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): August 5, 2024

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.)

100 Park Ave., 23rd Floor, New York, NY 10017
(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 August 5, 2024, Actinium Pharmaceuticals, Inc. (the "Company") issued a press release announcing a regulatory update on the Company's planned Biologics License Application ("BLA") filing for Iomab-B in patients with active relapsed or refractory acute myeloid leukemia (r/r AML). A copy of the press release is attached as Exhibit 99.1 to this Current Report on Form 8-K. 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 No.	Description
99.1	Press Release, dated August 5, 2024.
104	Cover Page Interactive Data File (embedded within the Inline XBRL document)

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: August 5, 2024

/s/ Sandesh Seth

Name: Sandesh Seth
Title: Chairman and Chief Executive Officer

Actinium Provides Regulatory Update on Planned BLA Filing and Future Plans for Iomab-B in the U.S.

- FDA determined that the Phase 3 SIERRA trial is not adequate to support a BLA filing for Iomab-B despite its statistically significant primary endpoint
- Additional head-to-head randomized clinical trial demonstrating overall survival benefit with Iomab-B is required by FDA to support a BLA filing
- Actinium to request a meeting with the FDA to further discuss specifics of additional trial
- Actinium will seek strategic partner for Iomab-B in the U.S. following completion of FDA interactions and focus development efforts on Actimab-A, Iomab-ACT and preclinical programs

NEW YORK, NY – August 05, 2024 – **Actinium Pharmaceuticals, Inc.** (NYSE AMERICAN: ATNM) ("Actinium" or the "Company"), a leader in the development of Antibody Radiation Conjugates ("ARCs") and other targeted radiotherapies, today announced a regulatory update on the Company's planned Biologics License Application ("BLA") filing for Iomab-B in patients with active relapsed or refractory acute myeloid leukemia ("r/r AML"). Iomab-B is an induction and conditioning targeted radiotherapy agent comprised of an anti-CD45 monoclonal antibody and Iodine-131 radioisotope payload. The Company announced that it has now concluded both its clinical and Chemistry, Manufacturing and Controls ("CMC") interactions with the FDA regarding the BLA pathway for Iomab-B. Despite the SIERRA trial meeting the primary endpoint of durable Complete Remission ("dCR") with statistical significance (p-value<0.0001) and other positive secondary endpoints including Event Free Survival ("EFS") and safety, the FDA has now determined that demonstrating an overall survival benefit in a randomized head-to-head trial is required for a BLA filing. The FDA has advised Actinium to conduct a study to evaluate allogeneic bone marrow transplant (BMT) using Iomab-B plus a reduced intensity conditioning regimen of fludarabine and total body irradiation ("Flu/TBI") versus allogeneic BMT using reduced intensity conditioning comprised of cyclophosphamide plus Flu/TBI, a difference from the SIERRA trial, which had allowed physician's choice of salvage therapies and heterogenous conditioning regimens in the control arm. Additionally, the proposed new study will not allow patients to crossover from the control arm which was allowed in the SIERRA trial and confounded the overall survival analysis in the intent to treat ("ITT") patient population, as nearly 60% of patients crossed over from the control arm.

The Phase 3 SIERRA trial enrolled 153 patients with r/r AML and compared outcomes of patients receiving Iomab-B and BMT to patients receiving physician's choice of care with salvage chemotherapy and standard allogeneic BMT in the control arm. In February 2023, Actinium announced that the SIERRA trial met the primary endpoint with statistical significance as 22% of patients (13/76) on the Iomab-B arm achieved dCR compared to 0% of patients (0/77) on the control arm resulting in a p-value of <0.0001. The SIERRA trial was conducted in accordance with guidance from the End of Phase 2 meeting with the FDA, which stated that positive results for dCR as the primary endpoint would be an acceptable endpoint to support an Iomab-B BLA filing. SIERRA did not meet the secondary endpoint of overall survival on an intent to treat basis analysis due to the high crossover rate with nearly 60% of control arm patients receiving Iomab-B followed by a BMT. Over the last several years, a majority of therapies for patients with AML have been approved based on achieving a positive overall survival endpoint.

Actinium presented several additional analyses from the SIERRA study to the FDA including long-term follow-up that demonstrated a trend towards improved overall survival and evidence of survival benefit in patients with high-risk TP53 mutations to support Iomab-B's impact on overall survival. The SIERRA trial data were presented in 12 oral presentations at several leading bone marrow transplant, hematology and nuclear medicine conferences in both the U.S. and Europe, which Actinium believes demonstrates the high unmet medical need and scientific importance of Iomab-B's ability to provide improved access and outcomes for patients with active r/r AML to the transplant community. However, the FDA has now determined that the analyses from the SIERRA trial do not adequately support a BLA filing for Iomab-B and requires an additional clinical study. Actinium expects the safety and efficacy data from the SIERRA trial will provide supportive evidence for a future Iomab-B BLA filing**.**

