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, 2019**

or

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

For the transition period from _____ to _____

COMMISSION FILE NUMBER: 000-52446

ACTINIUM PHARMACEUTICALS, INC.
(Exact name of registrant as specified in its charter)

Delaware	**74-2963609**
(State or other jurisdiction of incorporation or organization)	(I.R.S. Employer Identification No.)

275 Madison Avenue, 7th Fl.
New York, NY 10016
(Address of principal executive offices) (Zip Code)

(646) 677-3870
Registrant's telephone number, including area code

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	Trading symbol	Name of exchange on which registered
Common stock, par value $0.001	**ATNM**	**NYSE American**

Securities registered pursuant to Section 12(g) of the Act: None

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

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

Indicate by check mark whether the registrant: (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes ☒ No ☐

Indicate by check mark whether the registrant has submitted electronically every Interactive Date File required to be submitted pursuant to Rule 405 of Regulation S-T (Section 232.405 of the chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit such files). Yes ☒ No ☐

Indicate by check mark if disclosure of delinquent filers pursuant to Item 405 of Regulation S-K is not contained herein, and will not be contained, to the best of registrant's knowledge, in definitive proxy or information statements incorporated by reference in Part III of this Form 10-K or any amendment to this Form 10-K. ☐

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, 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 28, 2019, 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 28, 2019 was $39,794,272.

As of May 7, 2020, 303,343,699 shares of common stock, $0.001 par value per share, were outstanding.

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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 other 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 applying its proprietary platform technology and deep understanding of radiobiology to the development of novel targeted therapies known as ARCs or Antibody Radiation-Conjugates. Radiation is an effective therapeutic modality that is used in the treatment of over fifty percent of all cancer patients and often combined with chemotherapy and immunotherapy for greater therapeutic effect. Radiation is typically administered from outside the body, which constrains the amount that can be administered to patients due to dose-limiting toxicities. In addition, due to the diffuse nature of the external radiation beam, its usage is limited to solid tumors and cannot be used in blood cancers, which are diffuse. ARCs combine the cell-killing ability of a radioisotope payload with a targeting agent, such as a monoclonal antibody, or mAb, to deliver radiation inside the body to specific cells, to potentially generate greater efficacy and less toxicity. ARCs usage is broader than external delivered radiation as they can be used for both solid tumors and blood cancers. Blood or hematologic cancers are highly sensitive to radiation and our clinical pipeline is focused on ARCs targeting the antigens CD45 and CD33, both of which are expressed in multiple hematologic cancers. Our clinical programs are focused on two primary areas: targeted conditioning prior to a cell or gene therapy procedure and therapeutics, either in combination with other agents or as a monotherapy. Our product development strategy is actively informed by clinical data with our ARCs in over 500 patients, including the ongoing SIERRA trial. Our clinical pipeline has emanated from our AWE, or Antibody Warhead Enabling technology platform, which is protected by over 110 issued and pending patents, trade secrets and know-how.

Targeted Conditioning

We are advancing the only multi-target, multi-indication clinical-stage pipeline for targeted conditioning and the only ARC-based targeted conditioning regimens in development. Our ARCs for targeted conditioning are intended to potentially enable improved access to cell-based therapies with curative potential, including BMT, or bone marrow transplant, ACT, or adoptive cell therapy such as CAR-T, and Gene Therapy, as well as improved outcomes. Conditioning in the context of BMT, ACT or Gene Therapy is the act of depleting certain blood and immune-forming cells, including bone marrow stem cells and, in some cases, diseased cells prior to transplanting new cells into a patient. Currently, conditioning is accomplished using a combination of chemotherapeutic agents and external radiation. These non-targeted conditioning regimens may prevent a patient from receiving a potentially curative therapy and hinder outcomes due to their toxicities. ARCs have the potential to increase patient access and outcomes by way of their ability to selectively deplete targeted cells while sparing normal healthy cells. We use our ARCs at high isotope dose levels to achieve myeloablation, which fully depletes bone marrow stem cells and at lower isotope dose levels to achieve lymphodepletion, which spares bone marrow stem cells from depletion. In addition, dosing may be titrated downward from myeloablative doses to achieve partial myeloablation, which may be appropriate for certain gene therapy programs.

CD45 Targeted Conditioning Program

Our CD45 ARC is comprised of the anti-CD45 monoclonal antibody known as apamistamab (formerly BC8) and the radioisotope I-131 or Iodine-131. CD45 is an antigen expressed on leukemia, lymphoma and myeloma cancer cells, as well as nucleated immune cells, but is not expressed outside of the hematopoietic, or blood, system. This unique expression on blood cancer and immune cells enables simultaneous depletion of both cell types, making CD45 an optimal antigen for targeted conditioning applications. CD45 is a cell surface antigen with an average expression of 200,000 copies per cell, however, it only internalizes at a rate of 10-15%. We believe our ARC approach is the most effective method to target CD45 positive cells, as the radioisotope payload linear energy transfer can readily ablate a targeted cell without requiring payload internalization like an antibody drug conjugate or rely on biological effector function processes like a naked antibody. Furthermore, since CD45 expression level varies from low to high antigen density as the immune cells become more terminally differentiated, we can selectively condition depending on the therapeutic application, from full myeloablation to transient lymphodepletion, by adjusting the dose or intensity of the I-131 isotope payload. Full myeloablation can be achieved with high doses of I-131, as its energy pathlength and crossfire effect can penetrate into bone marrow niches to target and deplete blood and immune system forming bone marrow stem cells. Myeloablation is applicable to autologous or allogeneic BMT and to autologous gene-edited or modified therapies that can reconstitute a patient's blood and immune systems. Alternatively, low doses of I-131 can be transiently lymphodepleting and spare a patient's bone marrow stem cells, which we believe is ideal for ACT applications such as CAR-T. We intend to develop our CD45 targeted conditioning program for BMT, ACT and Gene Therapy applications for malignant and non-malignant diseases.

Our lead CD45 targeted conditioning product candidate is Iomab-B, which uses high doses of I-131 to achieve myeloablative conditioning prior to a BMT. Iomab-B is currently being studied in the pivotal Phase 3 Study of Iomab-B in Elderly Relapsed or Refractory AML, or SIERRA, clinical trial for targeted conditioning prior to an allogeneic BMT for patients with active, relapsed or refractory (r/r) Acute Myeloid Leukemia, or AML, who are age 55 or older. Patients with active, r/r AML are not normally considered eligible for BMT and the SIERRA trial is the only randomized Phase 3 trial to offer BMT as a treatment option for this patient population. The SIERRA trial compares 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 receive the study arm treatment if they meet the eligibility criteria. The primary endpoint of the SIERRA trial is durable Complete Remission, or dCR, of six months and the secondary endpoint is one-year Overall Survival, or OS. When the crossover patients receive Iomab-B and BMT, they have not achieved remission with their salvage therapy and are considered to be failures for the primary endpoint of the study. The SIERRA trial is currently active at 20 sites in the United States and Canada, which includes many of the leading BMT sites based on volume. We expect to complete enrollment of the SIERRA trial and have topline data that we believe will support the submission of a Biologics License Application, or BLA, with the U.S. Food and Drug Administration, or FDA, in 2021. If approved, our initial commercial launch would target the leading 50-100 BMT and medical centers that perform the vast majority of BMT's in the United States. In the European Union or EU, we received favorable feedback from the European Medicines Agency or EMA via their scientific advice program that the trial design, primary endpoint and planned statistical analysis from the SIERRA trial are acceptable as the basis for a Marketing Authorization Application or MAA. Additionally, the EMA commented that it does not anticipate the need for further standalone preclinical toxicology or safety studies. Overall, transplant procedures in the EU are approximately fifty percent higher than in the United States with a similar market dynamic with a majority of BMT volume being conducted in a concentrated number of leading medical centers. We intend to secure a partner for Iomab-B in the EU.

Safety and feasibility data from the first 75 patients enrolled on the SIERRA trial, which represents 50% of the total of 150 patients to be enrolled in the trial, was presented in an oral presentation at the Transplantation & Cellular Therapy Meetings of the American Society for Transplantation and Cellular Therapy (ASTCT) and Center for International Bone & Marrow Transplant Research (CIBMTER) in February 2020. It was reported that 100% of patients (31/31) on the study arm that received a therapeutic dose of Iomab-B received a BMT, with a median time to BMT of 30 days, and all patients achieved neutrophil and platelet engraftment in a median time of 20 days despite a high median blast count of 30%. On the control arm, only 18% of patients (7/38) achieved remission after salvage therapy, and then received a BMT with a median time to BMT of 67 days and median blast count of 26%. Of the 82% of patients failing to achieve a CR with conventional care (31/38), 20 patients were eligible to cross over to the study arm. These patients are considered as having failed the primary endpoint of the study. All crossover patients who received the therapeutic dose of Iomab-B (20/20) received a BMT, with a median time to BMT of 64 days and all patients achieved engraftment in a median time of 19 days despite high median blast count of 35% at time of crossover. It was also reported that 100-day non-relapse transplant-related mortality (100-day TRM) of the study or Iomab-B arm was 6% (2/31) of patients that received a BMT compared to 29% of patients (2/7) who received a BMT after salvage therapy on the control arm. The universal engraftment rate and low 100-day TRM rate of the Iomab-B arm resulted in 29 patients potentially evaluable for the primary endpoint compared to 5 patients in the control arm, a nearly six times difference.

The SIERRA trial is powered for up to two interim analyses of the primary endpoint exercisable at our discretion and triggered by an enrollment range of 70 to 110 patients to evaluate, the primary endpoint of dCR of 180 days. We intend to exercise an ad-hoc analysis, basing our decision to do so on the data reported from SIERRA thus far and comfort with the pace and current status of enrollment as of April 2020, which could generate topline data for the primary endpoint in late 2020 and early termination of the trial if positive. Based on the statistical plan of the study, a single ad-hoc analysis would result in a minimal alpha spend of no more than 0.00925, depending on the number of patients included in the ad-hoc analysis.

Our Iomab-ACT program is intended for targeted conditioning prior to ACT or Gene Therapy and uses the same ^{131}I-apamistamab ARC construct as Iomab-B at varying doses. At lower doses of one-eighth to one-sixth of the myeloablative dose, it is applicable for lymphodepletion prior to CAR-T or certain Gene Therapy applications where stem cell myeloablation is not necessary. At higher doses it is applicable for Gene Therapy applications where stem cell myeloablation is necessary.

We announced a collaboration with University of California Davis to utilize Iomab-ACT conditioning in an ongoing Phase 1/2 trial with a novel anti-HIV autologous stem cell gene therapy for patients with HIV-related lymphoma. This is the first Gene Therapy trial to use an ARC-based conditioning regimen. ^{131}I-Apamistamab has clinical proof of concept as a targeted conditioning regimen for patients with high-risk, relapsed or refractory lymphoma prior to an autologous stem cell transplant from a previous study, where a favorable safety profile with no dose-limiting toxicities and minimal non-hematologic toxicities were observed and promising efficacy with median overall survival not reached (range: 29 months to not reached) and 31% of patients in prolonged remission at a median of 36 months follow up (range: 25 – 41 months). In this study, Iomab-ACT is intended to replace the chemotherapy-based condition regimen known as BEAM (BCNU/carmustine, etoposide, cytarabine, and melphalan) to simultaneously kill the patient's lymphoma cells and deplete the patient's stem cells to make room for the transplant. Upon engraftment, the transplanted gene-modified autologous stem cells containing three anti-HIV genes are intended to equip the patient with a new immune system that is resistant to the HIV virus. Iomab-ACT will be substituted for BEAM in the ongoing Phase 1/2 trial and we expect to have clinical proof of concept data in 2021.

