

Actinium Pharmaceuticals, Inc.
Form S-3/A
April 10, 2014

As filed with the Securities and Exchange Commission on April 10, 2014

Registration No. _____

UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

FORM S-3/A
Amendment No. 1
REGISTRATION STATEMENT UNDER THE SECURITIES ACT OF 1933

Actinium Pharmaceuticals, Inc.
(Exact name of registrant as specified in its charter)

Delaware
(State or other jurisdiction of
incorporation or organization)

88-0378336
(I.R.S. Employer
Identification Number)

501 5th Avenue, 3rd Floor
New York, New York 10017
(646) 459-4201

(Address, including zip code, and telephone number, including area code, of registrant's principal executive offices)

Kaushik J. Dave
President and Chief Executive Officer
Actinium Pharmaceuticals, Inc.
501 5th Avenue, 3rd Floor
New York, New York 10017
(646) 459-4201

(Name, address, including zip code, and telephone number, including area code, of agent for service)

Copies of all communications, including communications sent to agent for service, should be sent to:

Thomas Slusarczyk, Esq.
Hiscock & Barclay, LLP
One Park Place
300 South State Street
Syracuse, New York 13202
Tel. (315) 425-2700
Fax (315) 425-2701

Approximate date of commencement of proposed sale to the public: From time to time after this Registration Statement becomes effective.

If the only securities being registered on this Form are being offered pursuant to dividend or interest reinvestment plans, please check the following box:

If any of the securities being registered on this Form are to be offered on a delayed or continuous basis pursuant to Rule 415 under the Securities Act of 1933, other than securities offered only in connection with dividend or interest reinvestment plans, check the following box:

If this Form is filed to register additional securities for an offering pursuant to Rule 462(b) under the Securities Act, please check the following box and list the Securities Act registration statement number of the earlier effective registration statement for the same offering.

If this Form is a post-effective amendment filed pursuant to Rule 462 I under the Securities Act, check the following box and list the Securities Act registration statement number of the earlier effective registration statement for the same offering.

If this Form is a registration statement filed pursuant to General Instruction I.D. or a post-effective amendment thereto that shall become effective upon filing with the Commission pursuant to Rule 462(e) under the Securities Act, check the following box.

If this Form is a post-effective amendment to a registration statement filed pursuant to General Instruction I.D. filed to register additional securities or additional classes of securities pursuant to Rule 413(b) under the Securities Act, check the following box.

Indicate by check mark whether the Registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer or a smaller reporting company. See the definitions of "large accelerated filer," "accelerated filer" and "smaller reporting company" in Rule 12b-2 of the Exchange Act.

Large accelerated filer <input type="checkbox"/>	Accelerated filer <input type="checkbox"/>
Non-accelerated filer <input type="checkbox"/> (Do not check if a smaller reporting company)	Smaller reporting company <input checked="" type="checkbox"/>

CALCULATION OF REGISTRATION FEE

Title of each class of securities to be registered	Amount to be registered(1)	Proposed maximum offering price per security(2)	Proposed maximum aggregate offering price	Amount of registration fee
Common Stock, \$0.001 par value per share(2)	— \$	— \$	— \$	—
Preferred Stock, \$0.001 par value per share(2)	—	—	—	—
Debt Securities	—	—	—	—
Warrants(2)	—	—	—	—
Rights	—	—	—	—
Purchase Contracts	—	—	—	—
Units	—	—	—	—
Total Offering	\$ 200,000,000	\$ —	\$ 200,000,000	\$ 25,760(3)

(1) There are being registered hereunder such indeterminate number of shares of common stock and preferred stock, such indeterminate principal amount of debt securities, such indeterminate number of warrants to purchase common stock, preferred stock or debt securities, and such indeterminate number of rights, purchase contracts, or units as shall have an aggregate initial offering price not to exceed \$200,000,000, less the aggregate dollar amount of all securities previously sold hereunder. If any debt securities are issued at an original issue discount, then the offering price of such debt securities shall be in such greater principal amount as shall result in an aggregate initial offering price not to exceed \$200,000,000, less the aggregate dollar amount of all securities previously issued hereunder. Any securities registered hereunder may be sold separately or as units with other securities registered hereunder. Any securities registered hereunder may be sold separately or as units with the other securities registered hereunder. The proposed maximum offering price per unit will be determined, from time to time, by the registrant in connection with the issuance by the registrant of the securities registered hereunder. The securities registered hereunder also include such indeterminate number of shares of common stock, preferred stock and principal amounts of debt securities as may be issued upon conversion of or exchange for preferred stock or debt securities that provide for conversion or exchange, upon exercise of warrants or pursuant to the antidilution provisions of any of such securities. In addition, pursuant to Rule 416 under the Securities Act, the shares being registered hereunder include such indeterminate number of shares of common stock, preferred stock or debt securities as may be issuable with respect to the shares being registered hereunder as a result of stock splits, stock dividends or similar transactions.

