Actinium Pharmaceuticals, Inc.
Form DEF 14A
November 14, 2017
UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

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SCHEDULE 14A
Proxy Statement Pursuant to Section 14(a) of the Securities Exchange Act of 1934
(Amendment No.)

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Actinium Pharmaceuticals, Inc.

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Letter to Shareholders

November 14, 2017

Dear Actinium Shareholders,

A luminary in biotech once let on to me that the most important thing he always looked for in a biotech company as a predictor of success was the team, as a good team could create value from even mediocre assets. Well, we believe firmly that we have stellar assets, and in the middle of this year, Actinium was afforded the opportunity to refresh and recalibrate the senior team. With the new team in place, we have had one of the most eventful periods for Actinium Pharmaceuticals to date. For example, we have enrolled more patients in the past few months than in the five prior years combined. This improved operational capability is critical as we drive toward the visible clinical milestones that are needed to establish the value of our clinical assets. As this year comes to a close, I would like to review our progress and accomplishments for you and also provide an outlook for what is promising to be a transformational period with significant value creation potential for the Company.

Today, Actinium is actively engaged in conducting three clinical trials with assets that have either first-in-class or best-in-class potential. The high quality of the hospitals and reputation of the doctors involved in our trials are the envy of many larger companies. These trials are all expected to yield visible clinical results during the remainder of this year and in 2018-2019. We have for the first time, fielded, and had accepted, multiple publications at the prestigious American Society of Hematology, or ASH Meeting, that show case the multi-faceted nature of Actinium's assets and technology platform. We have launched the AWE Program or Actinium Warhead Enabling Program on the back of experimental results that showcase the power of our platform technology in enabling improved cell killing efficacy of daratumumab, or Darzalex®, a blockbuster product in multiple myeloma after it has been coupled with actinium-225. We have successfully manufactured enough antibody drug supply to satisfy our needs for the next couple of years. Importantly, we are bringing to bear the experience of the new team members to clinical drug development. This is clearly evidenced not only by the meaningful progress made in patient enrollment across our trials but also by our ability to smartly think about the data signals we have received in the Actimab-A trial and to exploit those for further development.

This improved productivity in all areas of the company is a direct result of a higher functioning team which we will continue to grow selectively and strengthen. We anticipate that the expected clinical results of Iomab-B, Actimab-A and Actimab-M, the AWE Program, and other clinical programs that we will unveil going forward will facilitate strategic collaborations and help drive value for the Company and you, our loyal shareholders. As a preview, and a harbinger of things to come please read the section on our CD33 program in this letter. We thank you for your support that allows us to work in realizing our vision for this company. It is with a sense of pride that we review our key accomplishments thus far in 2017.

2017 Review

- Iomab-B Pivotal Phase 3 Trial — All is well. Met target of activating the SIERRA trial at 15 leading U.S. bone marrow transplant centers. Growing enrollment expected to yield visible clinical milestones.

• Data Driven Newsflash. Not just Actimab-A, not just Actimab-M but an emerging, industry leading CD33 program applicable to numerous hematologic indications due to the power of our alpha radiation approach.

- Recent Developments. Drug approvals and strategic deals in industry validate our CD33 approach.

- Lightbulb Moments. Potential to build an Industry leading CD33 program based on evidence from current trials.

- Actimab-A Update. Strong single agent activity seen in Phase 2. On track for topline results in 2018.

- Actimab-M Update. Trial expanded due to encouraging initial data and strong interest. On track for topline results in 2018.

• AWE Technology enables AWE Program launch based on AWEsome experimental results.

• Strong balance sheet allows us to execute on value-enhancing milestones.

Going forward, we believe that the clinical progress and data generated in 2017 will enable our strengthened team to deliver on the multiple, significant value-creation milestones expected between now and the end of 2018 and we provide that outlook after the detailed review below.