We believe our 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. CD45 is an antigen expressed on certain immune cell types 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 may limit the safety, efficacy and durability of response of these CAR-T therapies including Cytokine Release Syndrome, or CRS, and neurotoxicity. Some of these limitations may be attributable to the chemotherapy-based conditioning agents that are being used prior to CAR-T therapies. Preclinical data supporting the rational for our Iomab-ACT program was presented at multiple medical conferences in 2019. Unlike chemotherapy, preclinical data suggests Iomab-ACT is targeted in nature and, due to this targeted effect, we expect we can improve CAR-T cell expansion more efficiently, potentially resulting in responses that are more durable, but also resulting in reduced CAR-T related toxicities. Importantly, we expect the Iomab-ACT program construct to enable lymphodepletion through a single-dose, outpatient administration versus Flu/Cy or other chemotherapy-based lymphodepletion regimens that can require multiple infusion cycles over several days. Because of this potentially superior profile, the Iomab-ACT construct could result in improved access to CAR-T therapy and better outcomes. We intend to begin a clinical trial with ^{131}I-apamistamab as a targeted conditioning agent prior to CAR-T, subject to identifying a suitable partner and we expect to have Phase 1 clinical proof of concept data in 2021.

CD33 Program: Targeted Conditioning, Combinations and Therapeutics

Our CD33 program is evaluating the clinical utility of an ARC comprised of the anti-CD33 mAb lintuzumab linked to the potent alpha-emitting radioisotope Actinium-225 or Ac-225. CD33 is expressed in the majority of patients with AML and myelodysplastic syndrome, or MDS, as well as approximately one third of patients with multiple myeloma. Our CD33 development program is driven by data obtained from over one hundred treated patients, including results from a Phase 1/2 trial that was conducted in 58 patients with newly diagnosed AML, which was completed in 2018. This clinical data, as well as our experience with Iomab-B, is shaping a two-pronged approach with our CD33 program, where at high doses we are exploring its use for targeted conditioning and at low doses we are exploring its use for therapeutic purposes as a single agent, or in combination with other modalities.

Actimab-MDS is our second clinical trial focused on targeted conditioning, in this case for patients with high-risk MDS and is our second pivotal program. Actimab-MDS is informed by prior experience with our CD33 ARC in multiple trials for patients with AML, MDS and for patients that have 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 complete remissions (CRs) in certain patients at varying dose levels with minimal non-hematologic extramedullary toxicities. However, dose-dependent myelosuppression, a class effect of CD33 directed therapies, was seen in many of these patients. Given that myelosuppression is necessary prior to a BMT and that a BMT can rescue patients with myelosuppression, we decided to pursue a trial in targeted conditioning in high-risk MDS patients with this ARC in combination with Reduced Intensity Conditioning, or RIC, regimens. RIC regimens are comprised of low doses of chemotherapies such as fludarabine, cytarabine, busulfan or melphalan. A BMT is the only curative treatment option for these patients with high-risk MDS who have poor, or very poor cytogenetics. However, these patients have poor outcomes due to high relapse rates following a BMT. Based on our interactions with FDA to date, we will conduct a Phase 1 dose-finding clinical trial that will be followed by a randomized trial that, depending on the results observed, may potentially serve as a pivotal trial to support the submission of a Biologics License Application, or BLA. We are currently finalizing discussions with the FDA.

Our CD33 development program is also studying the construct at various dose levels and dosing regimens either in combination or alone in multiple hematologic disease indications. We currently have multiple clinical trials ongoing, in startup phase and in planning, to study 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 mechanistic rationale supported by our own clinical data, preclinical research and scientific evidence in the literature. We are also studying our CD33 ARC as a monotherapy in the case of multiple myeloma, or MM. Our CD33 ARC development program encompasses the following ongoing and planned trials:

Combination Trials:

- Phase 1 investigator initiated 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. At the 2019 American Society of Hematology Annual Meeting, it was reported that 86% of patients (6/7) receiving 0.50 µCi/kg of Actimab-A, and CLAG-M achieved a complete remission after receiving Actimab-A + CLAG-M, which is nearly 60% greater than the 55% remission rate observed in a study of CLAG-M alone conducted at MCW in the same r/r AML patient population. In addition, 71% of these patients (5/7) achieved negative minimal residual disease status, indicating that these are deep remissions. The 0.50 µCi/kg dose of Actimab-A was shown to be subtherapeutic as a single agent., Since the combination to date has been well tolerated, the study progressed to the third and final cohort that will study Actimab-A at a dose of 0.75 µCi/kg in March 2020 and we expect to complete this trial by the end of 2020. Upon completion, we intend to explore a regulatory pathway for a pivotal trial that could potentially support a registration. The combination of Actimab-A + CLAG-M is supported by mechanistic rationale for combining inhibitors of DNA replication and/or repair processes such as mitoxantrone, a topoisomerase-II inhibitor, and radiation, as imparted by tumor targeting of Ac-225 with Actimab-A. The Actimab-A + CLAG-M combination study has provided proof of principle that the addition of subtherapeutic doses of Actimab-A to other AML therapies can lead to well tolerated regimens with improved responses.

  Phase 1 Actimab-A + Ven combination trial with the BCL-2 inhibitor Venetoclax (Ven) for patients with relapsed or refractory AML. This trial will be led by UCLA Medical Center and will be conducted at three additional trial sites. This combination is supported by mechanistic evidence in preclinical studies using Ven-resistant AML tumor cell lines. In these models, we have demonstrated that Actimab-A can deplete Mcl-1 and Bcl-XL, two proteins implicated in mediating resistance to venetoclax, in addition to causing potentially lethal double-stranded DNA breaks in these CD33 targeted cells. Furthermore, in vivo studies in animal models of Ven-resistant AML demonstrated robust tumor regression and improved survival in cohorts receiving the Actimab-A Ven combination compared to Ven alone. The rationale for this clinical study is that the addition of Actimab-A will; 1) have a direct anti-tumor effect via double-stranded DNA breaks and 2) deplete Mcl-1 and BCL-XL making the AML cells more susceptible to Ven. We expect to initiate the trial and have preliminary proof of concept clinical data from this combination study by the end of 2020.

- Phase 1 Actimab-A + 7+3 combination trial in patients with newly diagnosed AML with intermediate or high-risk cytogenetics or molecular markers. In February 2020, we announced plans to initiate this combination trial to add Actimab-A to 7+3, which is the standard of care chemotherapy regimen comprised of cytarabine and daunorubicin for patients with newly diagnosed AML who are fit for intensive therapy. As we have seen with the combination of Actimab-A + CLAG-M chemotherapy, we believe that Actimab-A will have synergistic and potentiating properties when added to 7+3, which causes DNA damage and has radiation sensitizing properties since daunorubicin is an anthracycline antibiotic that cytotoxically inhibits DNA replication and repair and RNA synthesis through inhibition of topoisomerase II. The rationale for studying Actimab-A in combination with 7+3 is the potential for both additive and synergistic effects due to the interplay of various mechanisms including DNA damage from alpha radiation and the chemotherapy combination, radiation sensitization, and prevention of DNA damage repair. We expect to initiate this Phase 1 trial by the end of 2020 and have proof of concept data in 2021.

Monotherapy Trial:

- Multi-center Phase 1 Actimab-M trial for patients with penta refractory MM. Approximately one third of patients with MM have CD33 expression, which is associated with poorer outcomes. MM is exquisitely sensitive to radiation, but patients do not receive radiation currently because external delivery could result in significant toxicities given that the disease is spread throughout the body. The rationale for this trial is to use a new therapeutic modality of alpha radiation, which MM cells have no known resistance mechanism against, for this high-risk patient population. We have recently initiated Memorial Sloan Kettering Cancer Center as a clinical trial site in the Actimab-M trial, which is currently active at three other trial sites in the United States. We expect to have initial proof of concept data from this trial in 2021.

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 ARCs and certain of their components. Our AWE technology patent portfolio includes 28 patent families comprised of over 110 issued and pending patent applications, of which 9 are issued and 23 pending in the United States, and 81 are issued and pending internationally. The effective life of the patents in our portfolio range from expirations between 2020 to 2039. Our 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 AWE intellectual property covers various methods of use for ARCs in multiple diseases, including indication, dose and scheduling, radionuclide warhead, and therapeutic combinations.

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 May 2020, our patent portfolio includes: 28 patent families comprised of 122 issued and pending patent applications, of which 9 are issued and 22 are pending in the United States, and 91 are issued and pending internationally. Several non-provisional patent applications are expected to be filed in 2020 based on provisional patent applications filed in 2019. More than 90% of our patents are Actinium-owned and the remainder are in-licensed from third parties. 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 49 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 through 2030. Three related global patents are pending. We own or have licensed the rights to four issued patents in the United States and 8 issued patents outside of the United States related to the generation of radioimmunoconjugates that will expire between 2021 and 2037. Twelve related United States or global patents are pending, Further, we own the rights to 32 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 9 patents pending 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 anti-CD45 and anti-CD117 (cKIT) Antibody Drug Conjugates (ADCs) that are in the preclinical stage of development and Jasper Therapeutics, Inc, who is developing an anti-CD117 monoclonal antibody that is being studied in a Phase 1 clinical trial. Forty Seven, Inc.(acquired by Gilead), who is developing a conditioning regimen comprised of the anti-CD47 monoclonal antibody Magrloimab that is being studied in a Phase 2 clinical trial as a therapeutic with an anti-CD117 monoclonal antibody, which is in preclinical development, in collaboration with bluebird bio, Inc., Molecular Templates, who is developing conditioning regimens using its Engineered Toxin Bodies (ETBs) with two targets that have not been disclosed in collaboration with Vertex. Allogene Therapeutics, who is developing an anti-CD52 monoclonal antibody for use as a lymphodepletion agent in conjunction with CAR-T therapies. 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 trials 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 May 7, 2020, we have 25 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

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, 2019 and December 31, 2018, we had an accumulated deficit of $208.8 million and $186.9 million, respectively. We reported a net loss of $21.9 million and $23.6 million for the years ended December 31, 2019 and 2018, 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.

On April 24, 2020, we issued and sold 210.8 million shares of common stock (or pre-funded warrants to purchase shares of common stock in lieu thereof). Gross proceeds from this offering to us were $31.6 million, before deducting underwriting discounts and commissions and other offering expenses payable by us. As of the date of filing this report, we expect that our existing resources will be more than sufficient to fund our planned operations for more than 12 months following the date of this report.

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 many not 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 trials 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.

Our business could be adversely affected by the effects of health epidemics, including the global COVID-19 pandemic.

In December 2019, a novel strain of COVID-19 was reported in China. Since then, COVID-19 has spread globally, to include Canada, the United States and several European countries. The spread of COVID-19 from China to other countries has resulted in the World Health Organization (WHO) declaring the outbreak of COVID-19 as a "pandemic," or a worldwide spread of a new disease, on March 11, 2020. Many countries around the world have imposed quarantines and restrictions on travel and mass gatherings to slow the spread of the virus and have closed non-essential businesses.

As local jurisdictions continue to put restrictions in place, our ability to continue to operate our business may also be limited. Such events may result in a period of business, supply and drug product manufacturing disruption, and in reduced operations, any of which could materially affect our business, financial condition and results of operations. In response to COVID-19, we implemented remote working and thus far have not experienced a significant disruption or delay in our operations as it relates to the clinical development of our drug candidates

The spread of COVID-19, which has caused a broad impact globally, may materially affect us economically. While the potential economic impact brought by, and the duration of, COVID-19 may be difficult to assess or predict, a widespread pandemic could result in significant disruption of global financial markets, reducing our ability to access capital, which could in the future negatively affect our liquidity. In addition, a recession or market correction resulting from the spread of COVID-19 could materially affect our business and the value of our common shares.