(2) The proposed maximum offering price per security will be determined from time to time by the registrant in connection with, and at the time of, the issuance of the securities and is not specified as to each class of security pursuant to General Instruction II.D. of Form S-3, as amended.

(3) Calculated pursuant to Rule 457(o) under the Securities Act based on the proposed maximum aggregate offering price of all securities listed.

* Previously paid.

THE REGISTRANT HEREBY AMENDS THIS REGISTRATION STATEMENT ON SUCH DATE OR DATES AS MAY BE NECESSARY TO DELAY ITS EFFECTIVE DATE UNTIL THE REGISTRANT SHALL FILE A FURTHER AMENDMENT WHICH SPECIFICALLY STATES THAT THIS REGISTRATION STATEMENT SHALL THEREAFTER BECOME EFFECTIVE IN ACCORDANCE WITH SECTION 8(a) OF THE SECURITIES ACT OF 1933, AS AMENDED, OR UNTIL THE REGISTRATION STATEMENT SHALL BECOME EFFECTIVE ON SUCH DATE AS THE SECURITIES AND EXCHANGE COMMISSION, ACTING PURSUANT TO SAID SECTION 8(a), MAY DETERMINE.

EXPLANATORY NOTE

This Registration Statement contains two prospectuses:

- a base prospectus which covers the offering, issuance and sale by us of up to \$200,000,000 of our common stock, preferred stock, debt securities, warrants, rights, purchase contracts, and/or units; and
- a sales agreement prospectus covering the offering, issuance and sale by us of up to a maximum aggregate offering price of \$75,000,000 of our common stock that may be issued and sold under a sales agreement with MLV & Co. LLC.

The base prospectus immediately follows this explanatory note. The specific terms of any securities to be offered pursuant to the base prospectus will be specified in a prospectus supplement to the base prospectus. The sales agreement prospectus immediately follows the base prospectus. The \$75,000,000 of common stock that may be offered, issued and sold under the sales agreement prospectus is included in the \$200,000,000 of securities that may be offered, issued and sold by us under the base prospectus.

The information in this prospectus is not complete and may be changed. We may not sell these securities until the registration statement filed with the Securities and Exchange Commission is effective. This prospectus is not an offer to sell these securities and it is not soliciting an offer to buy these securities in any state where the offer or sale is not permitted.

SUBJECT TO COMPLETION, DATED April 10, 2014

PROSPECTUS

\$200,000,000
Common Stock
Preferred Stock
Debt Securities
Warrants
Rights
Purchase Contracts
Units

We may offer and sell from time to time, in one or more series or issuances and on terms that we will determine at the time of the offering, any combination of the securities described in this prospectus, up to an aggregate amount of \$200,000,000.

We will provide specific terms of any offering in a supplement to this prospectus. Any prospectus supplement may also add, update, or change information contained in this prospectus. You should carefully read this prospectus and the applicable prospectus supplement as well as the documents incorporated or deemed to be incorporated by reference in this prospectus before you purchase any of the securities offered hereby.

These securities may be offered and sold in the same offering or in separate offerings; to or through underwriters, dealers, and agents; or directly to purchasers. The names of any underwriters, dealers, or agents involved in the sale of our securities, their compensation and any over-allotment options held by them will be described in the applicable prospectus supplement. See "Plan of Distribution."

Our common stock is presently traded on the NYSE MKT under the symbol "ATNM." On April 9, 2014, the last reported sale price of our common stock was \$12.60 per share. On March 26, 2014 our common stock commenced trading on the NYSE MKT exchange. We recommend that you obtain current market quotations for our common stock prior to making an investment decision. We will provide information in any applicable prospectus supplement regarding any listing of securities other than shares of our common stock on any securities exchange.

You should carefully read this prospectus, any prospectus supplement relating to any specific offering of securities, and all information incorporated by reference herein and therein.

