

**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 7, 2024

AADI BIOSCIENCE, INC.

(Exact name of registrant as specified in its charter)

Delaware
(State or other jurisdiction of incorporation)

001-38560
(Commission File Number)

61-1547850
(I.R.S. Employer Identification No.)

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

90272
(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 2.02. Results of Operations and Financial Condition.

On August 7, 2024, Aadi Bioscience, Inc. (the "**Company**") issued a press release announcing its financial results for the quarter ended June 30, 2024. A copy of the press release is attached hereto as Exhibit 99.1 and is incorporated herein by reference.

All of the information furnished in this Item 2.02 and Item 9.01 (including Exhibit 99.1) shall not be deemed to be "filed" for 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 into any filing under the Securities Act of 1933, as amended, or the Exchange Act, except as shall be expressly set forth by specific reference in such a filing.

Item 9.01. Financial Statements and Exhibits.

(d) Exhibits

Exhibit Number	Description
99.1	Press Release, dated August 7, 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.

August 7, 2024

/s/ Scott Giacobello

Scott Giacobello

Chief Financial Officer



Aadi Bioscience Announces Financial Results for the Second Quarter 2024 and Provides Corporate Update

FYARRO® sales of \$6.2 million for Q2 2024, a 15% quarter over quarter sales growth

Interim analysis of two-thirds of fully enrolled PRECISION1 trial planned for Q3 2024

Conference call to be held today at 8:30 am EDT

LOS ANGELES, CA, August 7, 2024 – Aadi Bioscience, Inc. (NASDAQ: AADI), a commercial-stage, precision oncology company focused on developing and commercializing therapies for cancers with alterations in the mTOR pathway, today announced financial results for the second quarter ended June 30, 2024, and highlighted recent corporate progress.

“The second quarter saw quarter over quarter sales growth for FYARRO, as anticipated, and an increase in demand across both new and existing accounts, including from major oncology centers. Approximately 80 percent of accounts have ordered multiple times already this year, reflecting the clinical value of FYARRO for patients with advanced malignant PEComa,” said Dave Lennon, President and CEO of Aadi Bioscience. “Looking ahead, we will provide the next interim update from PRECISION1, a tumor-agnostic study that enrolled any tumor type presenting with qualifying *TSC1* or *TSC2* inactivating alterations, later in the third quarter. With this study, *nab*-sirolimus has the potential to demonstrate a meaningful impact on the lives of patients who have already received standard therapies appropriate for their tumor type and stage of disease.”

Recent Operational Highlights

- **FYARRO net product sales were \$6.2 million in the second quarter**, an increase of 15 percent from Q1 2024 and in line with the prior year period.
- **Two-thirds interim analysis of registration-intended PRECISION1 trial is planned for Q3 2024.** PRECISION1 is exploring *nab*-sirolimus in solid tumors with *TSC1* or *TSC2* inactivating alterations. The trial is fully enrolled, and study completion is expected by year-end.
- **Enrollment into two additional Phase 2 trials is ongoing, with initial data expected by the end of the year.** These tumor specific, open-label trials are investigating the potential of *nab*-sirolimus for difficult-to-treat mTOR-driven cancers: advanced or recurrent endometrioid-type endometrial cancer (EEC) in combination with letrozole, and neuroendocrine tumors (NETs) of the lung, gastrointestinal tract and pancreas.

Second Quarter 2024 Financial Results

- Cash, cash equivalents and short-term investments as of June 30, 2024, were \$78.6 million as compared to \$108.8 million as of December 31, 2023, which is expected to fund operations into Q4 2025 based on current plans.
- Total revenue for the quarter ended June 30, 2024, was \$6.2 million, resulting from sales of FYARRO.
- Net loss for the three months ended June 30, 2024, was \$14.6 million as compared to \$18.0 million for the three months ended June 30, 2023.

Conference Call Information

The Aadi management team is hosting a conference call and webcast today at 8:30 am EDT (5:30 am PDT) to provide a corporate update and discuss results for the second quarter 2024.

Participants may access a live webcast of the call and the associated slide presentation on the “Investors & News” page of the Aadi Bioscience website at aadibio.com. To participate via telephone, please register in

advance at this [link](#). Upon registration, all telephone participants will receive a confirmation email detailing how to join the conference call, including the dial-in number along with a unique passcode and registrant ID that can be used to access the call. A replay of the conference call and webcast will be archived on the Company's website for at least 30 days.

About Aadi Bioscience

Aadi is a commercial-stage precision oncology company focused on the development and commercialization of therapies for cancers with alterations in the mTOR pathway, a key regulator of cell growth and cancer progression. To unlock the full potential of mTOR inhibition, Aadi uniquely combines nanoparticle albumin-bound (*nab*) technology with the potent mTOR inhibitor, sirolimus. Aadi received FDA approval and commercializes FYARRO® for the treatment of adult patients with locally advanced unresectable or metastatic malignant perivascular epithelioid cell tumor (PEComa).

