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

FORM 8-K

CURRENT REPORT

Pursuant to Section 13 or 15(d) of the
Securities Exchange Act of 1934

Date of Report (Date of earliest event reported): October 31, 2022

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

Delaware	001-36374	74-2963609
(State or other jurisdiction of incorporation)	(Commission File Number)	(IRS Employer Identification No.)

275 Madison Avenue, 7th Floor, New York, NY 10016
(Address of Principal Executive Offices)

Registrant's telephone number: (646) 677-3870
(Former name or former address, if changed since last report)

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions (see General Instruction A.2. below):

☐ Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)

☐ Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)

☐ Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))

☐ Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

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

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
Common Stock, par value $0.001 per share	**ATNM**	**NYSE American**

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (§230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§240.12b-2 of this chapter).

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. ☐

Item 7.01 Regulation FD Disclosure.

On October 31, 2022, Actinium Pharmaceuticals, Inc. (the "Company"), issued a press release that provided information regarding top-line results from the Company's pivotal Phase SIERRA trial for Iomab-B for patients with active relapsed or refractory acute myeloid leukemia age 55 and above. The press release stated that the pivotal Phase 3 SIERRA trial met its primary endpoint of durable complete remission of 6-months following initial complete remission after a bone marrow transplant with statistical significance p-value <0.0001. A copy of the press release is furnished as Exhibit 99.1 to this Current Report on Form 8-K and is incorporated by reference herein. The Company undertakes no obligation to update, supplement or amend the materials attached hereto as Exhibit 99.1.

In accordance with General Instruction B.2 of Form 8-K, the information in this Item 7.01 of this Current Report on Form 8-K, including Exhibit 99.1, shall not be deemed "filed" for the purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the "Exchange Act"), or otherwise subject to the liabilities of that section, nor shall it be deemed incorporated by reference in any filing under the Exchange Act or the Securities Act of 1933, as amended, except as shall be expressly set forth by reference in such a filing. Furthermore, the furnishing of information under Item 7.01 of this Current Report on Form 8-K is not intended to constitute a determination by the Company that the information contained herein, including the exhibits hereto, is material or that the dissemination of such information is required by Regulation FD.

Item 9.01 Financial Statements and Exhibits

(d) Exhibits.

Exhibit Number	Description
99.1	Press Release, dated October 31, 2022 (furnished herewith pursuant to Item 7.01)
104	Cover Page Interactive Data File (formatted as Inline XBRL)

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

Actinium Pharmaceuticals, Inc.

Date: October 31, 2022

/s/ Sandesh Seth

Name: Sandesh Seth
Title: Chairman and Chief Executive Officer

Actinium Announces Positive Top-line Results from Pivotal Phase 3 SIERRA Trial of Iomab-B in Patients with Active Relapsed or Refractory Acute Myeloid Leukemia

- Iomab-B met the primary endpoint of durable complete remission of 6-months following initial complete remission after HCT with a p-value of <0.0001

NEW YORK, NY – October 31, 2022 – **Actinium Pharmaceuticals, Inc.** (NYSE AMERICAN: ATNM) (Actinium or the Company), a leader in the development of targeted radiotherapies, today announced positive top-line results from the pivotal Phase 3 trial for its lead product candidate Iomab-B. The SIERRA (Study of Iomab-B in Elderly Relapsed or Refractory AML) trial was conducted in patients 55 years of age or older who had active disease (relapsed or refractory AML). The SIERRA trial is a randomized, multi-center, controlled study which compared Iomab-B as a conditioning regimen prior to a Bone Marrow Transplant (BMT) versus a control arm which allowed all current means of conventional care with the intent to transplant these patients. The SIERRA trial met its primary endpoint of durable complete remission or dCR of 6 months post initial remission after a BMT in Iomab-B arm compared to conventional care arm demonstrating statistical significance p<0.0001.