2017 Review — Company Achievements Enable Multiple Value Creating Events Going Forward

Iomab-B Pivotal Phase 3 Trial — All Is Well. Met Target of Activating the SIERRA Trial at 15 Leading U.S. Bone Marrow Transplant Centers. Growing Enrollment Expected to Yield Visible Clinical Milestones.

Iomab-B is our first-in-class, lead drug product candidate that targets CD-45, an antigen expressed on all proliferating blood cancer and bone marrow cells. The intent of Iomab-B is to safely destroy all cancer and bone marrow cells before a patient can get a potentially curative Bone Marrow Transplant, or BMT. Currently, chemotherapy is used to destroy or condition the bone marrow and due to its toxicity, it is not well tolerated. Often times, chemotherapy cannot be used for elderly patients with relapsed or refractory Acute Myeloid Leukemia for which Iomab-B is intended. As a result, these patients for whom no other conventional chemotherapy works cannot receive a BMT which is potentially curative, and they tend to have a very short life span. Thereby, Iomab-B offers these patients a chance for a BMT and a chance of a cure or longer survival.

At present, the pivotal, Phase 3 SIERRA (Study of Iomab-B in Elderly Relapsed or Refractory AML) trial for Iomab-B is being conducted at 15 leading bone marrow transplant centers in the United States. We are proud to have met this target and believe that we will add selectively another 3-7 premier sites. The sites where the trial is being conducted perform over 30% of the BMT procedures in the U.S. each year. Our team worked tirelessly to initiate the trial at these BMT centers and has done a stellar job educating and supporting their staffs. We have found that once a site has dosed its first patient, the pace of enrollment at that site subsequently increases. At this time, our clinical team is working hard with the sites to ensure that enrollment continues to remain strong and we continue to believe that enrollment of the Iomab-B clinical trial by the end of 2018, along with the interim Data Monitoring Committee readouts at 25 percent, 50 percent and 75 percent of enrollment will be achievable.

In initiating the SIERRA trial at these top BMT centers, we gained invaluable insights into the operations and dynamics at top BMT centers. We will use this to our advantage as we begin to think about the commercialization of Iomab-B. In the U.S., the top 50 centers perform more than 80% of all BMT procedures. Our commercial efforts will focus on implementing Iomab-B at these centers. We are confident that we will succeed in accomplishing this based on the success our team has had in implementing the Iomab-B pivotal trial at centers such as MD Anderson Cancer Center, the Mayo Clinic, Memorial Sloan Kettering Cancer Center, Baylor and many of the other top BMT centers.

Actinium is focused on and committed to enabling safer myeloablation for BMT to drive better outcomes for patients. We are determined to complete the pivotal, Phase 3 SIERRA trial as efficiently as possible and to submit a Biologics License Application (BLA) to the FDA for approval in 2019. We are confident in our ability to build a bone marrow transplant franchise based around Iomab-B that will have commercial operations servicing the top 50 BMT centers in the U.S., which we believe will be an asset in and of itself, as we will embark on life cycle management activities with Iomab-B during this timeframe. As mentioned during the mid-year review and worthwhile repeating, we note that Iomab-B still stands alone as the only induction and conditioning agent currently in clinical development with no

visible competition evident in the clinic. This is an important fact to keep in mind.

Finally, we look forward to providing updates on the trial by the end of this year and continuing to provide updates in 2018 as we progress towards the completion of enrollment and prepare for regulatory filings.

Data Driven Newsflash. Not Just Actimab-A, Not Just Actimab-M But an Emerging, Industry Leading CD33 Program Applicable to Numerous Hematologic Indications Due to the Power of Our Technology Platform Using Alpha Radiation Approach.

Recent Development. Drug Approvals and Strategic Deals in Industry Validate Our CD33 Approach.