Aadi is exploring *nab*-sirolimus in PRECISION1, a Phase 2 tumor-agnostic registration-intended trial in mTOR inhibitor-naïve malignant solid tumors harboring *TSC1* or *TSC2* inactivating alterations. Aadi is also exploring *nab*-sirolimus in two tumor specific Phase 2 trials for difficult-to-treat mTOR-driven cancers: neuroendocrine tumors (NETs) of the lung, gastrointestinal tract and pancreas, and advanced or recurrent endometrioid-type endometrial cancer (EEC) in combination with letrozole. More information on the Company's development pipeline 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 fourth quarter of 2025; the anticipated timing of commencement, enrollment, data releases and completion of the Company's clinical trials, including the expected PRECISION1 two-thirds interim analysis in Q3 2024 and study completion by year-end and Phase 2 trials in EEC and NETs later in 2024; the Company's expectations regarding a return to sales growth and continued advancements, including in potential additional indications; expectations regarding the beneficial characteristics, safety, efficacy, therapeutic effects and the size of the potential targeted markets with respect to FYARRO, including in *TSC1*, *TSC2*, NETs and EEC; plans and potential for success relating to commercializing FYARRO; 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, uncertainties associated with the clinical development and regulatory approval of FYARRO in additional indications, including potential delays in the commencement, enrollment and completion of clinical trials for additional indications; risks associated with the ability to successfully commercialize FYARRO; failure to demonstrate the efficacy of FYARRO in clinical trials for additional indications; the risk that unforeseen adverse reactions or side effects may occur in the course of commercializing, developing and testing FYARRO; 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.

Contact:

IR@aadibio.com



AADI BIOSCIENCE, INC.
CONDENSED CONSOLIDATED BALANCE SHEETS
(In thousands)
(Unaudited)

	June 30, 2024	December 31, 2023
Assets		
Current assets:		
Cash and cash equivalents	\$ 41,139	\$ 62,888
Short-term investments	37,429	45,957
Accounts receivable, net	5,920	5,488
Inventory	6,098	6,427
Prepaid expenses and other current assets	2,419	3,826
Total current assets	93,005	124,586
Property and equipment, net	6,004	4,802
Operating lease right-of-use assets	982	1,169
Other assets	1,629	1,866
Total assets	\$ 101,620	\$ 132,423
Liabilities and stockholders' equity		
Current liabilities:		
Accounts payable	\$ 2,265	\$ 5,898
Accrued liabilities	13,751	14,306
Operating lease liabilities, current portion	374	434
Due to licensor payable	5,757	5,757
Total current liabilities	22,147	26,395
Operating lease liabilities, net of current portion	682	833
Total liabilities	22,829	27,228
Stockholders' equity:		
Common stock	2	2
Additional paid-in capital	380,651	374,129
Accumulated other comprehensive (loss) income	(27)	27
Accumulated deficit	(301,835)	(268,963)
Total stockholders' equity	78,791	105,195
Total liabilities and stockholders' equity	\$ 101,620	\$ 132,423



AADI BIOSCIENCE, INC.
CONDENSED CONSOLIDATED STATEMENT OF OPERATIONS
(In thousands, except shares and earnings per share amounts)
(Unaudited)

	Three Months Ended June 30,		Six Months Ended June 30,	
	2024	2023	2024	2023
Revenue				
Product sales, net	\$ 6,179	\$ 6,202	\$ 11,532	\$ 12,069
Total revenue	<u>6,179</u>	<u>6,202</u>	<u>11,532</u>	<u>12,069</u>
Operating expenses				
Selling, general and administrative	7,892	11,776	18,512	22,983
Research and development	13,093	13,315	26,686	24,271
Cost of goods sold	778	656	1,430	1,185
Total operating expenses	<u>21,763</u>	<u>25,747</u>	<u>46,628</u>	<u>48,439</u>
Loss from operations	<u>(15,584)</u>	<u>(19,545)</u>	<u>(35,096)</u>	<u>(36,370)</u>
Other income (expense)				
Foreign exchange loss	(2)	(3)	(3)	(3)
Interest income	1,061	1,635	2,343	3,295
Interest expense	(58)	(58)	(116)	(116)
Total other income (expense), net	<u>1,001</u>	<u>1,574</u>	<u>2,224</u>	<u>3,176</u>
Net loss	<u>\$ (14,583)</u>	<u>\$ (17,971)</u>	<u>\$ (32,872)</u>	<u>\$ (33,194)</u>
Net loss per share, basic and diluted	<u>\$ (0.54)</u>	<u>\$ (0.67)</u>	<u>\$ (1.22)</u>	<u>\$ (1.23)</u>
Weighted average number of common shares outstanding, basic and diluted	<u>27,010,013</u>	<u>26,879,089</u>	<u>26,995,356</u>	<u>26,878,672</u>