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 16, 2024

AADI BIOSCIENCE, INC.
(Exact name of registrant as specified in its charter)

Delaware	**001-38560**	**61-1547850**
(State or other jurisdiction of incorporation)	**(Commission File Number)**	**(I.R.S. Employer Identification No.)**

17383 Sunset Boulevard, Suite A250	
Pacific Palisades, California	**90272**
(Address of principal executive offices)	**(Zip code)**

Registrant's telephone number, including area code: (424) 744-8055

(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:

☐ 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 $0.0001 per share	AADI	The Nasdaq Stock Market LLC

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 2.05 Costs Associated with Exit or Disposal Activities.

On August 16, 2024, the Board of Directors (the "Board") of Aadi Bioscience, Inc. (the "Company") approved a plan of termination that will result in a workforce reduction of 22 employees, representing approximately 32% of the Company's workforce.

The Company estimates that it will incur non-recurring charges of approximately $2.2 to $2.5 million in connection with the workforce reduction, primarily consisting of severance payments, employee benefits contributions and related costs. The Company expects that the majority of these charges will be incurred in the third quarter of 2024 and that the implementation of the headcount reductions, including cash payments, will be complete by the end of the fourth quarter of 2024. The costs that the Company expects to incur are subject to a number of assumptions, and actual results may differ from the Company's original estimate. The Company may also incur additional costs not currently contemplated due to events that may occur as a result of, or that are associated with, these actions. If the Company subsequently determines that it will incur additional significant costs associated with these actions, it will amend this Current Report on Form 8-K to disclose such information.

This Item 2.05 contains forward-looking statements, including, but not limited to, statements related to the expected severance costs and related estimated severance-related charge and the timing for completion of the reduction in force. These forward-looking statements are based on the Company's current expectations and inherently involve significant risks and uncertainties. The Company's actual results and the timing of events could differ materially from those anticipated in such forward looking statements as a result of these risks and uncertainties, which include, without limitation, those included in the Company's Annual Report on Form 10-K for the fiscal year ended December 31, 2023, including under the caption "Item 1A. Risk Factors," and in the Company's subsequent Quarterly Reports on Form 10-Q, and elsewhere in the Company's reports and other documents that the Company has filed, or will file, with the SEC from time to time and available at www.sec.gov. The Company undertakes no duty or obligation to update any forward-looking statements contained in this Item 2.05 as a result of new information, future events or changes in its expectations.

Item 8.01. Other Events.

On August 20, 2024, the Company issued a press release announcing efficacy results from an interim analysis of participants in its PRECISION1 trial, a registration-directed tumor-agnostic Phase 2 study of FYARRO® (sirolimus protein-bound particles for injectable suspension (albumin-bound); nab-sirolimus) in patients with Tuberous Sclerosis Complex 1 and Tuberous Sclerosis Complex 2 alterations. The press release is attached hereto as Exhibit 99.1 and is incorporated herein by reference.

Item 9.01. Financial Statements and Exhibits.

(d) Exhibits

Exhibit Number	Description
99.1	Press Release, dated August 20, 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.

Dated: August 20, 2024

/s/ Scott Giacobello
Scott Giacobello
Chief Financial Officer

Exhibit 99.1

Aadi Bioscience Provides PRECISION1 Trial and Corporate Updates

PRECISION1 tumor-agnostic trial unlikely to meet regulatory threshold to support an accelerated approval and will be halted

Aadi will focus on FYARRO® commercial business for its approved indication, PEComa, and conduct a comprehensive strategic review to maximize shareholder value

To further preserve cash position, Aadi will adjust ongoing Phase 2 trials and reduce R&D headcount by 80%, thereby extending cash runway into at least 2H 2026

LOS ANGELES, CA, August 20, 2024 – Aadi Bioscience, Inc. (NASDAQ: AADI) today announced it will halt the registration-intended PRECISION1 trial of *nab*-sirolimus in patients with solid tumors harboring *TSC1* or *TSC2* inactivating alterations. An analysis by the Independent Data Monitoring Committee demonstrated that the study was unlikely to exceed an efficacy threshold necessary to support an accelerated approval, the key goal of this Phase 2 study. The approximately 25 patients in PRECISION1 who are still benefiting from *nab*-sirolimus will be eligible for transition to a planned expanded access protocol, and a complete analysis of the PRECISION1 trial will be provided at a later date.