Currently, the pivotal Phase 3 SIERRA trial for our lead program, Iomab-B, continues to remain active at a majority of our clinical trial sites, with investigators providing feedback that recruitment and enrollment will remain active because of the acute nature of the disease, the high unmet needs of patients with relapsed or refractory AML, the potentially curative nature of BMT and the differentiated profile of Iomab-B. We currently anticipate that sites currently not actively enrolling due to COVID-19 may resume recruitment and enrollment during the third quarter. In addition, we believe our earlier stage clinical trials for our CD33 program will continue to recruit and enroll patients given the acute nature of relapsed or refractory AML. The continued spread of COVID-19 globally could adversely affect our planned clinical trial operations, including our ability to initiate the trials on the expected timelines and recruit and retain patients and principal investigators and site staff who, as healthcare providers, may have heightened exposure to COVID-19 if an outbreak occurs in their geography. Further, the COVID-19 outbreak could result in delays in our clinical trials due to prioritization of hospital resources toward the outbreak, restrictions in travel, potential unwillingness of patients to enroll in trials at this time, or the inability of patients to comply with clinical trial protocols if quarantines or travel restrictions impede patient movement or interrupt healthcare services. In addition, we rely on independent clinical investigators, contract research organizations and other third-party service providers to assist us in managing, monitoring and otherwise carrying out our preclinical studies and clinical trials, and the outbreak may affect their ability to devote sufficient time and resources to our programs or to travel to sites to perform work for us.

Additionally, COVID-19 may also result in delays in receiving approvals from local and foreign regulatory authorities, delays in necessary interactions with IRB's or Institutional Review Boards, local and foreign regulators, ethics committees and other important agencies and contractors due to limitations in employee resources or forced furlough of government employees.

To date, COVID-19 has not had a financial impact on the Company. However, COVID-19 has caused severe disruptions in transportation and limited access to our facility, resulting in limited support from our staff and professional advisors. The small size of our accounting staff and the additional responsibilities emanating from COVID-19 have presented difficulties to our ability to complete this Report on Form 10-K, resulting in its delay, and may continue to cause a delay in our ability to complete subsequent reports in a timely manner.

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. 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, the 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. Further, we own issued and pending patents related to methods for drug conjugation and isotope labeling and for methods of isotope production. 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. We own an issued patent in the US relating to composition of the Iomab-B product candidate. Five related patents are also pending in the US and internationally. 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.

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 lintzumab-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 currently source medical grade I-131 from three 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 multiple 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 I-131 or obtain I-131 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 grade 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.

The antibodies we use in our antibody radiation-conjugate product candidates may be subject to generic competition.

We are not aware of any existing or pending regulations or legislation that pertains to generic radiopharmaceutical products such as our antibody radiation-conjugate product candidates. 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. Even if a biosimilar gets approved for one of the antibodies that we use, the final constructs of our drug candidates consist of an antibody, radioisotope and in some cases a linker. Therefore, we do not believe that the final drug product of our candidates can be subject to competition from a biosimilar as outlined in BPCIA.

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 the components of our drug product candidates including monoclonal antibodies, linkers and radioisotopes, as well as the final construct which comprises our drug product candidates. We expect to continue to depend on third-party manufacturers for the foreseeable future. Any performance failure on the part of our existing or future manufacturers could delay clinical development, cause us to suspend or terminate development or delay or prohibit regulatory approval of our product candidates or commercialization of any approved products. Further avenues of disruption to our clinical or eventual commercial supply may also occur due to the sale, acquisition, business reprioritization, bankruptcy or other unforeseen circumstances that might occur at any of our suppliers or contract manufacturing partners including an inability to come to terms on renewal of existing contracts or new contracts. With a view to maintaining business continuity we are evaluating alternatives and second and even third sources of supply or manufacturing for our core suppliers and manufacturing partners, however there can be no assurances that we will be able to identify such suppliers or partners and assuming we did, that we would be able to enter into contracts that are on favorable terms or on terms that will enable sufficient supply to ensure business continuity and support our growth plans.

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.

We depend on vendors with specialized operations, equipment and know-how to manufacture the respective components of our drug candidates. We have entered into manufacturing and supply agreements with these third-parties and in some instances, we have agreed that they be the exclusive manufacturer and supplier. If any of the third-parties we depend on encounter difficulties in their operations, fail to comply with required regulations or breach their contractual obligations it may be difficult, or we may be unable to identify suitable alternative third-party manufacturers. While we identify and evaluate third-party manufacturers from time to time, even if we do identify suitable alternative third-parties, we may fail to reach agreement on contractual terms, it may be prohibitively expensive and there can be no assurance that we can successfully complete technology transfer and development work necessary or complete the necessary work in a timely manner. Any of which could prevent us from commencing manufacturing with third-parties. which could cause delays or suspension of our clinical trials and pre-clinical work that may have a negative impact on our business.

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 develop or 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 is considered a Penny Stock.

During the years of 2019 and 2018, the price of our common stock has traded below $5.00 per share, and therefore is 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.

We may be required to effectuate a reverse stock split to be able to maintain compliance with applicable listing requirements or standards of the NYSE AMERICAN exchange or our common stock could get delisted.

On April 29, 2020, we received a deficiency letter from the NYSE American LLC, or NYSE American, indicating that the Company is not in compliance with the NYSE American continued listing standard set forth in Section 1003(f)(v) of the NYSE American Company Guide because our common shares have been selling for a substantial period of time at a low price per share. The letter did not result in the immediate delisting of our common shares from the NYSE American Market.

Pursuant to Section 1003(f)(v) of the NYSE American Company Guide, the NYSE American staff determined that the Company's continued listing is predicated on our effecting a reverse stock split of our common shares or otherwise demonstrating sustained price improvement within a reasonable period of time, which the staff determined to be no later than October 29, 2020.

If we do not effectuate a reverse stock split to maintain compliance with NYSE American listing requirements, we could be delisted from the exchange. We may elect to seek approval for and if authorized, effectuate a reverse stock split to increase the price of our common stock so that our stock is no longer considered a penny stock and to make our stock more marketable to institutional investors that cannot buy stocks below certain prices.

At our Annual Meeting of Stockholders held on December 18, 2019, our stockholders approved an amendment to our certificate of incorporation to effectuate a reverse split at the discretion of our Board of Directors, or Board, at a specific ratio up to 1 for 75 shares as determined by them at their sole discretion. If the Board decided to proceed with a reverse split, we would also need the approval of the Financial Regulatory Authority, or FINRA. There is no guarantee that we would be successful in obtaining the necessary approval from FINRA.

If we fail to maintain compliance with NYSE American listing requirements and our stock is delisted, the market price and liquidity of our common stock could be adversely impacted. This may also reduce our ability to raise additional capital. Even if our Board approves a reverse stock split, there can be no assurance that instuitional investors will buy shares of our common stock. There can be no assurance that our common stock can maintain its post-reverse split price and it may be treated as a penny stock. In the event, that our common stock is delisted from the NYSE AMERICAN or another national securities exchange, trading of our common stock could occur in the over-the-counter market or on an electronic bulletin board established for unlisted securities such as the OTC Bulletin Board or Pink Sheets. This could result in adverse impact on the market price and liquidity of our common stock, a reduction in coverage by security analysts and impair our ability to raise additional capital, all of which could cause the price of our common stock to decline.

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, 2019 and 2018 and while our testing did not reveal any material weaknesses in our internal controls, any material weaknesses in our internal controls in the future would require us to remediate in a timely manner so as to be able to comply with the requirements of Section 404 each year. If we are not able to comply with the requirements of Section 404 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 $341,610. 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 $391,327 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".

Holders

As of May 7, 2020, there were 303,343,699 shares of common stock issued and outstanding, which were held by approximately 99 holders of record. There are no shares of preferred stock outstanding. On May 7, 2020, the closing price of our common stock as reported on the NYSE AMERICAN was $0.19 per share.

Securities Authorized for Issuance under Equity Compensation Plans

We currently have three equity compensation plans defined as follows:

At our Annual Meeting of Stockholders held on December 18, 2019, our stockholders authorized the implementation of a 2019 Stock Plan, to be implemented at the discretion of our Board before December 18, 2020. The 2019 Stock Plan as authorized, if implemented, would have 10,000,000 shares to be issued, in addition to the shares remaining to be issued under our 2013 Stock Plan. As of the date of this report, the 2019 Stock Plan has not been implemented.

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.

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.

The following table indicates shares of common stock authorized for issuance under our equity compensation plans as of December 31, 2019:

Plan category	Number of securities to be issued upon exercise of outstanding options	Weighted-average exercise price of outstanding options	Number of securities remaining available for future issuance
Equity compensation plans approved by security holders	11,385,301	$ 1.17	21,802,069
Equity compensation plans not approved by security holders	-	-	-
Total	11,385,301	$ 1.17	21,802,069

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,	
	2019	2018
Statements of Operations Data:		
Revenues	$ -	$ -
Loss from operations	$ (22,071,447)	$ (23,827,322)
Net loss	$ (21,899,054)	$ (23,653,963)
Net loss per common share:		
Basic and diluted	$ (0.15)	$ (0.22)
Weighted-average common shares outstanding:		
Basic and diluted	149,271,663	106,041,809

	As of December 31,	
	2019	2018
Balance Sheet Data:		
Cash and cash equivalents	$ 9,253,831	$ 13,673,308
Total assets	$ 11,670,407	$ 14,889,394
Total liabilities	$ 6,025,944	$ 6,076,597
Stockholders' equity	$ 5,644,463	$ 8,812,797

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, 2019 and 2018. 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 developing ARCs or Antibody Radiation-Conjugates, which combine the targeting ability of antibodies with the cell killing ability of radiation. Actinium's lead application for our ARCs is targeted conditioning, which is intended to selectively kill patient's cancer cells and certain immune cells prior to a Bone Marrow Transplant, or BMT, CAR-T and other cell therapies. With our ARC approach, we seek to improve patient outcomes and access to these potentially curative treatments by eliminating or reducing the non-targeted chemotherapy that is used for conditioning in standard practice currently. Our lead product candidate, Iomab-B is being studied in the ongoing pivotal Phase 3 Study of Iomab-B in Elderly Relapsed or Refractory Acute Myeloid Leukemia ("SIERRA") trial for BMT conditioning. The SIERRA trial achieved fifty percent patient enrollment in July 2019 and is our leading clinical priority. Beyond Iomab-B, we are developing a multi-disease, multi-target pipeline of clinical-stage ARCs targeting the antigens CD45 and CD33 for targeted conditioning and as a therapeutic either in combination with other therapeutic modalities or as a single agent for patients with a broad range of hematologic malignancies including AML or Acute Myeloid Leukemia, MDS or Myelodysplastic Syndrome, and MM or Multiple Myeloma. Underpinning our clinical programs is our proprietary AWE or Antibody Warhead Enabling technology platform. This is where our intellectual property portfolio of over 100 patents, know-how, collective research and expertise in the field are being leveraged to construct and study novel ARCs and ARC combinations to bolster our pipeline and for strategic purposes. Our AWE technology platform is currently being utilized in a collaborative research partnership with Astellas Pharma, Inc.

On April 24, 2020, we issued and sold 210.8 million shares of common stock (or pre-funded warrants to purchase shares of common stock in lieu thereof). The price to the public in this offering for each share of common stock was $0.15, and the price to the public in this offering for each pre-funded warrant was $0.1499. Each pre-funded warrant has an exercise price of $0.0001 per share. The pre-funded warrants are exercisable immediately upon issuance until all of the pre-funded warrants are exercised in full. The warrants are subject to certain limitations on beneficial ownership. Gross proceeds from this offering to us were $31.6 million, before deducting underwriting discounts and commissions and other offering expenses payable by us. As of the date of filing this report, we expect that our existing resources will be more than sufficient to fund our planned operations for more than 12 months following the date of this report.