Dr. Avinash Desai, Actinium's Chief Medical Officer, added, "We are excited that the randomized, controlled, multi-center, pivotal SIERRA trial has delivered these results for patients that need new treatment options. Our goal is to increase access to BMT and improve patient outcomes with Iomab-B, and these topline results move us in this direction given their statistical significance. We will continue to work on our Biologics License Application (BLA) submission to the US Food and Drug Administration (FDA) for approval of Iomab-B. On behalf of Actinium, I'd like to thank the patients who took the leap of faith and enrolled in the SIERRA trial, their families and caregivers who supported them and the investigators who contributed their efforts and advice who made this trial possible. Without them it would not have been possible to yield these results that will enable us to continue to develop Iomab-B."

Sandesh Seth, Actinium's Chairman and CEO, said, "This is a significant milestone in Actinium's lifecycle and a testimony to the quality of our team who undertook a pioneering study in a patient population that is considered largely futile to treat. Despite being perennially under-staffed and under resourced, their passion and perseverance has yielded a clinically meaningful dividend. Our recently strengthened team is executing to enable our mission to disrupt the field of bone marrow conditioning with Iomab-B, first in r/r AML and then by building upon its robust prior clinical results in several hematological diseases. We look forward to sharing additional clinical data from the SIERRA trial by year end."

About Iomab-B and the Pivotal Phase 3 SIERRA Trial

Iomab-B is a first-in-class targeted radiotherapy intended to improve patient access to potentially curative BMT by simultaneously and rapidly depleting blood cancer, immune and bone marrow stem cells that uniquely express CD45. Multiple studies have demonstrated increased survival in patients receiving BMT, however, an overwhelming majority of patients with blood cancers do not receive BMT as current approaches do not produce a remission, which is needed to advance to BMT, or are too toxic. Studied in over 400 patients, prior studies with Iomab-B have demonstrated nearly universal access to BMT, increased survival and tolerability in multiple clinical trials including the recently completed pivotal Phase 3 SIERRA trial in patients with active (leukemic blasts >5%), relapsed or refractory acute myeloid leukemia (r/r AML) age 55 and above. The SIERRA trial produced positive topline results, meeting its primary endpoint of durable Complete Remission (dCR) of 6 months with statistical significance (p<0.0001). Actinium intends to submit a Biologics License Application (BLA) seeking approval for Iomab-B to address patients age 55+ with r/r AML who cannot access BMT with currently available therapies. Iomab-B has been granted Orphan Drug Designation from the U.S. Food and Drug Administration (FDA) and has patent protection into 2037.

The pivotal Phase 3 SIERRA (Study of Iomab-B in Elderly relapsed or refractory AML) is a 153-patient, randomized, multi-center clinical trial, studying Iomab-B compared to the control arm of physician's choice of salvage therapy. Control arm options included chemotherapies like cytarabine and daunorubicin and targeted agents such as a Bcl-2 inhibitor (Venetoclax), FLT3 inhibitors and IDH 1/2 inhibitors. The SIERRA control arm reflects real-world treatment of r/r AML patients with over 20 single agents or combination of agents as no standard of care exists for this patient population. Data from full patient enrollment presented at the Transplantation & Cellular Therapy Tandem Meetings in April 2022 showed that 100% of patients receiving Iomab-B accessed BMT and engrafted without delay. Iomab-B was also shown to be well tolerated given its targeted nature, consistent with its previous clinical data. The SIERRA trial enrolled patients at 24 leading transplant centers in the United States and Canada that perform over 30% of AML BMTs.

Developed at the Fred Hutchinson Cancer Research Center, a pioneer in the field of BMT, Iomab-B is supported by data in six disease indications including leukemias, lymphomas and multiple myeloma, which afflict over 100,000 patients annually. Actinium intends to pursue additional indications for Iomab-B beyond AML. Actinium also intends to pursue international regulatory approvals independently and through partnerships. In April 2022, Actinium licensed the European, Middle East and North African commercial rights for Iomab-B to Immedica AB, a fully-fledged independent pharmaceutical company headquartered in Sweden. In exchange, Actinium received an upfront payment of $35 million USD with the potential for an additional $417 million USD in regulatory and sales milestones and mid-twenty percent royalties. Europe represents a commercial opportunity double the size of the United States by number of patients with AML receiving BMT. Iomab-B has been granted Orphan Drug Designation by the European Medicines Agency (EMA) and has received positive Scientific Advice from the Committee for Medicinal Products for Human Use (CHMP) of the EMA indicating that the Phase 3 SIERRA trial design, primary endpoint and planned statistical analysis are acceptable as the basis for a Marketing Authorization Application.