Investing in our securities involves a high degree of risk. These risks are discussed in this prospectus under "Risk Factors" beginning on page 8 and in the documents incorporated by reference into this prospectus.

Neither the Securities and Exchange Commission nor any state securities commission has approved or disapproved of these securities or passed upon the adequacy or accuracy of this prospectus. Any representation to the contrary is a criminal offense.

The date of this prospectus is , 2014

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ABOUT THIS PROSPECTUS

This prospectus is part of a registration statement on Form S-3 that we filed with the Securities and Exchange Commission using a “shelf” registration process. Under this shelf process, we may, from time to time, sell any combination of the securities described in this prospectus in one or more offerings up to a total amount of \$200,000,000.

This prospectus provides you with a general description of the securities we may offer. Each time we sell securities, we will provide a prospectus supplement that will contain specific information about the terms of that offering. The prospectus supplement may also add to, update or change information contained in the prospectus and, accordingly, to the extent inconsistent, information in this prospectus is superseded by the information in the prospectus supplement.

The prospectus supplement to be attached to the front of this prospectus may describe, as applicable: the terms of the securities offered; the public offering price; the price paid for the securities; net proceeds; and the other specific terms related to the offering of the securities.

You should only rely on the information contained or incorporated by reference in this prospectus and any prospectus supplement or issuer free writing prospectus relating to a particular offering. No person has been authorized to give any information or make any representations in connection with this offering other than those contained or incorporated by reference in this prospectus, any accompanying prospectus supplement and any related issuer free writing prospectus in connection with the offering described herein and therein, and, if given or made, such information or representations must not be relied upon as having been authorized by us. Neither this prospectus nor any prospectus supplement nor any related issuer free writing prospectus shall constitute an offer to sell or a solicitation of an offer to buy offered securities in any jurisdiction in which it is unlawful for such person to make such an offering or solicitation. This prospectus does not contain all of the information included in the registration statement. For a more complete understanding of the offering of the securities, you should refer to the registration statement, including its exhibits.

You should read the entire prospectus and any prospectus supplement and any related issuer free writing prospectus, as well as the documents incorporated by reference into this prospectus or any prospectus supplement or any related issuer free writing prospectus, before making an investment decision. Neither the delivery of this prospectus or any prospectus supplement or any issuer free writing prospectus nor any sale made hereunder shall under any circumstances imply that the information contained or incorporated by reference herein or in any prospectus supplement or issuer free writing prospectus is correct as of any date subsequent to the date hereof or of such prospectus supplement or issuer free writing prospectus, as applicable. You should assume that the information appearing in this prospectus, any prospectus supplement or any document incorporated by reference is accurate only as of the date of the applicable documents, regardless of the time of delivery of this prospectus or any sale of securities. Our business, financial condition, results of operations and prospects may have changed since that date.

PROSPECTUS SUMMARY

This summary provides an overview of selected information contained elsewhere or incorporated by reference in this prospectus and does not contain all of the information you should consider before investing in our securities. You should carefully read the prospectus, the information incorporated by reference and the registration statement of which this prospectus is a part in their entirety before investing in our securities, including the information discussed under “Risk Factors” in this prospectus and the documents incorporated by reference and our financial statements and notes thereto that are incorporated by reference in this prospectus. As used in this prospectus, unless the context otherwise indicates, the terms “we,” “our,” “us,” or “the Company” refer to Actinium Pharmaceuticals, Inc., a Delaware corporation, and its subsidiaries taken as a whole.

The Company

Business Overview

We are a biopharmaceutical company focused on the \$54 billion market for cancer drugs. Our most advanced products are ActimabTM-A, an antibody-drug construct containing actinium 225 (Ac-225), currently in human clinical trials for acute myeloid leukemia (AML) and IomabTM-B, an antibody-drug construct containing iodine 131 (I-131), used in myeloconditioning for hematopoietic stem cells transplantation (HSCT) in various indications. We are currently designing a trial which we intend to submit for registration approval in HSCT in the settings of refractory and relapsed acute myeloid leukemia in older patients. We are developing our cancer drugs using our expertise in radioimmunotherapy. In addition, the Ac-225 based drugs development relies on the patented Alpha Particle Immunotherapy Technology (APIT) platform technology co-developed with Memorial Sloan Kettering Cancer Center (MSKCC), whose indirect subsidiary, Actinium Holdings Ltd., is a significant stockholder of us. The APIT technology couples monoclonal antibodies (mAb) with extremely potent but comparatively safe alpha particle emitting radioactive isotopes, in particular actinium 225 and bismuth 213. The final drug construct is designed to specifically target and kill cancer cells while minimizing side effects. We intend to develop a number of products for different types of cancer and derive revenue from partnering relationships with large pharmaceutical companies and/or direct sales of its products in specialty markets in the U.S.

