of \$1.39 per share. On July 13, 2018, Mr Steinhart was granted an option to purchase 75,000 shares at an exercise price of \$0.7829 per share. All options are subject to vesting. Within 60 days of March 5, 2019, 185,446 options will have vested. Includes 9,500 shares of Common Stock and 10,500 March 2018 Series B Warrants.

(10) Includes warrants to purchase 226,989 shares of Common Stock, vested options to purchase 2,684,796 shares of Common Stock and 308,188 shares of Common Stock.

**ITEM 13. CERTAIN RELATIONSHIPS AND RELATED TRANSACTIONS, AND DIRECTOR INDEPENDENCE**

**Transactions with Related Persons**

None.

**Non-Competition Agreements**

Our executive officers have signed non-competition agreements, which provide that all inventions become the immediate property of us and require invention assignments. The agreements provide that the executive officers will hold proprietary information in the strictest confidence and not use the confidential information for any purpose not expressly authorized by us.

**ITEM 14. PRINCIPAL ACCOUNTANT FEES AND SERVICES**

The table below shows the aggregate fees billed for professional services for the audits and audit-related fees of the Company's annual financial statements included in Form 10-K for the time periods of August 9, 2018 through December 31, 2018 by Marcum LLP, or Marcum, and for January 1, 2018 through August 8, 2018 by GBH CPAs PC, or GBH, and for the year ended December 31, 2017 by GBH. GBH resigned as the Company's auditors as a result of combining its practice with Marcum effective July 1, 2018.

	Year Ended December 31, 2018	Year Ended December 31, 2017
Audit Fees	\$ 113,000	\$ 116,500
Audit – Related Fees	28,800	60,800
Tax Fees	-	-
All Other Fees	-	-
Total	\$ 141,800	\$ 177,300

**Pre-Approval Policy**

In 2015, the Audit Committee adopted policies and procedures for the pre-approval of audit and non-audit services performed by the independent registered public accountants pursuant to which the Audit Committee generally is required to pre-approve the audit and permissible non-audit services performed by the independent registered public accountants in order to ensure that the provision of such services does not impair the registered accountants' independence.