In the past few months there has been a lot of excitement related to Acute Myeloid Leukemia treatments as four therapies have received approval after decades of stagnation, with just one therapy having been approved in the forty years prior. That therapy was the CD33-targeting Antibody Drug Conjugate (ADC) Mylotarg which had been initially approved under the leadership of our Chief Medical Officer, Dr. Mark Berger, who led its clinical development. Highly relevant to us, the CD33 field in AML has been very active of late with the reapproval of Mylotarg, which had been withdrawn from the market by Pfizer for safety issues, and strategic transactions like Jazz Pharmaceuticals' $75 million upfront licensing deal with Immunogen, which included their CD33 targeting ADC currently in a Phase 1 trial. We are encouraged about Mylotarg's reapproval as it represents validation of the CD33 target, which is expressed in virtually all patients with AML. We are also delighted to see strategic partners showing interest in this field, as we believe we have a superior technological approach that will differentiate us from other CD33 targeting therapies and AML therapies. We have been planning and intend to reveal between year-end and mid-2018 various initiatives that will clearly demonstrate the superior potential of our CD33 program.

Lightbulb Moments. Potential to Build an Industry Leading CD33 Program Based on Evidence From Current Trials.

The studies to date using our CD33 targeting antibody linked to alpha radiation (Bismab-A (discontinued), Actimab-A, Actimab-M) have taught us a great deal about the strengths of using our Antibody Radiation Conjugate (ARC) approach and Actinium intends to take advantage of these strengths. We will address three of them here. One of those strengths (as discussed briefly in the paragraph on Actimab-A below) is simply the ability to treat AML, a cancer known to be a radiosensitive, with radiation and produce a response rate that provides clear evidence of the potency of the drug candidate as a single agent. Instead of continuing to add additional cytotoxic chemotherapies to produce combination cytotoxic treatments, adding Actimab-A to intensive cytotoxic treatments would enable us to bring an entirely different treatment modality to the combination. Secondly, as discussed in our ASH abstract for Actimab-A (and in the paragraph below), the dose of Actimab-A initially used as a front-line therapy for older AML patients unfit for intensive chemotherapies in our current Phase 2 trial was associated with myelosuppression that lasted longer than was clinically desirable. We also determined that the safety profile of Actimab-A outside of myelosuppression is extremely benign with no extramedullary (outside the bone marrow) toxicity. Given this profile we believe that Actimab-A would likely also have great clinical potential in situations such as preparation for allogeneic bone marrow transplant, where myelosuppression is not a problem since the bone marrow is going to be replaced. Lastly, we've also learned that Actimab-A is most effective when the peripheral blast burden is low, as then it's able to distribute well to all the AML cells in the bone marrow. So, another potential use for Actimab-A would be after initial therapy has produced a remission, as it's known that without further therapy, relapse rates will be high. At remission, of course, there are no peripheral blasts, so this may be a fruitful time to use Actimab-A at lower doses given its potency and safety profile, particularly in older patients who cannot tolerate multiple intensive therapies. Again, we intend to reveal between year-end and mid-2018 various initiatives designed to clearly demonstrate the superior potential of our CD33 program compared to the competition.

Actimab-A Update. Strong Single Agent Activity Seen in Phase 2. On Track for Topline Results in 2018.

Our thinking regarding the CD33 program has evolved, in part, due to certain developments in the Actimab-A Phase 2 trial and alluded to in the ASH abstract published November 1, 2017, highlighting preliminary data from the current Phase 2 trial of Actimab-A. Encouragingly, as a single agent administered twice and 7 days apart, Actimab-A at 2 uCi/kg of body weight showed a 56% response rate in patients over the age of 60 who are unfit for intensive chemotherapy. The Actimab-A presentation at ASH will have additional data on this trial. Our target patient population does not have effective treatment options and is very difficult to treat. The patients enrolled in our trial thus

far had a median age of 75 with many having unfavorable cytogenetics and prior hematologic diseases like myelodysplastic syndrome, making treatment of these patients even more complex. We are excited to see Actimab-A's ability to produce responses for these patients as a single agent which clearly demonstrate its efficacy potential and are constructive about the topline results expected in 2018. Equally exciting is that minimal non-hematologic toxicities were observed in patients receiving Actimab-A, particularly lack of veno-occlusive