Business Strategy

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

Market Opportunity

We are competing in the marketplace for cancer treatments estimated at over \$54 billion in 2011 sales pursuant to an IMS Health report and projected to exceed \$76 billion per year by 2015, according to the Global Academy for Medical Education. While surgery, radiation and chemotherapy remain staple treatments for cancer, their use is

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

Our most advanced products are Actimab™-A, Ac-225 labeled mAb for treatment of newly diagnosed AML, a cancer of the blood, in patients ineligible for currently approved therapies, and Iomab™-B, I-131 labeled mAb for preparation of relapsed and refractory AML patients for HSCT. Iomab™-B offers a potentially curative treatment for these patients most of whom do not survive beyond a year after being diagnosed with this condition. Iomab™-B has also demonstrated efficacy in HSCT preparation for other blood cancer indications, including Myelodysplastic Syndrome (MDS), acute lymphoblastic leukemia (ALL), Hodgkin's Lymphoma, and NHL. These are all follow-on indications for which Iomab™-B can be developed and it is our intention to explore these opportunities when financing becomes available.

There are currently no FDA approved treatments for either Actimab™-A or Iomab™-B targeted patients.

Other potential product opportunities in which a significant amount of preclinical work is being undertaken include metastatic colorectal cancer, metastatic prostate cancer and antiangiogenesis which reduces the blood supply to solid tumors.

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

Clinical Trials

Actimab-A

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

Previous clinical trials leading to this trial included:

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

Completed Actimab-A related clinical trials outcomes:

- The Phase 2 arm of the Bismab®-A drug study has shown signs of the drug's efficacy and safety, including reduction in peripheral blast counts and complete responses in some patients. Bi-213 is a daughter, i.e., product of the degradation of Ac-225, with cancer cell killing properties similar to Ac-225 but is less potent. The Phase 1 Actimab-A trial at MSKCC with a single-dose administration of Actimab™-A showed elimination of leukemia cells from blood in 67% of all evaluable patients who receive a full dose and in 83% of those treated at dose levels above 0.5 microcuries per kilogram (μCi/kg), and eradication of leukemia cells in both blood and bone

marrow in 20% of all evaluable patients and 25% of those treated at dose levels above 0.5 $\mu\text{Ci}/\text{kg}$. Maximum tolerated single dose in this trial was established at 3 $\mu\text{Ci}/\text{kg}$.

Ongoing Actimab-A trial:

We have commenced our first company sponsored Phase 1/2 multi-center trial with fractionated (two) doses of Actimab™-A, Actinium’s lead product for treatment of elderly AML that consists of an AML specific monoclonal antibody (HuM195, also known as Lintuzumab™) and the actinium 225 radioactive isotope attached to it. We are conducting this trial at world-class cancer institutions such as MSKCC, Johns Hopkins Medicine, University of Pennsylvania Health System, Fred Hutchinson Cancer Center and MD Anderson Cancer Center.

Bismab®-A trials and the Phase 1 Actimab™-A trial were focused on relapsed, refractory and other difficult to treat acute myeloid leukemia patients. The current multicenter Phase 1/2 trial is focused on newly diagnosed AML patients who have historically had better outcomes. In addition, the new trial includes low doses of chemotherapy with the goal of further improving patient outcomes.

Iomab-B

Iomab-B is currently in preparation for a pivotal Phase 3 multicenter clinical trial. It consists of the monoclonal antibody BC8 and beta emitting radioisotope iodine 131 (I-131). The indication for that trial is bone marrow conditioning for hematopoietic stem cell transplant in relapsed and refractory AML patients over the age of 55.

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

Indications	N	Key Findings
AML, MDS, ALL (adult)	34	-7/34 patients with median disease free state (DFS) of 17 years. -18/34 patients in remission at day 80
AML >1st remission (adult)	23	-15/23 in remission at day 28
AML 1st remission (age 16-50)	43	-23/43 DFS from 5-16 years -30/43 in remission at day 28 -33/43 in remission at day 80
High-risk MDS, advanced AML (age 50+)	68 in dose escalation study 31 treated at MTD	