On April 29, 2020, we received a deficiency letter from the NYSE American LLC, or NYSE American, indicating that the Company is not in compliance with the NYSE American continued listing standard set forth in Section 1003(f)(v) of the NYSE American Company Guide because our common shares have been selling for a substantial period of time at a low price per share. The letter did not result in the immediate delisting of our common shares from the NYSE American Market.

Pursuant to Section 1003(f)(v) of the NYSE American Company Guide, the NYSE American staff determined that the Company's continued listing is predicated on our effecting a reverse stock split of our common shares or otherwise demonstrating sustained price improvement within a reasonable period of time, which the staff determined to be no later than October 29, 2020.

If we do not effectuate a reverse stock split to maintain compliance with NYSE American listing requirements, we could be delisted from the exchange. We may elect to seek approval for and if authorized, effectuate a reverse stock split to increase the price of our common stock so that our stock is no longer considered a penny stock and to make our stock more marketable to institutional investors that cannot buy stocks below certain prices.

At our Annual Meeting of Stockholders held on December 18, 2019, our stockholders approved an amendment to our certificate of incorporation to effect a reverse stock split of our outstanding common stock by combining outstanding shares of common stock into a lesser number of outstanding shares of common stock by a ratio of not more than 1-for-75 prior to December 18, 2020, with the exact ratio to be set within this range by our Board of Directors, or Board, at its sole discretion. The Board may alternatively elect to abandon such proposed amendment and not effect the reverse stock split authorized by stockholders, in its sole discretion. Upon the effectiveness of the amendment to our certificate of incorporation effecting the reverse stock split, the outstanding shares of our common stock will be reclassified and combined into a lesser number of shares such that one share of our common stock will be issued for a specified number of shares.

Our Board has the sole discretion to effect the amendment and reverse stock split, and to fix the specific ratio for the reverse stock split, provided that the ratio would be not be more than 1-for-75. The reverse stock split would become effective upon the filing of an amendment to our certificate of incorporation with the Secretary of State of the State of Delaware, or at the later time set forth in the amendment. The exact timing of the amendment will be determined by our Board based on its evaluation as to when such action will be the most advantageous to us and our stockholders. In addition, our Board reserves the right, notwithstanding stockholder approval and without further action by our stockholders, to abandon the amendment and the reverse stock split if, at any time prior to the effectiveness of the filing of the amendment with the Secretary of State, our Board determines that it is no longer in our best interest and the best interests of our stockholders to proceed.

Results of Operations – Year Ended December 31, 2019 Compared to the Year Ended December 31, 2018

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

	For the year ended December 31,		Increase
	2019	2018	(Decrease)
Revenues	$ -	$ -	$ -
Operating expenses:			
Research and development, net of reimbursements	16,549,693	17,094,778	(545,085)
General and administrative	5,521,754	6,732,544	(1,210,790)
Total operating expenses	22,071,447	23,827,322	(1,755,875)
Other income			
Interest income – net	172,393	173,359	(966)
Total other income	172,393	173,359	(966)
Net loss	$ (21,899,054)	$ (23,653,963)	$ 1,754,909

Revenues

We recorded no commercial revenues for the years ended December 31, 2019 and 2018, respectively.

Research and Development Expense

Research and development expenses declined by $0.6 million to $16.5 million for the year ended December 31, 2019 compared to $17.1 million for the year ended December 31, 2018. The decrease was primarily attributable to lower expenses related to our CD33 program.

General and Administrative Expenses

General and administrative expenses declined by $1.2 million to $5.5 million for the year ended December 31, 2019 compared to $6.7 million for the year ended December 31, 2018, primarily attributable to lower professional fees and lower non-cash stock-based compensation expense.

Other Income

Other income of $0.2 million for both time periods was attributable to interest income - net.

Net Loss

Net loss decreased by $1.8 million to $21.9 million for the year ended December 31, 2019 compared to $23.7 million for the year ended December 31, 2018. The decrease was primarily due to lower general and administrative expenses and research and development expenses.

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,	
	2019	2018
Cash used in operating activities	$ (21,461,449)	$ (20,571,056)
Cash used in investing activities	(63,893)	(96,092)
Cash provided by financing activities	17,114,078	16,981,086
Net change in cash, cash equivalents and restricted cash	$ (4,411,264)	$ (3,686,062)

Net cash used in operating activities for the year ended December 31, 2019 of $21.5 million increased by $0.9 million from $20.6 million for the prior year, primarily due to the timing of payments to vendors.

Net cash used in investing activities of $64 thousand and $96 thousand for the years ended December 31, 2019 and December 31, 2018, 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 and proceeds from the exercise of warrants.

On April 24, 2020, we issued and sold 210.8 million shares of common stock (or pre-funded warrants to purchase shares of common stock in lieu thereof). Gross proceeds from this offering to us were $31.6 million, before deducting underwriting discounts and commissions and other offering expenses payable by us.

In April 2019, we sold 42.9 million shares of common stock at an offering price of $0.385 per share and warrants to purchase up to 42.9 million shares of common stock at an exercise price of $0.50 per share and with a term of 5 years, resulting in gross proceeds of $16.5 million and net proceeds of $15.1 million after deducting underwriting and other offering expenses.

During 2019, we sold 2.8 million common shares through our at-the-market program with an investment bank, resulting in net proceeds of $0.8 million.

In October, 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 $15.1 million, (each unit was sold at $0.50 per unit), and net proceeds of $13.8 million after deducting expenses relating to dealer-manager fees and other offering expenses.

As of the date of filing this report, we expect that our existing resources will be more than sufficient to fund our planned operations for more than 12 months following the date of this report.

Impact of COVID–19 Pandemic

In December 2019, a novel strain of COVID-19 was reported in China. Since then, COVID-19 has spread globally, to include Canada, the United States and several European countries. The spread of COVID-19 from China to other countries has resulted in the World Health Organization (WHO) declaring the outbreak of COVID-19 as a "pandemic," or a worldwide spread of a new disease, on March 11, 2020. Many countries around the world have imposed quarantines and restrictions on travel and mass gatherings to slow the spread of the virus and have closed non-essential businesses.

As local jurisdictions continue to put restrictions in place, our ability to continue to operate our business may also be limited. Such events may result in a period of business, supply and drug product manufacturing disruption, and in reduced operations, any of which could materially affect our business, financial condition and results of operations. In response to COVID-19, we implemented remote working and thus far have not experienced a significant disruption or delay in our operations as it relates to the clinical development of our drug candidates.

The spread of COVID-19, which has caused a broad impact globally, may materially affect us economically. While the potential economic impact brought by, and the duration of, COVID-19 may be difficult to assess or predict, a widespread pandemic could result in significant disruption of global financial markets, reducing our ability to access capital, which could in the future negatively affect our liquidity. In addition, a recession or market correction resulting from the spread of COVID-19 could materially affect our business and the value of our common shares.

Currently, the Phase 3 SIERRA trial for our lead program, Iomab-B, continues to remain active at a majority of our clinical trial sites, with investigators providing feedback that recruitment and enrollment will remain active because of the acute nature of the disease, the high unmet needs of patients with relapsed or refractory AML, the potentially curative nature of BMT and the differentiated profile of Iomab-B. We currently anticipate that sites currently not actively enrolling due to COVID-19 will likely resume recruitment and enrollment in the summer timeframe. We also believe our earlier stage clinical trials for our CD33 program will also continue to recruit and enroll patients given the acute nature of relapsed or refractory AML. The continued spread of COVID-19 globally could adversely affect our planned clinical trial operations, including our ability to initiate the trials on the expected timelines and recruit and retain patients and principal investigators and site staff who, as healthcare providers, may have heightened exposure to COVID-19 if an outbreak occurs in their geography. Further, the COVID-19 outbreak could result in delays in our clinical trials due to prioritization of hospital resources toward the outbreak, restrictions in travel, potential unwillingness of patients to enroll in trials at this time, or the inability of patients to comply with clinical trial protocols if quarantines or travel restrictions impede patient movement or interrupt healthcare services. In addition, we rely on independent clinical investigators, contract research organizations and other third-party service providers to assist us in managing, monitoring and otherwise carrying out our preclinical studies and clinical trials, and the outbreak may affect their ability to devote sufficient time and resources to our programs or to travel to sites to perform work for us.

Additionally, COVID-19 may also result in delays in receiving approvals from local and foreign regulatory authorities, delays in necessary interactions with IRB's or Institutional Review Boards, local and foreign regulators, ethics committees and other important agencies and contractors due to limitations in employee resources or forced furlough of government employees.

To date, COVID-19 has not had a financial impact on the Company. However, COVID-19 has caused severe disruptions in transportation and limited access to our facility, resulting in limited support from our staff and professional advisors. The small size of our accounting staff and the additional responsibilities emanating from COVID-19 have presented difficulties to our ability to complete this Report on Form 10-K, resulting in its delay, and may continue to cause a delay in our ability to complete subsequent reports in a timely manner.

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.

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

Historically, we accounted for certain instruments, which do not have fixed settlement provisions, as derivative instruments in accordance with the Financial Accounting Standards Board, or FASB, Accounting Standards Codification, or 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 we issue 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 our Consolidated Statements of Operations. In July 2017, FASB, issued Accounting Standard Update, or 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 and did not have a significant impact to our financial statements.

In February 2016, FASB issued ASU No. 2016-02 *Leases* (Topic 842), which created 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. The guidance in ASU 2016-02 is effective for annual and interim reporting periods beginning after December 15, 2018. In July 2018, FASB issued ASU No. 2018-11*, Leases (Topic 842) -Targeted Improvements*, providing an optional transition method that allows entities to initially apply the new leases standard at the adoption date. The Company adopted this Standard effective January 1, 2019, see Note 5.

In June 2018, 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 adopted this Standard effective January 1, 2019. There was no material impact on our financial statements.

Recent Accounting Standards

In August 2018, 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 impact the standard will have on our financial statements.

In November 2018, FASB issued ASU 2018-18, C*ollaborative 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

Since December 31, 2019, we sold 9.5 million common shares through our at-the-market program and realized net proceeds of $2.6 million.

Since December 31, 2019, we elected to sell to Lincoln Park 0.8 million shares and received $0.2 million.

On April 24, 2020, we issued and sold 210.8 million shares of common stock (or pre-funded warrants to purchase shares of common stock in lieu thereof). The price to the public in this offering for each share of common stock was $0.15, and the price to the public in this offering for each pre-funded warrant was $0.1499. Each pre-funded warrant has an exercise price of $0.0001 per share. The pre-funded warrants are exercisable immediately upon issuance until all of the pre-funded warrants are exercised in full. The warrants are subject to certain limitations on beneficial ownership. Gross proceeds from this offering to us were $31.6 million, before deducting underwriting discounts and commissions and other offering expenses payable by us. Net proceeds from this offering were $29.1 million.

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, 2019, 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, 2019 and 2018, respectively.

ITEM 8. FINANCIAL STATEMENTS AND SUPPLEMENTARY DATA.

REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

To the Board of Directors and Stockholders of
Actinium Pharmaceuticals, Inc.

Opinion on the Financial Statements

We have audited the accompanying consolidated balance sheets of Actinium Pharmaceutical, Inc. (the "Company") as of December 31, 2019 and 2018, the related consolidated statements of operations, changes in stockholders' equity and cash flows for the years 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, 2019 and 2018, and the results of its operations and its cash flows for the years then ended, in conformity with accounting principles generally accepted in the United States of America.

Change in Accounting Principle

As discussed in Note 1 to the consolidated financial statements, the Company has changed its method of accounting for leases as of January 1, 2019 due to adoption of Accounting Standards Codification (ASC) 842, *Leases*.