Key Outcomes and Implications of FDA Interactions

- Phase 3 SIERRA trial results are not adequate to support a BLA filing for Iomab-B in patients with active r/r AML
- FDA is requiring an additional randomized head-to-head trial to demonstrate an overall survival benefit evaluating allogeneic BMT using Iomab-B plus a reduced intensity conditioning regimen of fludarabine and total body irradiation (Flu/TBI) to allogeneic BMT using reduced intensity conditioning comprised of cyclophosphamide plus Flu/TBI
- Proposed additional clinical trial to evaluate Iomab-B plus Flu/TBI compared to a single regimen comprised of cyclophosphamide plus Flu/TBI which differs from the SIERRA trial that allowed physician's choice of salvage therapy and heterogenous conditioning regimens in the control arm
- The proposed additional clinical trial will not allow crossover, which was allowed in SIERRA, and confounded the overall survival analysis in the intent to treat (ITT) patient population as nearly 60% of patients crossed over from the control arm
- Actinium intends to further discuss the specifics of the additional clinical trial including the patient population, which the FDA has suggested could include all adult AML patients
- Upon conclusion of its interactions with the FDA, Actinium will seek a strategic partner for Iomab-B for the U.S.

Dr. Avinash Desai, Actinium's Chief Medical Officer, said, "While this is not the outcome we expected, we will work with the FDA to further discuss specifics of the proposed randomized head-to-head clinical study to determine its strategic feasibility. The 12 oral presentations of the SIERRA results at prestigious bone marrow transplant, hematology and nuclear medicine medical conferences in the U.S. and EU are an attestation of the strong interest from the transplant community for better conditioning regimens due to the high unmet need. We are grateful to the patients, their families, as well as the study investigators and their staff who participated in the SIERRA trial. As a first of its kind study, SIERRA broadened the investigation of Iomab-B as a targeted induction and conditioning agent from a single center to twenty-four leading bone marrow transplant centers in North America, demonstrating its potential for the first time in a randomized, controlled study. Through the conduct of SIERRA, Actinium also built strong relationships with key thought leaders. This track record will provide a solid foundation to work with a partner on a subsequent Iomab-B trial, and we look forward to finalizing the path forward for Iomab-B in the U.S. with the FDA."

Sandesh Seth, Actinium's Chairman and CEO, said, "We are disappointed that the positive results from the SIERRA trial are not deemed adequate by the FDA to support a BLA filing despite meeting the primary endpoint with statistical significance and producing positive efficacy and safety outcomes on several measures. SIERRA represented a first of its kind radiotherapeutic trial and demonstrated Actinium's ability to execute seamlessly across manufacturing, supply chain, clinical development, and operations. We intend to leverage these capabilities as we continue to advance our highly differentiated antibody radiation conjugate pipeline for cell & gene therapy conditioning, hematology therapeutics and solid tumor candidates. We are committed to establishing the best development path forward for Iomab-B in the U.S. and finding a partner, while keeping internal resources and strategic priorities in focus."

About Actinium Pharmaceuticals, Inc.

Actinium develops Antibody Radiation Conjugates ("ARCs") and other targeted radiotherapies intended to meaningfully improve outcomes for people who have failed existing oncology therapies. Iomab-B is an induction and conditioning agent prior to bone marrow transplant in patients with relapsed and refractory acute myeloid leukemia ("r/r AML"), which Actinium plans to advance with a potential strategic partner in the U.S. following completion of FDA interactions. The company continues to advance its development for product candidate Actimab-A, a therapeutic agent that has demonstrated potential activity in r/r AML patients. In addition, Actinium is engaged with the National Cancer Institute ("NCI") under the Cooperative Research and Development Agreement ("CRADA") for development of Actimab-A in AML and other myeloid malignancies. Iomab-ACT, Actinium's next generation conditioning candidate, is being developed with the goal of improving patient access and outcomes for potentially curative cell and gene therapies. In addition, the company's R&D efforts are primarily focused on advancing several preclinical programs for solid tumor indications. Actinium holds more than 235 patents and patent applications including several patents related to the manufacture of the isotope Ac-225 in a cyclotron.

For more information, please visit: https://www.actiniumpharma.com/

Forward-Looking Statements

This press release may contain projections or other "forward-looking statements" within the meaning of the "safe-harbor" provisions of the private securities litigation reform act of 1995 regarding future events or the future financial performance of the Company which the Company undertakes no obligation to update. These statements are based on management's current expectations and are subject to risks and uncertainties that may cause actual results to differ materially from the anticipated or estimated future results, including the risks and uncertainties associated with preliminary study results varying from final results, estimates of potential markets for drugs under development, clinical trials, actions by the FDA and other governmental agencies, regulatory clearances, responses to regulatory matters, the market demand for and acceptance of Actinium's products and services, performance of clinical research organizations and other risks detailed from time to time in Actinium's filings with the Securities and Exchange Commission (the "SEC"), including without limitation its most recent annual report on form 10-K, subsequent quarterly reports on Forms 10-Q and Forms 8-K, each as amended and supplemented from time to time.

Investors:

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