**PART IV**

**ITEM 15. EXHIBITS, FINANCIAL STATEMENT SCHEDULES**

Exhibit Number	Description
1.1	<u>Underwriting Agreement, dated September 28, 2016, by and between H.C. Wainwright &amp; Co., LLC and Actinium Pharmaceuticals, Inc. (incorporated by reference to Exhibit 1.1 to Form 8-K filed on September 29, 2016).</u>
1.2	<u>At Market Issuance Sales Agreement, dated March 16, 2017, between FBR Capital Markets &amp; Co. and Actinium Pharmaceuticals, Inc. (incorporated by reference to Exhibit 1.2 to Form S-3 filed on March 16, 2017).</u>
1.3	<u>Amended and Restated At-the-Market Market Issuance Sales Agreement, dated July 3, 2017, among FBR Capital Markets &amp; Co., MLV &amp; Co. LLC, JonesTrading Institutional Services LLC, and Actinium Pharmaceuticals, Inc. (incorporated by reference to Exhibit 10.5 to Form 10-Q filed on August 4, 2017).</u>
1.4	<u>Underwriting Agreement, dated as of July 28, 2017, by and between Actinium Pharmaceuticals, Inc. and Oppenheimer &amp; Co. Inc. as representative of the several underwriters party thereto (incorporated by reference to Exhibit 1.1 to Form 8-K filed on July 28, 2017).</u>
1.5	<u>Dealer-Manager Agreement, dated February 15, 2018, between Maxim Group LLC and Actinium Pharmaceuticals, Inc. (incorporated by reference to Exhibit 1.1 to Form 8-K filed on February 15, 2018).</u>
2.1	<u>Share Exchange Agreement, dated December 28, 2012, by and among Cactus Ventures, Inc., Actinium Pharmaceuticals, Inc., Diane S. Button, and the shareholders of Actinium Pharmaceuticals, Inc. (incorporated by reference to Exhibit 2.1 to Form 8-K filed on January 2, 2013).</u>
2.2	<u>Share Exchange Agreement, dated March 11, 2013, by and among Cactus Ventures, Inc., Actinium Pharmaceuticals, Inc. and the shareholders of Actinium Pharmaceuticals, Inc. (incorporated by reference to Exhibit 10.1 to Form 8-K filed on March 11, 2013).</u>
2.3	<u>Share Exchange Agreement, dated August 22, 2013, by and among Actinium Pharmaceuticals, Inc., Actinium Corporation, and the shareholders of Actinium Corporation (incorporated by reference to Exhibit 2.3 to Form S-1/A filed on August 22, 2013).</u>
3.1	<u>Certificate of Incorporation of Actinium Pharmaceuticals, Inc. (incorporated by reference to Exhibit 3.1 of the Company's Form 8-K filed with the SEC on April 17, 2013).</u>
3.2	<u>Certificate of Amendment to Certificate of Incorporation filed January 7, 2014 (incorporated by reference to Exhibit 3.5 to Form S-1 filed on January 31, 2014).</u>
3.3	<u>Certificate of Amendment to Certificate of Incorporation filed February 3, 2014. (incorporated by reference to Exhibit 3.1 to Form 8-K filed on February 7, 2014).</u>
3.4	<u>Certificate of Amendment to Certificate of Incorporation (incorporated by reference to Exhibit 3.1 to Form 8-K filed on March 4, 2015).</u>
3.5	<u>Amended and Restated Bylaws, dated August 8, 2018 (incorporated by reference to Exhibit 3.1 to Form 10-Q filed on August 9, 2018).</u>
3.6	<u>Certificate of Amendment to Actinium's Certificate of Incorporation, as amended, filed on February 26, 2018 (incorporated by reference to Exhibit 3.1 to Form 8-K filed on February 26, 2018).</u>

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

- 3.7 Certificate of Amendment to Actinium's Certificate of Incorporation, as amended, filed on March 6, 2019
- 4.1 Form of Common Stock Warrant, dated December 27, 2013 and January 10, 2014 (incorporated by reference to Exhibit 4.8 to Form S-1 filed on January 31, 2014).
- 4.2 Form of Warrant (incorporated by reference to Exhibit 4.1 to Form 8-K filed on February 6, 2015).
- 4.3 Form of Warrant (incorporated by reference to Exhibit 10.1 to Form 8-K filed on July 28, 2017).
- 4.4 Form of Warrant Agency Agreement between Action Stock Transfer Corporation and Actinium Pharmaceuticals, Inc. (incorporated by reference to Exhibit 4.1 to Form 8-K filed on February 15, 2018).
- 4.5 Form of Series A Warrant (incorporated by reference to Exhibit 4.2 to Form 8-K filed on February 15, 2018).
- 4.6 Form of Series B Warrant (incorporated by reference to Exhibit 4.3 to Form 8-K filed on February 15, 2018).
- 4.7 Form of Non-Transferable Subscription Rights Certificate (incorporated by reference to Exhibit 4.4 to Form 8-K filed on February 15, 2018).
- 4.8 Revised Form of Non-Transferable Subscription Rights Certificate. (incorporated by reference to Exhibit 4.1 to Form 8-K filed on February 26, 2018).
- 4.9 Amendment to Warrant to Purchase Common Stock, dated November 8, 2018, issued to Amrosan LLC (incorporated by reference to Exhibit 4.1 to Form 10-Q filed on November 9, 2018).
- 4.10 Amendment to Warrant to Purchase Common Stock, dated November 8, 2018, issued to Carnegie Hill Partners (incorporated by reference to Exhibit 4.2 to Form 10-Q filed on November 9, 2018).
- 4.11 Amendment to Warrant to Purchase Common Stock, dated November 8, 2018, issued to Bioche Asset Management, LLC (incorporated by reference to Exhibit 4.3 to Form 10-Q filed on November 9, 2018).