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 audits to obtain reasonable assurance about whether the financial statements are free of material misstatement, whether due to error or fraud. The Company is not required to have, nor were we engaged to perform, an audit of its internal control over financial reporting as of December 31, 2019. As part of our audits we are required to obtain an understanding of internal control over financial reporting but not for the purpose of expressing an opinion on the effectiveness of the Company's internal control over financial reporting. Accordingly, we express no such opinion.

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/ Marcum LLP

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

Marcum LLP
Houston, Texas
May 8, 2020

Actinium Pharmaceuticals, Inc.
Consolidated Balance Sheets

	December 31, 2019	December 31, 2018
Assets		
Current Assets:		
Cash and cash equivalents	$ 9,253,831	$ 13,673,308
Restricted cash – current	48,092	40,075
Prepaid expenses and other current assets	785,715	616,222
Total Current Assets	10,087,638	14,329,605
Property and equipment, net of accumulated depreciation of $237,417 and $266,381	113,136	118,799
Operating lease right-of-use assets	807,374	-
Finance leases right-of-use assets	221,073	-
Security deposit	49,859	49,859
Restricted cash	391,327	391,131
Total Assets	**$ 11,670,407**	**$ 14,889,394**
Liabilities and Stockholders' Equity		
Current Liabilities:		
Accounts payable and accrued expenses	$ 4,597,824	$ 5,814,004
Note payable	380,545	249,239
Operating leases current liability	286,532	-
Finance leases current liability	78,732	-
Total Current Liabilities	5,343,633	6,063,243
Long-term operating lease obligations	531,372	-
Long-term finance lease obligations	150,939	13,354
Total Liabilities	6,025,944	6,076,597
Commitments and contingencies		
Stockholders' Equity:		
Preferred stock, $0.001 par value; 50,000,000 shares authorized, 0 shares issued and outstanding	-	-
Common stock, $0.001 par value; 1,000,000,000 and 600,000,000 shares authorized; 164,701,167 and 115,703,044 shares issued and outstanding	164,701	115,703
Additional paid-in capital	214,237,323	195,554,332
Accumulated deficit	(208,757,561)	(186,857,238)
Total Stockholders' Equity	5,644,463	8,812,797
Total Liabilities and Stockholders' Equity	**$ 11,670,407**	**$ 14,889,394**

See accompanying notes to the consolidated financial statements.

Actinium Pharmaceuticals, Inc.
Consolidated Statements of Operations

	For the Year ended December 31,	
	2019	**2018**
Revenue	$ -	$ -
Operating expenses:		
Research and development, net of reimbursements	16,549,693	17,094,778
General and administrative	5,521,754	6,732,544
Total operating expenses	22,071,447	23,827,322
Loss from operations	(22,071,447)	(23,827,322)
Other income:		
Interest income - net	172,393	173,359
Total other income	172,393	173,359
Net loss	**$ (21,899,054)**	**$ (23,653,963)**
Deemed dividend for warrant down-round protection provision	(1,269)	-
Net loss applicable to common stockholders	**$ (21,900,323)**	**$ (23,653,963)**
Loss per common share - basic and diluted	$ (0.15)	$ (0.22)
Weighted average common shares outstanding - basic and diluted	149,271,633	106,041,809

See accompanying notes to the consolidated financial statements.

Actinium Pharmaceuticals, Inc.
Consolidated Statement of Changes in Stockholders' Equity
For the Years Ended December 31, 2019 and 2018

	Common Stock		Additional Paid-In	Accumulated	Stockholders'
	Shares	Amount	Capital	Deficit	Equity
Balance, January 1, 2018	**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**
Stock-based compensation	394,300	394	1,294,313	-	1,294,707
Sale of common stock and warrants, net of offering costs	46,060,067	46,060	15,886,191	-	15,932,251
Issuance of common stock from exercise of warrants	2,543,756	2,544	1,501,218	-	1,503,762
Deemed dividend for warrant down-round protection provision	-	-	1,269	(1,269)	-
Net loss	-	-	-	(21,899,054)	(21,899,054)
Balance, December 31, 2019	**164,701,167**	**$ 164,701**	**$ 214,237,323**	**$ (208,757,561)**	**$ 5,644,463**

See accompanying notes to the consolidated financial statements.

Actinium Pharmaceuticals, Inc.
Consolidated Statements of Cash Flows

	For the Year ended December 31,	
	2019	**2018**
Cash Flows from Operating Activities:		
Net loss	$ (21,899,054)	$ (23,653,963)
Adjustments to reconcile net loss to net cash used in operating activities:		
Stock-based compensation expense	1,294,707	1,798,655
Depreciation and amortization expense	420,089	50,721
Changes in operating assets and liabilities:		
Decrease in:		
Prepaid expenses and other current assets	253,335	100,032
Increase (decrease) in:		
Accounts payable and accrued expenses	(1,255,740)	1,133,499
Operating lease liabilities	(274,786)	-
Net Cash Used In Operating Activities	(21,461,449)	(20,571,056)
Cash Flows from Investing Activities:		
Purchase of property and equipment	(63,893)	(96,092)
Net Cash Used In Investing Activities	(63,893)	(96,092)
Cash Flows from Financing Activities:		
Payments on note payable	(249,239)	-
Payments on finance leases	(72,696)	-
Proceeds from sales of shares of common stock and warrants, net of offering costs	15,932,251	16,976,237
Proceeds from the exercise of warrants	1,503,762	4,849
Net Cash Provided By Financing Activities	17,114,078	16,981,086
Net change in cash, cash equivalents and restricted cash	(4,411,264)	(3,686,062)
Cash, cash equivalents and restricted cash at beginning of year	14,104,514	17,790,576
Cash, cash equivalents and restricted cash at end of year	**$ 9,693,250**	**$ 14,104,514**
Supplemental disclosures of cash flow information:		
Cash paid for interest	$ 26,547	$ -
Cash paid for taxes	$ -	$ -
Supplemental disclosure of non-cash investing and financing activities:		
Prepaid expenses financed by accounts payable and notes payable	$ 422,828	$ 276,932
Capital lease of office equipment	$ -	$ 16,078
Deemed dividend for warrant down-round protection provision	$ 1,269	$ -

See accompanying notes to the 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.

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.

Impact of COVID–19 Pandemic on Financial Statements

In December 2019, a novel strain of COVID-19 was reported in China. Since then, COVID-19 has spread globally, to include Canada, the United States and several European countries. The spread of COVID-19 from China to other countries has resulted in the World Health Organization (WHO) declaring the outbreak of COVID-19 as a "pandemic," or a worldwide spread of a new disease, on March 11, 2020. Many countries around the world have imposed quarantines and restrictions on travel and mass gatherings to slow the spread of the virus and have closed non-essential businesses.

As local jurisdictions continue to put restrictions in place, our ability to continue to operate our business may also be limited. Such events may result in a period of business, supply and drug product manufacturing disruption, and in reduced operations, any of which could materially affect our business, financial condition and results of operations. In response to COVID-19, the Company implemented remote working and thus far, has not experienced a significant disruption or delay in our operations as it relates to the clinical development or drug production of our drug candidates.

To date, COVID-19 has not had a financial impact on the Company. However, COVID-19 has caused severe disruptions in transportation and limited access to the Company's facility, resulting in limited support from its staff and professional advisors. The small size of the Company's accounting staff and the additional responsibilities emanating from COVID-19 have presented difficulties to the Company's ability to complete this Report on Form 10-K, resulting in its delay, and may continue to cause a delay in the Company's ability to complete subsequent reports in a timely manner.

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.

Following is a summary of cash, cash equivalents and restricted cash at December 31, 2019 and December 31, 2018:

	December 31, 2019	December 31, 2018
Cash and cash equivalents	$ 9,253,831	$ 13,673,308
Restricted cash – current	48,092	40,075
Restricted cash – long-term	391,327	391,131
Cash, cash equivalents and restricted cash	$ 9,693,250	$ 14,104,514

Current restricted cash relates to credit card accounts, while long-term restricted cash relates to a certificate of deposit held as collateral for a letter of credit issued in connection with the Company's lease for corporate office space.

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.

Leases – The Company has operating and finance leases for corporate office space, office equipment and furniture located at the corporate office space. Leases with an initial term of 12 months or less are not recorded on the balance sheet; lease expense for these leases is recognized on a straight-line basis over the lease term.

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.

Income Taxes - The Company accounts for income taxes in accordance with FASB ASC 740 Income Taxes, which requires the asset and liability method to calculate deferred taxes. Deferred taxes are recognized based on the differences between the financial reporting and income tax bases of assets and liabilities using the enacted tax rates and laws that will be in effect when the differences are expected to reverse. The Company reviews deferred tax assets for a valuation allowance based upon whether it is more likely than not that the deferred tax asset will be fully realized.

FASB ASC 740 prescribes guidance for the financial statement recognition, measurement and disclosure of uncertain tax positions. Tax positions must meet a "more-likely-than-not" recognition threshold to be recognized. 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

Revenue Recognition - The Company adopted new accounting guidance for revenue recognition, effective January 1, 2018, which had no impact on the Company's financial statements. Beginning January 1, 2018, revenues will be 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. These costs include the costs of manufacturing drug product, the costs of clinical trials, costs of employees and associated overhead, and depreciation and amortization costs related to facilities and equipment. 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.

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 periods of net income, and when the effects are not anti-dilutive, diluted earnings per share is computed by dividing net income available to common stockholders by the weighted-average number of shares outstanding plus the impact of all potential dilutive common shares, consisting primarily of common shares underlying common stock options and warrants using the treasury stock method. For periods of net loss, diluted loss per share is calculated similarly to basic loss per share because the impact of all potential dilutive common shares is anti-dilutive. For the years ended December 31, 2019 and 2018, 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, 2019	December 31, 2018
Options	11,385,301	7,236,101
Warrants	86,140,575	55,820,876
Total	97,525,876	63,056,977

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

Accounting Standards Recently Adopted -

Historically, the Company accounted for certain instruments, which do not have fixed settlement provisions, as derivative instruments in accordance with the Financial Accounting Standards Accounting Board, or FASB, Accounting Statement Codification, or 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 Consolidated Statements of Operations. In July 2017, FASB issued Accounting Standard Update, or 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 and did not have a significant impact to the Company's financial statements. See Note 2 for further discussion.

In February 2016, the FASB issued ASU No. 2016-02, Leases (Topic 842). In July 2018, the FASB issued ASU No. 2018-10, Codification Improvements to Topic 842, Leases (ASU 2018-10), which provides narrow amendments to clarify how to apply certain aspects of the new lease standard, and ASU No. 2018-11, Leases (Topic 842) —Targeted Improvements (ASU 2018-11), which addressed implementation issues related to the new lease standard. These and certain other lease-related ASUs have generally been codified in ASC 842. ASC 842 supersedes the lease accounting requirements in ASC Topic 840, Leases (ASC 840). ASC 842 establishes a right-of-use model that requires a lessee to record a right-of-use asset and a lease liability on the balance sheet for all leases. Under ASC 842, leases are classified as either finance or operating, with classification affecting the pattern of expense recognition in the income statement. ASU 2016-02 was effective for annual reporting periods beginning after December 15, 2018 and interim periods within that reporting period. The Company adopted ASC 842 on January 1, 2019 using the effective date transition method. Prior period results continue to be presented under ASC 840 based on the accounting standards originally in effect for such periods.

The Company has elected certain practical expedients permitted under the transition guidance within ASC 842 to leases that commenced before January 1, 2019, including the package of practical expedients. The election of the package of practical expedients resulted in the Company not reassessing prior conclusions under ASC 840 related to lease identification, lease classification and initial direct costs for expired and existing leases prior to January 1, 2019. The Company elected the practical expedient to not record short-term leases on its consolidated balance sheet. The adoption of ASU 2016-02 did not have a significant impact on the Company's consolidated results of operations or cash flows. See Note 5 for additional information.