Aadi will now focus on preserving cash while maximizing its commercial business. Aadi's marketed product, FYARRO®, is the only preferred treatment for patients with advanced malignant PEComa, a rare and aggressive cancer. In the second quarter of this year, FYARRO delivered sales of $6.2M.

To further preserve cash runway, Aadi will pause new enrollment, but continue dosing previously enrolled patients, in two, ongoing Phase 2 trials of *nab*-sirolimus for advanced or recurrent endometrioid-type endometrial cancer (EEC) and neuroendocrine tumors (NETs). Both studies have enrolled sufficient patients (n=20 and n=10 for EEC and NETs, respectively) to assess initial efficacy signals later this year. Aligned to these pipeline adjustments, the Company is reducing its Research & Development workforce by 80%. Together these actions extend cash runway into at least 2H 2026.

"We are humbled by the effort of the investigators, support staff, and most importantly, the patients and their families who took part in PRECISION1. While *nab*-sirolimus showed monotherapy activity in the study population, the trial fell short of delivering what we believe would be required to support an accelerated approval in the broad *TSC1/TSC2* inactivating mutations indication. We look forward to providing the full trial analysis at a later date," said David Lennon, President and CEO of Aadi Bioscience. "I want to thank the dedicated Aadi employees who worked tirelessly on this trial and are negatively impacted by this outcome. Given the change in the development pipeline, we have taken the necessary steps to immediately preserve cash runway, and have hired an advisory firm to explore all options to maximize value for shareholders."

About Aadi Bioscience

Aadi is a precision oncology company focused on the commercialization of FYARRO® for the treatment of adult patients with locally advanced unresectable or metastatic malignant perivascular epithelioid cell tumor (PEComa). More information on the Company is available on the Aadi website at www.aadibio.com and connect with us on Twitter and LinkedIn.

Forward-Looking Statements

This press release contains certain forward-looking statements regarding the business of Aadi Bioscience that are not a description of historical facts within the meaning of the Private Securities Litigation Reform Act of 1995. Forward-looking statements are based on the Company's current beliefs and expectations and may include, but are not limited to, statements relating to: the Company's cash runway extending into the second half of 2026; the Company's strategic review; the Company's workforce reduction; the anticipated timing of data releases of the Company's clinical trials, including the analysis of the PRECISION1 trial and initial efficacy signals of the EEC and NETS trials; and the sufficiency of the Company's existing capital resources and the expected timeframe to fund the Company's future operating expenses and capital expenditure requirements. Actual results could differ materially from those anticipated in such forward-looking statements as a result of these risks and uncertainties, which include, without limitation, risks associated with the ability to successfully commercialize FYARRO; the risk that unforeseen adverse reactions or side effects may occur in the course of commercializing, developing and testing FYARRO; uncertainties associated with the clinical development and regulatory approval of FYARRO in additional indications; failure to demonstrate the efficacy of FYARRO in clinical trials for additional indications; and risks related to the Company's estimates regarding future expenses, capital requirements and need for additional financing.

Additional risks and uncertainties that could cause actual outcomes and results to differ materially from those contemplated by the forward-looking statements are included in the Company's Annual Report on Form 10-K for the fiscal year ended December 31, 2023, including under the caption "Item 1A. Risk Factors," and in Aadi's subsequent Quarterly Reports on Form 10-Q, and elsewhere in Aadi's reports and other documents that Aadi has filed, or will file, with the SEC from time to time and available at www.sec.gov.

All forward-looking statements in this press release are current only as of the date hereof and, except as required by applicable law, Aadi undertakes no obligation to revise or update any forward-looking statement, or to make any other forward-looking statements, whether as a result of new information, future events or otherwise. All forward-looking statements are qualified in their entirety by this cautionary statement. This cautionary statement is made under the safe harbor provisions of the Private Securities Litigation Reform Act of 1995.

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