disease, a liver toxicity that is seen in ADC's such as Mylotarg and which led to the discontinuation of Seattle Genetics' high profile CD33 program this year. Based on the Actimab-A results, we are of the view that our CD33 program has the potential to be best in class based on its activity as a single agent and safety profile. We believe that this profile is a function of our technological approach of using an ARC (versus ADC's). Our targeting agent linked to Actinium-225 does not have to be internalized like ADC's and can still kill cells from the outside, either by direct binding of the antibody to the cell surface or by cross fire. We believe this characteristic of our product will allow us to expand into other areas and the Actimab-M trial is the first of several that we are planning in order to better exploit the signals we have obtained from our clinical data set.

Actimab-M Update. Trial Expanded Due to Initial Data, Strong Interest. On Track for Topline Results in 2018.

In 2016 we committed to initiating a third clinical program in 2017. We achieved this goal in early February of 2017 with the initiation of our Actimab-M Phase 1 trial which targets CD33 positive, multiple myeloma patients with advanced disease that were relapsed or refractory to several lines of therapy. This is an out-of-the-box idea with a strong scientific, clinical and commercial rationale for targeting multiple myeloma with a CD33 targeting ARC. First, myeloma is a radiation-sensitive cancer which cannot be treated with external radiation due to is diffuse nature, so use of targeted radiation could be promising. There is a sizable segment of multiple myeloma patients that express CD33 at levels in line with AML (80-90%) so using an ARC proven to show efficacy in AML for these patients is supportive of our rationale. Further, the drugs approved to date have low efficacy as single agents and are either chemotherapy or immunotherapy based, none of them are curative, and standard treatment of these patients tends to be combination therapies. Using a different modality such as Actimab-M with current approaches could be promising, assuming we get an efficacy signal from this proof of concept trial. Lastly, the population of multiple myeloma patients that we target with Actimab-M is larger than AML, which assuming an efficacy signal, would make this program an attractive value proposition for a potential partner. At the present time, the Actimab-M trial is enrolling patients and based on interest from leading cancer centers in participating in this trial, we have taken over management of the trial and brought the Investigational New Drug (IND) in-house to facilitate expedited expansion. Preliminary positive safety information has prompted us to revise the protocol to allow for a higher dose level and revised dosing schedule in order to improve the odds of success. Despite these changes, we are projecting that we will be able to meet our objective of topline results in the Actimab-M trial in 2018.

AWE Technology Enables AWE Program Launch Based on AWEsome Experimental Results.

This year, we reinvigorated intellectual property generation using our AWE or Actinium Warhead Enabling technology platform with activity that has brought our portfolio to 72 patents granted, pending or filed in the U.S. and internationally. The time has also come for the Company to leverage its AWE technology platform for external purposes, in addition to pipeline expansion of our own programs. To this end, we have launched the AWE Program by showcasing the ability of using our AWE technology platform to produce superior drug candidates. The ASH poster demonstrating the vastly superior cell killing abilities of Actinium-225 labeled daratumumab compared to unlabeled daratumumab, or Darzalex®, a blockbuster, commercial product for multiple myeloma is the initial validation of the capabilities we have developed this year to support the AWE Program and also for the AWE technology platform. We intend to offer these capabilities in a collaborative fashion to potential partners who are seeking to develop ARC's for their own pipelines or biobetters of existing drugs. We believe there are myriad opportunities to create biobetters by increasing efficacy, improving safety, dosing or administration and providing companies with commercial drugs the means to manage their products' lifecycles. We believe that this is a strategy that can create tremendous value, as was recently shown by Novartis' announced acquisition of Advanced Accelerator Applications Inc. for $3.9 billion in large part because the latter's radiation-coupled somatostatin analog biobetter Lutathera® is showing a superior profile to Novartis' blockbuster drug Sandostatin®.