In June 2018, 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 adopted this Standard effective January 1, 2019 and did not have a significant impact to the Company's financial statements.

Recent Accounting Standards –

In August 2018, 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 impact the standard will have on its financial statements.

In November 2018, FASB issued ASU 2018-18, C*ollaborative 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.

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, net, in the Company's accompanying Consolidated Statements of Operations.

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 treated outstanding warrants as free-standing equity-linked instruments that were recorded as a charge to equity in the Consolidated Balance Sheet as of January 1, 2018. In accordance with the guidance presented in the ASU 2017-11, the fair value of the derivative liability balance for 57,212 warrants as of December 31, 2017 of $16 thousand was reclassified by means of a cumulative-effect adjustment to equity as of January 1, 2018. The impact of the adoption was as follows:

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

Note 3 - Prepaid Expenses and Other Current Assets

Prepaid expenses and other current assets consisted of the following at December 31, 2019 and 2018:

	December 31, 2019	December 31, 2018
Prepaid insurance	$ 479,783	$ 339,336
Prepaid clinical trial expenses	236,096	171,128
Other prepaid expenses and other current assets	69,836	105,758
Total prepaid expenses and other current assets	$ 785,715	$ 616,222

In December 2019, the Company renewed an insurance policy for $422,828, which is being financed through a third party premium financing company with a down payment of $42,283 recorded in accounts payable and accrued expenses on the consolidated balance sheets and a note payable of $380,545 issued for the remaining balance, payments are scheduled during 2020. In December 2018, the Company issued a note payable for $249,239 for insurance premiums, this note was repaid in 2019.

Note 4 - Property and Equipment

Property and equipment consisted of the following at December 31, 2019 and 2018:

	Lives	December 31, 2019	December 31, 2018
Lab equipment	5 years	$ 147,902	$ 176,500
Office equipment & furniture	3 - 7 years	202,651	208,680
Less: accumulated depreciation		(237,417)	(266,381)
Property and equipment, net		$ 113,136	$ 118,799

Depreciation expense consisted of the following for the years ended December 31, 2019 and 2018, respectively:

	December 31, 2019	December 31, 2018
Research & development	$ 31,732	$ 20,170
General administrative	21,746	30,551
Depreciation expense	$ 53,478	$ 50,721

Note 5 - Leases

The Company adopted ASC 842 as of January 1, 2019, using a modified retrospective approach and applying the standard's transition provisions at January 1, 2019, the effective date. The Company made an accounting policy election to exclude from balance sheet reporting those leases with initial terms of 12 months or less.

The Company determines if an arrangement is a lease at inception. This determination generally depends on whether the arrangement conveys to the Company the right to control the use of an explicitly or implicitly identified fixed asset for a period of time in exchange for consideration. Control of an underlying asset is conveyed to the Company if the Company obtains the rights to direct the use of and to obtain substantially all of the economic benefits from using the underlying asset. The Company has lease agreements which include lease and non-lease components, which the Company has elected to account for as a single lease component for all classes of underlying assets. Lease expense for variable lease components are recognized when the obligation is probable.

Right-of-use assets and liabilities are recognized at commencement date based on the present value of lease payments over the lease term. ASC 842 requires a lessee to discount its unpaid lease payments using the interest rate implicit in the lease or, if that rate cannot be readily determined, its incremental borrowing rate. As an implicit interest rate is not readily determinable in the Company's leases, the incremental borrowing rate is used based on the information available at commencement date in determining the present value of lease payments.

The lease term for all of the Company's leases includes the non-cancellable period of the lease plus any additional periods covered by either a Company option to extend (or not to terminate) the lease that the Company is reasonably certain to exercise, or an option to extend (or not to terminate) the lease controlled by the lessor. Options for lease renewals have been excluded from the lease term (and lease liability) for the majority of the Company's leases as the reasonably certain threshold is not met.

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 with an expiration date of September 6, 2022, with a current annual rate of $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 maintains a $391,327 certified deposit as collateral for the letter of credit. For accounting purposes, this lease is treated as an operating lease.

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. For accounting purposes, this lease is treated as a finance lease.

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. For accounting purposes, this lease is treated as a finance lease.

Upon adoption of ASC 842, the Company recognized $1.2 million of right-to-use assets as operating leases and $0.3 million of right-to-use assets as finance leases. The Company also recognized $0.9 million of long-term operating lease obligations, net of the current portion of $0.3 million and $0.2 million of long-term finance lease obligations, net of the current portion of $0.1 million.

The components of lease expense are as follows:

	Year ended December 31, 2019
Operating lease expense	$ 369,300
Finance lease cost	
Amortization of right-to-use assets	$ 81,295
Interest on lease liabilities	$ 21,562
Total finance lease cost	$ 102,857

Supplemental cash flow information related to leases are as follows:

	Year ended December 31, 2019
Cash flow information:	
Cash paid for amounts included in the measurement of lease liabilities:	
Operating cash flows from operating leases	$ 355,922
Operating cash flows from finance leases	$ 21,562
Financing cash flows from finance leases	$ 72,696
Non-cash activity:	
Right-of-use assets obtained in exchange for lease obligations at December 31, 2019:	
Operating leases	$ 807,374
Finance Leases	$ 221,073

Weighted average remaining lease terms are as follows at December 31, 2019:

Weighted average remaining lease term:	
Operating leases	2.7 years
Finance Leases	2.7 years

As the Company's leases do not provide an implicit rate, the Company used its incremental borrowing rate based on the information available at adoption date in determining the present value of lease payments. Below is information on the weighted average discount rates used:

Weighted average discount rates:	
Operating leases	8%
Finance Leases	8%

Maturities of lease liabilities are as follows:

Year ending December 31,	Operating Leases	Finance Leases
2020	$ 341,610	$ 94,260
2021	341,610	94,260
2022	227,740	64,144
2023	-	3,912
Total lease payments	$ 910,960	$ 256,576
Less imputed interest	(93,056)	(26,905)
Present value of lease liabilities	$ 817,904	$ 229,671

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:

a. 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, 2019 and 2018, the Company purchased material from ORNL of $0.2 million and $0.3 million, respectively. In November 2019, the Company signed a contract with ORNL to purchase $0.3 million of radioactive material during calendar year 2020.

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

c. 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, 2019, the remaining cost of the service agreement is $0.3 million. During the years ended December 31, 2019 and 2018, the Company paid Goodwin $1.5 million and $1.2 million, respectively.

d. On February 16, 2016, the Company entered into an agreement with Medpace, Inc. ("Medpace"), a contract research organization. Medpace provides project management services for the Iomab-B study. In January 2020, the Company and Medpace amended their agreement. The total project is currently estimated to cost $11.9 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, 2019 and 2018, the Company paid Medpace $3.1 million and $3.1 million, respectively. These payments are for Medpace project management services and pass-through expenses incurred by investigators and clinical sites.

Note 7 - Equity

In April 2019, the Company sold 42.9 million shares of common stock at an offering price of $0.385 per share and warrants to purchase up to 42.9 million shares of common stock at an exercise price of $0.50 per share and with a term of 5 years, resulting in gross proceeds of $16.5 million and net proceeds of $15.1 million after deducting underwriting and other offering expenses.

For the year ended December 31, 2019, the Company sold 2.8 million common shares through its at-the-market program with an investment bank, resulting in net proceeds of $0.8 million.

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 $32.5 million, 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 0.9 million 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 3.4 million shares of common stock, at a price of $0.74 per share, for a total gross purchase price of $2.5 million. 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 $30.0 million of shares of common stock, (subject to certain limitations), 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 thousand 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 $1.5 million, 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.

During 2019, the Company elected to sell to Lincoln Park 0.4 million shares and received $0.1 million. During 2018, the Company elected to sell to Lincoln Park 1.0 million shares and received $0.7 million.

In March 2018, the Company 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 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 the Company of $15.1 million (each unit was sold at $0.50 per unit), and net proceeds of $13.8 million after deducting expenses relating to dealer-manager fees and other offering expenses.

Authorized Shares

At the Company's Annual Meeting of Stockholders held on December 18, 2019, its stockholders approved an increase in the number of authorized shares of the Company's common stock to 1.0 billion shares.

Authorization for Reverse Stock Split

At the Company's Annual Meeting of Stockholders held on December 18, 2019, its stockholders approved an amendment to the Company's certificate of incorporation to effect a reverse stock split of its outstanding common stock by combining outstanding shares of common stock into a lesser number of outstanding shares of common stock by a ratio of not more than 1-for-75 prior to December 18, 2020, with the exact ratio to be set within this range by the Company's Board of Directors, or Board, at its sole discretion. The Board may alternatively elect to abandon such proposed amendment and not effect the reverse stock split authorized by stockholders, in its sole discretion.

2019 Stock Option Plan

At the Company's Annual Meeting of Stockholders held on December 18, 2019, its stockholders authorized the implementation of a 2019 Stock Plan, to be implemented at the discretion of the Company's Board before December 18, 2020. The 2019 Stock Plan as authorized, if implemented, would have 10.0 million shares to be issued. As of the date of this report, the 2019 Stock Plan has not been implemented.

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 at the time of approval, 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 2.75 million 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 9.25 million 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 12.75 million 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 17.75 million 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 22.75 million 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 thousand shares. In December 2013, the shareholders of the Company approved the plan and increased the number of shares authorized under the plan to 1 million shares.

Restricted Stock

During 2019, the Company granted 0.4 million restricted common shares for consulting services, which all vested during 2019. The shares had a total value of $0.1 million. During 2019, the Company issued 0.4 million common shares for restricted shares that became fully vested.

As of December 31, 2019, the Company has yet to issue 0.3 million common shares for restricted shares that have vested. All restricted shares granted were vested with no unamortized compensation expenses.

During 2018, the Company granted 108 thousand restricted common shares for consulting services, which all vested during 2018. The shares had a total value of $72 thousand. During 2018, the Company issued 156 thousand common shares for restricted shares that became fully vested, of which 81 thousand shares were granted prior to 2018.

During the years ended December 31, 2019 and 2018, the Company recorded stock-based compensation expense of $0.1 million for the restricted shares granted.

Stock Options

Following is a summary of option activities for the years ended December 31, 2019 and 2018:

	Number of Options	Weighted Average Exercise Price	Weighted Average Remaining Contractual Term (in years)	Aggregate Intrinsic Value
Outstanding, January 1, 2018	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
Granted	5,833,500	0.27		
Cancelled	(1,684,300)	0.48		
Outstanding, December 31, 2019	11,385,301	1.17	7.88	155
Exercisable, December 31, 2019	4,915,006	2.10	6.34	-

During 2019, the Company granted its employees and members of the Board options to purchase 5.8 million shares of Company common stock with an exercise price ranging from $0.2146 to $0.58 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 $1.1 million that was calculated using the Black-Scholes option-pricing model. Variables used in the Black-Scholes option-pricing model include: (1) discount rate range from 1.38% to 2.6% (2) expected life of 6 years, (3) expected volatility range from 78.5% to 81.8%, and (4) zero expected dividends.

During 2018, the Company granted its employees and members of the Board options to purchase 3.6 million shares of 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 years ended December 31, 2019 and 2018, options to purchase 1.7 million and 1.5 million common shares were cancelled, respectively, upon the termination of employment. There were no exercises of options during 2019 and 2018.

The fair values of all options issued and outstanding are being amortized over their respective vesting periods. The unrecognized compensation expense at December 31, 2019 was $2.1 million related to unvested options, which is expected to be expensed over a weighted average of 3.2 years. During 2019 and 2018, the Company recorded total option expense of $1.2 million and $1.7 million, respectively.