- 10.1 Third Amendment to the 2013 Amended and Restated Stock Plan, effective as of December 22, 2015 (incorporated by reference to Exhibit 10.56 to Form 10-K filed on March 11, 2016).
- 10.2 Office Space License Agreement, dated March 19, 2016, by and between Actinium Pharmaceuticals, Inc. and Relmada Therapeutics, Inc. (incorporated by reference to Exhibit 10.57 to Form 10-K filed on March 11, 2016).
- 10.3 Fourth Amendment to the 2013 Amended and Restated Stock Plan, effective as of December 13, 2016 (incorporated by reference to Exhibit 1.1 to Form 8-K filed on December 14, 2016).
- 10.4 Fifth Amendment to the 2013 Amended and Restated Stock Plan, as amended (incorporated by reference to Exhibit 10.59 to Form 10-K filed on March 16, 2017).
- 10.5 Amendment to Employment Agreement, dated March 16, 2017, by and between Actinium Pharmaceuticals, Inc. and Dragan Cacic. (incorporated by reference to Exhibit 10.60 to Form 10-K filed on March 16, 2017).
- 10.6 Amendment to Actinium Pharmaceuticals, Inc. Warrant to Purchase Common Stock, dated March 14, 2017 issued to Sandesh Seth (incorporated by reference to Exhibit 10.61 to Form 10-K filed on March 16, 2017).
- 10.7 Amendment to Actinium Pharmaceuticals, Inc. Warrant to Purchase Common Stock, dated March 14, 2017 issued to Amrosan LLC (incorporated by reference to Exhibit 10.62 to Form 10-K filed on March 16, 2017).
- 10.8 Warrant to Purchase Common Stock of Actinium Pharmaceuticals, Inc., dated March 14, 2017, issued to Sandesh Seth (incorporated by reference to Exhibit 10.63 to Form 10-K filed on March 16, 2017).
- 10.9 Offer Letter, dated December 27, 2016, by and between Dr. Mark S. Berger and Actinium Pharmaceuticals, Inc. (incorporated by reference to Exhibit 10.64 to Form 10-K filed on March 16, 2017).
- 10.10 Confidential Information and Invention Assignment Agreement, dated December 27, 2016, by and between Dr. Mark S. Berger and Actinium Pharmaceuticals, Inc. (incorporated by reference to Exhibit 10.65 to Form 10-K filed on March 16, 2017).
- 10.11 Indemnification Agreement, dated March 16, 2017, by and between Actinium Pharmaceuticals, Inc. and Mark S. Berger (incorporated by reference to Exhibit 10.66 to Form 10-K filed on March 16, 2017).
- 10.12 Director Agreement, dated March 28, 2017, between Ajit S. Shetty and Actinium Pharmaceuticals, Inc. (incorporated by reference to Exhibit 10.1 to Form 8-K filed on March 28, 2017).
- 10.13 Indemnity Agreement, dated March 28, 2017, between Ajit S. Shetty and Actinium Pharmaceuticals, Inc. (incorporated by reference to Exhibit 10.2 to Form 8-K filed on March 28, 2017).
- 10.14 Confidential Information and Invention Assignment Agreement, dated March 28, 2017, between Ajit S. Shetty and Actinium Pharmaceuticals, Inc. (incorporated by reference to Exhibit 10.3 to Form 8-K filed on March 28, 2017).
- 10.15 Amendment to Amended and Restated Consulting Agreement, dated May 5, 2017, by and between Actinium Pharmaceuticals, Inc. and Sandesh Seth (incorporated by reference to Exhibit 10.1 to Form 8-K filed on May 11, 2017).
- 10.16 Offer Letter, dated September 17, 2015, between Steve O'Loughlin and Actinium Pharmaceuticals, Inc. (incorporated by reference to Exhibit 10.1 to Form 10-Q filed on May 15, 2017).
- 10.17 Indemnification Agreement, dated May 15, 2017, between Steve O'Loughlin and Actinium Pharmaceuticals, Inc. (incorporated by reference to Exhibit 10.2 to Form 10-Q filed on May 15, 2017).
- 10.18 Assignment and Consent Agreement, dated June 6, 2017, between 275 Madison Avenue RPW 1 LLC and 275 Madison Avenue RPW 2 LLC, Relmada Therapeutics, Inc., and Actinium Pharmaceuticals, Inc. (incorporated by reference to Exhibit 10.1 to Form 10-Q filed on August 4, 2017).
- 10.19 Amended and Restated License Agreement, Dated June 8, 2017, between Relmada Therapeutics, Inc., and Actinium Pharmaceuticals, Inc. (incorporated by reference to Exhibit 10.3 to Form 10-Q filed on August 4, 2017).
- 10.20 Offer Letter, dated May 26, 2017, between Nitya G. Ray and Actinium Pharmaceuticals, Inc. (incorporated by reference to Exhibit 10.4 to Form 10-Q filed on August 4, 2017).
- 10.21 Agreement, dated June 6, 2017, between Sergio Traversa and Actinium Pharmaceuticals, Inc. (incorporated by reference to Exhibit 10.6 to Form 10-Q filed on August 4, 2017).