Strong Balance Sheet Allows Us to Execute on Value-Enhancing Milestones

We reported a cash balance of $20.5 million in our 3Q:2017 quarterly filing. We believe this capital will allow us to execute on several value-enhancing milestones that we highlight below. We pride ourselves on being a team of 25 employees that “punch above our weight” and that we keep things lean. Going forward, our team is committed to the development of drug candidates and the progression of clinical trials in the most efficient and cost-effective manner possible. We are confident in our ability to drive value for shareholders by building on our recent progress in team building and product development, leveraging our upgraded expertise and the recent clinical insights.

Company Outlook — Clinical Trial Progress And 2017 Data Will Enable Strengthened Team To Deliver On The Multiple, Significant Value-Creation Milestones Expected in 2018 That Can Transform The Company

Actinium has made tremendous progress in second half of 2017 with the advancement of our three clinical trials, innovative research that we expect will result in new clinical programs and drug candidates, and strategic programs such as AWE aimed at unlocking value. In addition to all that we have highlighted above, we have achieved several milestones and we expect to achieve additional milestones by the end of 2017 and in 2018. We expect 2018 to be a significant year for Actinium as we are focused on completing enrollment for Iomab-B and delivering visible clinical or topline data on all three ongoing trials. Assuming that the early signs bear themselves out and yield positive results, significant and transformative value creation is possible.

Key Value Enhancing Catalysts for the Remainder of 2017 and 2018

- Actimab-A Phase 2 clinical trial update via ASH poster presentation
- CD33 program update and unveiling of new clinical initiative
- Iomab-B SIERRA trial update by year end
- Iomab-B SIERRA trial site expansion and DMC enrollment updates
- Complete enrollment of the pivotal Phase 3 trial by year end
- Actimab-A Phase 2 clinical trial top line data
- Actimab-M Phase 1 clinical trial top line data
- Implementation of fourth clinical program
- Intellectual property generation leveraging our AWE Technology Platform
- AWE Program initiatives designed to facilitate collaborations
- Selective expansion of the team to further bolster clinical development and research & development
- Explore strategic initiatives to enhance our capabilities in supply chain and research & development

In the second half of 2017 our refreshed and recalibrated executive team has come together and is working towards a unified vision for what Actinium Pharmaceuticals will become. Our entire team has never been stronger, more aligned or energized. As a result, we have been able to accomplish a number of meaningful milestones, but perhaps most importantly, we have laid a foundation for 2018 and beyond, where we can finally begin to realize the true potential of Actinium’s assets. We believe a disconnect exists between the value of our drug candidates, technology and know-how, with respect to the value that is being ascribed to the Company in the public markets. We recognize that this is frustrating to you as shareholders and commit to you that we are focused on producing results to eliminate this dislocation of value. All of us at Actinium feel privileged to work on developing such promising therapies and technology, which we confidently believe will have meaningful impacts on the lives of patients with our drug candidates that are either first-in-class or best-in-class. We thank you for your support that allows us to work towards this worthwhile endeavor.

Please send in your completed proxy form as soon as possible as indicated in the proxy materials. We hope that you support the proposals in line with management and the board’s recommendations. We believe these proposals will

enable us to best succeed in our goal to build a leading company to develop and deliver transformative medicines for bone marrow transplants and blood cancers by harnessing the power of our proprietary assets and technology and in part by selectively acquiring enhanced capabilities that fit our strategy

Indeed, we are counting on your unfettered support as in the past!

Sincerely and with deep gratitude,

Sandesh Seth

Chairman and CEO

Forward-Looking Statements for Actinium Pharmaceuticals, Inc.

This letter contains “forward-looking statements” as defined in the Private Securities Litigation Reform Act of 1995. These statements are based on management’s current expectations and involve risks and uncertainties, which may cause actual results to differ materially from those set forth in the statements. The forward-looking statements may include statements regarding product development, product potential, or financial performance. No forward-looking statement can be guaranteed and actual results may differ materially from those projected. Actinium Pharmaceuticals undertakes no obligation to publicly update any forward-looking statement, whether as a result of new information, future events, or otherwise.

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