Warrants

Following is a summary of warrant activities for the years ended December 31, 2019 and 2018:

	Number of Warrants	Weighted Average Exercise Price	Weighted Average Remaining Contractual Term (in years)	Aggregate Intrinsic Value
Outstanding, January 1, 2018	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
Granted	42,900,000	0.50		
Exercised	(2,543,826)	0.59		
Cancelled	(10,036,475)	2.76		
Outstanding, December 31, 2019	86,140,575	0.69	2.95	301,092
Exercisable, December 31, 2019	85,928,076	0.68	2.95	301,092

In April 2019, the Company sold 42.9 million shares of common stock at an offering price of $0.385 per share and warrants to purchase up to 42.9 million shares of common stock at an exercise price of $0.50 per share and with a term of 5 years. The transaction date relative fair value of the April 2019 warrants of $5.3 million was determined utilizing the Black-Scholes option pricing model and variables of (1) a discount rate of 2.35%, (2) expected term of 5 years, (3) expected volatility of 78% and (4) zero expected dividends.

The Company has outstanding warrants to purchase 57 thousand shares that include down-round protection. For warrants with down-round protection, a deemed dividend is recorded for the change in fair value of the warrants when the down-round provision is triggered. As result of the April 2019 offering, the exercise price of the warrant was reset from $1.25 per share to $0.88 per share. The down-round protection provision in the above warrants created a deemed dividend to common stockholders of $1,269, which is reflected in the accompanying consolidated statement of operations and consolidated statement of changes in stockholders' equity.

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 30.2 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 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 2019, holders of 2.5 million series A warrants exercised their warrants and received 2.5 million common shares. The remaining 5.1 million series A warrants expired in March 2019.

During 2018, the Company granted 123 thousand 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 $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.

During the years ended December 31, 2019 and 2018, the Company recorded stock-based compensation expense related to warrants of $8 thousand and $33 thousand, respectively.

Note 8 - Income Taxes

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, 2019 and 2018 are as follows:

	2019	2018
Deferred tax assets:		
Net operating losses carry forward	$ 31,688,387	$ 34,531,577
Share-based compensation	1,421,701	2,950,963
Research and development/orphan drug credits	10,871,634	8,896,703
Intangibles	5,942,126	-
Others	13,172	15,285
Less: valuation allowance	(49,937,020)	(46,394,528)
Deferred tax assets, net	$ -	$ -

The Company has recorded a valuation allowance of $49.9 million and $46.4 million against its deferred tax assets at December 31, 2019 and 2018, 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 $140.6 million of unused net operating losses ("NOLs") at December 31, 2019 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 $71.5 million of unused NOLs at December 31, 2019 available for carry forward to future years. These NOLs will begin to expire in 2033 if unused.

The Company has federal research and development tax credits of $1.8 million at December 31, 2019 which will begin to expire in 2033 if unused and orphan drug credits of $9.1 million which will begin to expire in 2037 if unused.

Federal and state tax laws impose limitations on the utilization of net operating losses and credit carryforwards in the event of an ownership change for tax purposes, as defined in Section 382 of the Internal Revenue Code. 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, 2019 and 2018 are as follows:

	December 31, 2019		December 31, 2018	
Federal statutory income taxes	$ (4,598,801)	(21.0)%	$ (4,967,332)	(21.0)%
State income taxes	1,076,602	4.9%	1,413,678	6.0%
Deferred true-up	1,809,913	8.3%	-	-%
Research and Development/Orphan Drug Tax Credit	(1,974,931)	(9.0)%	(1,986,609)	(8.4)%
Other	144,725	0.6%	40,049	0.2%
Change in valuation allowance	3,542,492	16.2%	5,500,214	23.2%
Provision for income tax	$ -	-	$ -	-

Note 9 - Subsequent Events

Since December 31, 2019, the Company sold 9.5 million common shares through its at-the-market program and realized net proceeds of $2.6 million.

Since December 31, 2019, the Company sold 0.8 million shares to Lincoln Park and received $0.2 million.

On April 24, 2020, the Company issued and sold 210.8 million shares of common stock (or pre-funded warrants to purchase shares of common stock in lieu thereof). The price to the public in this offering for each share of common stock was $0.15, and the price to the public in this offering for each pre-funded warrant was $0.1499. Each pre-funded warrant has an exercise price of $0.0001 per share. The pre-funded warrants are exercisable immediately upon issuance until all of the pre-funded warrants are exercised in full. The warrants are subject to certain limitations on beneficial ownership. Gross proceeds from this offering to Actinium were $31.6 million, before deducting underwriting discounts and commissions and other offering expenses payable by the Company. Net proceeds from this offering were $29.1 million.

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) and 15d-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, 2019 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, 2019. 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, 2019, the Company's internal control over financial reporting was effective.

This Annual Report on Form 10-K does not include an attestation report from our registered public accounting firm regarding internal control over financial reporting. Our internal control over financial reporting was not subject to such attestation as we are a non-accelerated filer.

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.

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

None.

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 May 1, 2020, are as follows:

Name	Age	Position
Sandesh Seth	55	Chairman and Chief Executive Officer
Mark S. Berger, M.D.	65	Chief Medical Officer
Dale L. Ludwig, Ph.D.	58	Chief Scientific Officer
Steve O'Loughlin	35	Principal Financial Officer (Principal Financial and Accounting Officer)
Jeffrey W. Chell M.D.	65	Director
David Nicholson, Ph.D.	64	Lead Independent Director
Richard I. Steinhart	63	Director
Ajit S. Shetty, Ph.D.	73	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 was Chairman of Relmada Therapeutics Inc., a specialty pharma company focused on CNS therapeutics, which he helped co-found. 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. He has several patents related to use of radiopharmaceuticals as conditioning agents for adoptive cell therapies and as therapeutic combinations.

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.

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®, CyramzaTM, Portrazza®, and LartruvoTM 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 fivefold 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.

That Dr. Chell brings many years of experience with patient donor programs, knowledge of challenges related to bone marrow transplants, leadership of organizations and experience working in medical groups to our Board, led us to conclude that Dr. Chell should serve as a director.

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 Senior Vice President and 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. Form October 2015 to April 2017, Mr. Steinhart was Vice President and Chief Financial Officer at Remedy Pharmaceuticals, a privately-held, clinical stage pharmaceutical company. From January 2014 through September 2015 Mr. Steinhart worked as 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 executive-level financial 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:

Director	Class	Term (from 2019 Annual Meeting)
David Nicholson	Class I	1 year
Richard Steinhart	Class I	1 year
Sandesh Seth	Class II	2 years
Jeffrey W. Chell	Class II	2 years
Ajit Shetty	Class III	3 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 one-year term from the date of the 2019 Annual Shareholders Meeting; Class II shall serve a two-year term from the date of the 2019 Annual Shareholders Meeting; and Class III shall serve a three-year term from the date of the 2019 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 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 $561,350. 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 Compensation

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 $405,000 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.

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

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 $293,550 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 $334,750 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.

Board of Directors Meetings and Attendance

During the fiscal year 2019, 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, 2019. 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 2019.

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.

Audit Committee	Compensation Committee	Corporate Governance Committee
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 2019. 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 2019. 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 2019.

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, 2019, our executive officers and directors have complied on a timely basis with all Section 16(a) filing requirements.

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. At our 2019 Annual Meeting of Stockholders, our Stockholders voted on an advisory basis with respect to our compensation program during 2018 for named executive officers. Of the votes cast (excluding abstentions and broker non-votes), 72.1% were cast in support of the program. In light of this, in reviewing the executive compensation program for 2019, 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 four 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 and (4) Dale Ludwig, our Chief Scientific 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 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 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 once each year 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, 2019. 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 years ended December 31, 2019 and 2018 for our named executive officers.

Name/Position	Year	Salary	Bonus (1)	Option Awards (2)	All Other Compensation	Total
Sandesh Seth	2019	$ 561,350	$ 300,000	$ 241,367	$ -	$ 1,102,717
	2018	$ 545,000	$ 280,000	$ 549,253	$ -	$ 1,374,253
Mark Berger	2019	$ 405,000	$ 85,000	$ 64,364	$ -	$ 554,364
	2018	$ 400,000	$ 75,000	$ 137,313	$ -	$ 612,313
Anil Kapur	2019	$ 325,417	$ 102,250	$ 64,364	$ -	$ 492,031
Former Chief Commerce Officer (3)	2018	$ 294,402	$ -	$ 211,261	$ -	$ 505,663
Dale Ludwig	2019	$ 334,750	$ 97,500	$ 64,364	$ -	$ 496,614
	2018	$ 323,769	$ -	$ 100,926	$ -	$ 424,695
Nitya Ray	2019	$ -	$ -	$ -	$ -	$ -
Former Executive Vice President (5)	2018	$ 323,331	$ 35,000	$ 41,194	$ -	$ 399,525
Steve O'Loughlin	2019	$ 293,550	$ 85,000	$ 64,364	$ -	$ 442,914
	2018	$ 285,000	$ 75,000	$ 145,552	$ -	$ 505,552

(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) The dollar amounts in this column represent the aggregate grant date fair value of all option awards granted during the indicated year. These amounts have been calculated in accordance with FASB ASC Topic 718, using the Black-Scholes option-pricing model. For a discussion of valuation assumptions, see Note 7 to our financial statements. These amounts do not necessarily correspond to the actual value that may be recognized from the option awards by the NEOs.

(3) Mr. Kapur resigned from the company effective November 29, 2019.

(4) Dr. Ray resigned from the company effective December 21, 2018.

Director Compensation

The following table sets forth the compensation of our non-employee directors for the year ended December 31, 2019:

Name	Fees Earned	Stock Awards	Option Awards (1) (2)	All Other Compensation	Total
Jeffrey W. Chell (2)	$ 51,000	-	$ 40,228	-	$ 91,228
David Nicholson	$ 63,000	-	$ 40,228	-	$ 103,228
Ajit J. Shetty	$ 58,500	-	$ 40,228	-	$ 98,728
Richard Steinhart	$ 63,000	-	$ 40,228	-	$ 103,228

(1) The dollar amounts in this column represent the aggregate grant date fair value of all option awards granted during the indicated year. These amounts have been calculated in accordance with FASB ASC Topic 718, using the Black-Scholes option-pricing model. For a discussion of valuation assumptions, see Note 7 to our financial statements. These amounts do not necessarily correspond to the actual value that may be recognized from the option awards by the NEOs.

(2) At December 31, 2019, the aggregate number of option awards outstanding for each director was as follows: (i) for Dr. Chell, 400,000, (ii) for Dr. Nicholson, 599,900, (iii) for Dr. Shetty, 400,000, and (iv) for Mr. Steinhart, 549,950.

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 - 2019

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, 2019.

	Option Awards					Stock Awards			
Name (a)	Number of Securities Underlying Unexercised Options (#) (Exercisable) (b)	Number of Securities Underlying Unexercised Options (#) (Unexercisable) (c)	Equity Incentive Plan Awards: Number of Securities Underlying Unexercised Unearned 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 Other Rights That Have Not Vested (#) (i)	Equity Incentive Plan Awards: Market or Payout Value of Unearned Shares, Units or Other 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	-	-	-	-
	150,000	-	-	3.58	2/15/2025	-	-	-	-
	440,000	60,000	-	1.99	4/15/2026	-	-	-	-
	529,000	221,000	-	1.39	3/14/2027	-	-	-	-
	340,000	660,000	-	0.7829	7/13/2028	-	-	-	-
	150,000	1,350,000	-	0.232	7/12/2029	-	-	-	-
Mark Berger	240,500	84,500	-	1.04	1/17/2027	-	-	-	-
	85,000	165,000	-	0.7829	7/13/2028	-	-	-	-
	40,000	360,000	-	0.232	7/12/2029	-	-	-	-
Anil Kapur	218,500	-	-	0.6369	2/27/2020	-	-	-	-
	32,000	-	-	0.232	2/27/2020	-	-	-	-
Dale Ludwig	100,000	100,000	-	0.723	1/08/2028	-	-	-	-
	40,000	360,000	-	0.232	7/12/2029	-	-	-	-
Steve O'Loughlin	100,000	-	-	1.79	9/28/2025	-	-	-	-
	44,000	6,000	-	1.99	4/15/2026	-	-	-	-
	74,500	25,500	-	1.39	3/14/2027	-	-	-	-
	90,100	174,900	-	0.7829	7/13/2028	-	-	-	-
	40,000	360,000	-	0.232	7/12/2029	-	-	-	-

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 May 1, 2020 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 May 1, 2020, 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.