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

- 10.22 Consulting Agreement, dated May 22, 2017, between Dragan Cicic and Actinium Pharmaceuticals, Inc. (incorporated by reference to Exhibit 10.7 to Form 10-Q filed on August 4, 2017).
- 10.23 Separation and Settlement Agreement, dated May 12, 2017, between Kaushik Dave and Actinium Pharmaceuticals, Inc. (incorporated by reference to Exhibit 10.8 to Form 10-Q filed on August 4, 2017).
- 10.24 Separation and Settlement Agreement, dated May 12, 2017, between Dragan Cicic and Actinium Pharmaceuticals, Inc. (incorporated by reference to Exhibit 10.9 to Form 10-Q filed on August 4, 2017).
- 10.25 Sixth Amendment to the 2013 Amended and Restated Stock Plan, as amended (incorporated by reference to Exhibit 10.56 to Form 10-K filed on March 16, 2018).

- 10.26 Offer Letter, effective January 2, 2018, between Dale L. Ludwig and Actinium Pharmaceuticals, Inc. (incorporated by reference to Exhibit 10.57 to Form 10-K filed on March 16, 2018).
- 10.27 Indemnification Agreement, dated January 5, 2018, between Dale L. Ludwig and Actinium Pharmaceuticals, Inc. (incorporated by reference to Exhibit 10.58 to Form 10-K filed on March 16, 2018).
- 10.28 Offer Letter, effective January 31, 2018, between Anil Kapur and Actinium Pharmaceuticals, Inc. (incorporated by reference to Exhibit 10.59 to Form 10-K filed on March 16, 2018).
- 10.29 Indemnification Agreement, dated February 8, 2018, between Anil Kapur and Actinium Pharmaceuticals, Inc. (incorporated by reference to Exhibit 10.60 to Form 10-K filed on March 16, 2018).
- 10.30 Director Agreement, dated April 27, 2018, by and between Actinium Pharmaceuticals, Inc. and Jeffrey W. Chell (incorporated by reference to Exhibit 10.1 to Form 8-K filed on May 1, 2018).
- 10.31 Indemnity Agreement, dated April 27, 2018, by and between Actinium Pharmaceuticals, Inc. and Jeffrey W. Chell (incorporated by reference to Exhibit 10.2 to Form 8-K filed on May 1, 2018).
- 10.32 Confidential Information and Invention Assignment Agreement, dated April 27, 2018, by and between Actinium Pharmaceuticals, Inc. and Jeffrey W. Chell (incorporated by reference to Exhibit 10.3 to Form 8-K filed on May 1, 2018).
- 10.33 Employment Agreement, dated August 8, 2018, by and between Actinium Pharmaceuticals, Inc. and Sandesh Seth (incorporated by reference to Exhibit 10.1 to Form 10-Q filed on August 9, 2018).
- 10.34 Employment Agreement, dated August 8, 2018, by and between Actinium Pharmaceuticals, Inc. and Steve O'Loughlin (incorporated by reference to Exhibit 10.2 to Form 10-Q filed on August 9, 2018).
- 10.35 Purchase Agreement, dated October 18, 2018, by and between Actinium Pharmaceuticals, Inc. and Lincoln Park Capital Fund, LLC (incorporated by reference to Exhibit 10.1 to Form 8-K filed on October 18, 2018).
- 10.36 Registration Rights Agreement, dated October 18, 2018, by and between Actinium Pharmaceuticals, Inc. and Lincoln Park Capital Fund, LLC (incorporated by reference to Exhibit 10.2 to Form 8-K filed on October 18, 2018).