About Actinium Pharmaceuticals, Inc.

Actinium Pharmaceuticals, Inc. is a clinical-stage biopharmaceutical company developing targeted radiotherapies to deliver cancer-killing radiation with cellular level precision to treat patients with high unmet needs. Actinium's clinical pipeline is led by radiotherapies that are being applied to targeted conditioning, which is intended to selectively deplete a patient's disease or cancer cells and certain immune cells prior to a bone marrow transplant (BMT), gene therapy or adoptive cell therapy, such as CAR-T, to enable engraftment of these transplanted cells with minimal toxicities. Our lead product candidate, I-131 apamistamab (Iomab-B) has been studied in over four hundred patients in six disease indications including acute myeloid leukemia (AML), myelodysplastic syndrome (MDS), acute lymphoblastic leukemia (ALL), hodgkin's lymphoma, non-hodgkin's lymphoma (NHL) and multiple myeloma across twelve clinical trials including the pivotal Phase 3 Study of Iomab-B in Elderly Relapsed or Refractory Acute Myeloid

Leukemia (SIERRA) trial for BMT conditioning. Iomab-B targets CD45, a cell surface protein expressed on blood cancer cells, normal nucleated immune cells and bone marrow stem cells. Actinium licensed the world-wide exclusive rights to Iomab-B from the Fred Hutchinson Cancer Research Center, a noble prize-winning institution that pioneered the field of bone marrow transplant. Data. Data from the pivotal Phase 3 SIERRA trial has been presented at multiple international medical conferences such as the annual meeting of the American Society of Hematology (ASH) with recent topline data submitted for presentation at this year's meeting, the Tandem Meetings, Transplantation & Cellular Therapy Meetings of the American Society for Transplantation and Cellular Therapy (ASTCT) and the Center for International Blood & Marrow Transplant Research (CIBMTR), and the annual meeting of the Society of Hematologic Oncology (SOHO), where it was awarded honorable distinction in 2019. Post successful topline results, the Company expects to release a more comprehensive set of results by year-end 2022 and is working toward a BLA filing in 2023. Iomab-ACT, low dose I-131 apamistamab, is being studied as a targeted conditioning agent in a Phase 1 study with a CD19 CAR T-cell Therapy with Memorial Sloan Kettering Cancer Center with NIH funding. Iomab-ACT employs a lower dose of I-131 and is being developed to be a single-infusion, out-patient administered therapy that can transiently lymphodeplete patients prior to receiving their CAR-T cellular therapy. Actimab-A, our second most advanced product candidate has been studied in approximately 150 patients with Acute Myeloid Leukemia or AML, including in ongoing combination trials with the chemotherapy regimen CLAG-M and with venetoclax, a targeted therapy. Actimab-A or lintuzumab-Ac225 is an Actinium-225 based antibody radiation conjugate targeting CD33, a validated target in AML. Actinium is a pioneer and leader in the field of Actinium-225 alpha therapies with an industry leading technology platform comprising over 195 patents and patent applications including methods of producing the radioisotope AC-225. Our technology and expertise have enabled collaborative research partnerships with Astellas Pharma, Inc. for solid tumor theranostics, with AVEO Oncology Inc. to create an Actinium-225 HER3 targeting radiotherapy for solid tumors, and with EpicentRx, Inc. to create targeted radiotherapy combinations with their novel, clinical stage small molecule CD47-SIRPα inhibitor. More information is available on Actinium's website: https://www.actiniumpharma.com/.

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