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.

Executive Officers and Directors	**Number of Shares of Common Stock and Preferred Stock Beneficially Owned**	**Percentage of Ownership[(a)]**
Sandesh Seth	2,805,147(1)	*%
Steve O'Loughlin	501,200(2)	*%
Mark Berger, M.D.	531,500(3)	*%
Dale Ludwig, Ph.D.	234,000(4)	*%
Jeffrey W. Chell, M.D.	139,500(5)	*%
David Nicholson, Ph.D.	365,900(6)	*%
Ajit S. Shetty, Ph.D.	181,730(7)	*%
Richard I. Steinhart	320,700(8)	*%
All Directors and Officers as a Group (8 persons)	5,079,677(9)	**1.6%**
All other 5% holders		
Sabby Volatility Warrant Master Fund, Ltd. c/o Ogier Fiduciary Services (Cayman) Limited 89 Nexus Way, Camana Bay Grand Cayman KY1-9007 Cayman Islands		
Sabby Management, LLC 10 Mountainview Road, Suite 205 Upper Saddle River, New Jersey 07458		
Hal Mintz c/o Sabby Management, LLC 10 Mountainview Road, Suite 205 Upper Saddle River, New Jersey 07458	20,095,255(10)	6.62%

* less than 1%

(a) Based on 303,343,699 shares of Common Stock outstanding as of May 1, 2020

(1) Includes 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 at $0.880131 per share on May 1, 2020. 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. On July 17, 2019, Mr. Seth was granted an option to purchase 1,500,000 shares at an exercise price of $0.232 per share. All options are subject to vesting. Within 60 days of May 1, 2020, 2,439,950 options will have vested. Includes 161,458 shares of Common Stock and 39,375 March 2018 series B Warrants.

(2) 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 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. On July 17, 2019, Mr. O'Loughlin was granted an option to purchase 400,000 shares at an exercise price of $0.232 per share. All options are subject to vesting. Within 60 days of May 1, 2020, 458,200 options will have vested. Includes 35,500 shares of Common Stock and 7,500 March 2018 series B Warrants.

(3) On January 17, 2017, Dr. Berger was granted an option to purchase 325,000 shares with an exercise price of $1.04 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. On July 17, 2019, Dr. Berger was granted an option to purchase 400,000 shares at an exercise price of $0.232 per share. All options are subject to vesting. Within 60 days of May 1, 2020, 502,000 options will have vested. Includes 19,000 shares of Common Stock and 10,500 March 2018 series B Warrants.

(4) On January 8, 2018, Dr. Ludwig was granted an option to purchase 200,000 shares with an exercise price of $0.72 per share. On July 17, 2019, Dr. Ludwig was granted an option to purchase 400,000 shares at an exercise price of $0.232 per share. All options are subject to vesting. Within 60 days of May 1, 2020, 224,000 options will have vested. Includes 10,000 shares of Common Stock.

(5) On April 27, 2018, Dr. Chell was granted an option to purchase 75,000 shares with an exercise price of $0.347 per 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. On July 17, 2019, Dr. Chell was granted an option to purchase 250,000 shares at an exercise price of $0.232 per share. All options are subject to vesting. Within 60 days of May 1, 2020, 139,500 options will have vested.

(6) 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 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. On July 17, 2019, Dr. Nicholson was granted an option to purchase 250,000 shares at an exercise price of $0.232 per share. All options are subject to vesting. Within 60 days of May 1, 2020, 355,900 options will have vested. Includes 10,000 shares of Common Stock.

(7) On March 28, 2017, Dr. Shetty was granted an option to purchase 75,000 shares of Common Stock with an 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. On July 17, 2019, Dr. Shetty was granted an option to purchase 250,000 shares at an exercise price of $0.232 per share. All options are subject to vesting. Within 60 days of May 1, 2020, 159,000 shares will have vested. Includes 22,730 shares of Common Stock.

(8) 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. On July 17, 2019, Mr. Steinhart was granted an option to purchase 250,000 shares at an exercise price of $0.232 per share. All options are subject to vesting. Within 60 days of May 1, 2020, 305,950 options will have vested. Includes 9,500 shares of Common Stock and 10,500 March 2018 series B Warrants.

(9) Includes warrants to purchase 226,989 shares of Common Stock, vested options to purchase 4,584,500 shares of Common Stock and 268,188 shares of Common Stock.

(10) Based on a Schedule 13G filed on May 1, 2020.

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 years ending December 31, 2019 and 2018, respectively, by Marcum LLP.

	Year Ended December 31, 2019	Year Ended December 31, 2018
Audit Fees	$ 110,000	$ 113,000
Audit – Related Fees	37,000	28,800
Tax Fees	-	-
All Other Fees	-	-
Total	$ 147,000	$ 141,800

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	Underwriting Agreement, dated September 28, 2016, by and between H.C. Wainwright & Co., LLC and Actinium Pharmaceuticals, Inc. (incorporated by reference to Exhibit 1.1 to Form 8-K filed on September 29, 2016).
1.2	At Market Issuance Sales Agreement, dated March 16, 2017, between FBR Capital Markets & Co, and Actinium Pharmaceuticals, Inc. (incorporated by reference to Exhibit 1.2 to Form S-3 filed on March 16, 2017).
1.3	Amended and Restated At-the-Market Market Issuance Sales Agreement, dated July 3, 2017, among FBR Capital Markets & Co., MLV & 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).
1.4	Underwriting Agreement, dated as of July 28, 2017, by and between Actinium Pharmaceuticals, Inc. and Oppenheimer & 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).
1.5	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).
1.6	Underwriting Agreement, dated April 18, 2019, by and between Actinium Pharmaceuticals, Inc. and William Blair & Company, LLC (incorporated by reference to Exhibit 1.1 to Form 8-K filed on April 18, 2019).
1.7	Underwriting Agreement, dated as of April 21, 2020, by and between Actinium Pharmaceuticals, Inc. and H.C. Wainwright & Co., LLC. (incorporated by reference to Exhibit 1.1 to Form 8-K filed on April 24, 2020).
2.1	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).
2.2	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).
2.3	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).
3.1	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).
3.2	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).
3.3	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).
3.4	Certificate of Amendment to Certificate of Incorporation (incorporated by reference to Exhibit 3.1 to Form 8-K filed on March 4, 2015).
3.5	Amended and Restated Bylaws, dated August 8, 2018 (incorporated by reference to Exhibit 3.1 to Form 10-Q filed on August 9, 2018).
3.6	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).
3.7	Certificate of Amendment to Actinium's Certificate of Incorporation, as amended, filed on March 6, 2019 (incorporated by reference to Exhibit 3.7 to Form 10-K filed on March 15, 2019).
3.8	Amended and Restated Bylaws, dated May 7, 2020. .(incorporated by reference to Exhibit 3.1 to Form 8-K filed on May 5, 2020).
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).

4.12	Form of Warrant (incorporated by reference to Exhibit 4.1 to Form 8-K filed on April 18, 2019).
4.13	Form of Pre-Funded Warrant (incorporated by reference to Exhibit 4.1 to Form 8-K filed on April 24, 2020).
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 Cicic. (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).
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 (incorporated by reference to Exhibit 10.37 to Form 10-K filed on March 15, 2019).
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 (incorporated by reference to Exhibit 10.38 to Form 10-K filed on March 15, 2019).
10.39	Seventh Amendment to the 2013 Amended and Restated Stock Plan, as amended (incorporated by reference to Exhibit 10.39 to Form 10-K filed on March 15, 2019).
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 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: May 8, 2020

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.

Signature	Title	Date
/s/ Sandesh Seth Sandesh Seth	Chairman and Chief Executive Officer (Principal Executive Officer)	May 8, 2020
/s/ Jeffrey Chell Jeffrey Chell	Director	May 8, 2020
/s/ David Nicholson David Nicholson	Director	May 8, 2020
/s/ Richard I. Steinhart Richard I. Steinhart	Director	May 8, 2020
/s/ Ajit J. Shetty Ajit J. Shetty	Director	May 8, 2020

Exhibit 23.1

INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM'S CONSENT

We consent to the incorporation by reference in the Registration Statement No. 333-216748 on Form S-3 and Registration Statement No. 333-216746 and No. 333-197283 on Form S-8 of Actinium Pharmaceuticals, Inc. of our report dated May 8, 2020 with respect to our audits of the consolidated financial statements of Actinium Pharmaceuticals, Inc. as of December 31, 2019 and 2018 and for the years ended December 31, 2019 and 2018, which report is included in this Annual Report on Form 10-K of Actinium Pharmaceuticals, Inc. for the year ended December 31, 2019.

/s/ Marcum llp

Marcum llp
Houston, Texas
May 8, 2020

Exhibit 31.1

CERTIFICATION OF PRINCIPAL EXECUTIVE OFFICER
PURSUANT TO 18U.S.C SECTION 1350 AS ADOPTED
PURSUANT TO SECTION 302 OF THE SARBANES-OXELY ACT OF 2002

I, Sandesh Seth, certify that:

1. I have reviewed this report on Form 10-K of Actinium Pharmaceuticals, Inc. for the fiscal year ended December 31, 2019.

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a–15(e) and 15d–15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a–15(f) and 15d–15(f)) for the registrant and have:

    a. Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

    b. Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, 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;

    c. Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

    d. Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

    a. All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

    b. Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Dated: May 8, 2020

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

Exhibit 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-OXELY ACT OF 2002

I, Steve O'Loughlin, certify that:

1. I have reviewed this report on Form 10-K of Actinium Pharmaceuticals, Inc. for the fiscal year ended December 31, 2019.

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a–15(e) and 15d–15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a–15(f) and 15d–15(f)) for the registrant and have:

    a. Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

    b. Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, 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;

    c. Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

    d. Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

    a. All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

    b. Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Dated: May 8, 2020

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

Exhibit 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

In connection with the Annual Report of Actinium Pharmaceuticals, Inc. a Delaware corporation (the "Company"), on Form 10-K for the period ended December 31, 2019 as filed with the Securities and Exchange Commission (the "Report"), I, Sandesh Seth, Chief Executive Officer of the Company, certify, pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, 18 U.S.C. Section 1350), that to my knowledge:

(1) The Report fully complies with the requirements of section 13(a) or 15(d) of the Securities Exchange Act of 1934 (15 U.S.C. 78m or 78o(d)); and

(2) The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Dated: May 8, 2020

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

Exhibit 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

In connection with the Annual Report of Actinium Pharmaceuticals, Inc. a Delaware corporation (the "Company"), on Form 10-K for the period ended December 31, 2019 as filed with the Securities and Exchange Commission (the "Report"), I, Steve O'Loughlin, Principal Financial Officer of the Company, certify, pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, 18 U.S.C. Section 1350), that to my knowledge:

(1) The Report fully complies with the requirements of section 13(a) or 15(d) of the Securities Exchange Act of 1934 (15 U.S.C. 78m or 78o(d)); and

(2) The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Dated: May 8, 2020

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