- 10.37 Consulting Agreement, dated December 21, 2018, between Actinium Pharmaceuticals, Inc. and Nitya Ray.
- 10.38 Amended and Restated At Market Issuance Sales Agreement, dated December 28, 2018, by and among Actinium Pharmaceuticals, Inc. and B. Riley FBR, Inc. and JonesTrading Institutional Services LLC.
- 10.39 Seventh Amendment to the 2013 Amended and Restated Stock Plan, as amended.
- 14.1 Code of Ethics (incorporated by reference to Exhibit 14.1 to Form 8-K filed on January 2, 2013).
- 21.1 List of Subsidiaries (incorporated by reference to Exhibit 21.1 to Form 10-K filed on March 16, 2015).
- 23.1 Consent of GBH CPAs, PC.
- 23.2 Consent of Marcum LLP.
- 31.1 Certification of Principal Executive Officer, pursuant to 18 U.S.C. Section 1350 as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
- 31.2 Certification of Principal Financial and Accounting Officer, pursuant to 18 U.S.C. Section 1350 as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
- 32.1\* Certification of Principal Executive Officer, pursuant to 18 U.S.C. Section 1350 as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
- 32.2\* Certification of Principal Financial and Accounting Officer, pursuant to 18 U.S.C. Section 1350 as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.

101.INS \*\* XBRL Instance Document

101.SCH \*\* XBRL Taxonomy Schema

101.CAL \*\* XBRL Taxonomy Calculation Linkbase  
101.DEF \*\* XBRL Taxonomy Definition Linkbase  
101.LAB \*\* XBRL Taxonomy Label Linkbase  
101.PRE \*\* XBRL Taxonomy Presentation Linkbase

\*In accordance with SEC Release 33-8238, Exhibit 32.1 is being furnished and not filed.

Furnished herewith. XBRL (Extensible Business Reporting Language) information is furnished and not filed or a  
\*\* part of a registration statement or prospectus for purposes of Sections 11 or 12 of the Securities Act of 1933, as  
\*\* amended, is deemed not filed for purposes of Section 18 of the Securities Exchange Act of 1934, as amended, and  
otherwise is not subject to liability under these sections.

## SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, this report has been signed below by the following persons on behalf of the Registrant.

Dated: March 15,  
2019

**ACTINIUM PHARMACEUTICALS, INC.**

By: /s/ Sandesh Seth  
Sandesh Seth  
Chairman and Chief Executive Officer (Duly Authorized Officer,  
Principal Executive Officer)

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

Pursuant to the requirements of the Securities Exchange Act of 1934, this report has been signed below by the following person on behalf of the Registrant and in the capacities and on the dates indicated.

<b>Signature</b>	<b>Title</b>	<b>Date</b>
/s/ Sandesh Seth Sandesh Seth	Chairman and Chief Executive Officer (Principal Executive Officer)	March 15, 2019
/s/ Jeffrey Chell Jeffrey Chell	Director	March 15, 2019
/s/ David Nicholson David Nicholson	Director	March 15, 2019
/s/ Richard I. Steinhart Richard I. Steinhart	Director	March 15, 2019
/s/ Ajit J. Shetty Ajit J. Shetty	Director	March 15, 2019

