
**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): **March 13, 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 March 13, 2024, Aadi Bioscience, Inc. (the "**Company**") issued a press release announcing its financial results for the fiscal year ended December 31, 2023. 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 March 13, 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.

March 13, 2024

/s/ Scott Giacobello

Scott Giacobello

Chief Financial Officer



Aadi Bioscience Announces Financial Results for the Fourth Quarter and Full-Year 2023 and Provides Corporate Update

FYARRO® sales of \$6.3 million for Q4 2023 and \$24.4 million for FY 2023 representing year-over-year growth of 21% and 60%, respectively

Registration-directed PRECISION1 trial of nab-sirolimus in solid tumors with TSC1 or TSC2 inactivating alterations on track to complete enrollment by May; two-thirds interim analysis planned for Q3 2024

Phase 2 trials in Endometrial Cancer and Neuroendocrine Tumors (NETs) actively enrolling patients

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

LOS ANGELES, CA, March 13, 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 fourth quarter and full-year ended December 31, 2023, and highlighted recent corporate progress.

“With strong execution against our commercial and development goals, 2023 was a year of progress and momentum for Aadi,” said Dave Lennon, President and CEO of Aadi Bioscience. “As the preferred treatment for malignant PEComa, FYARRO saw significant growth and high penetration in academic and community settings. Clinically, we were encouraged by the interim results from the registration-directed PRECISION1 trial, and look forward to the two-thirds readout expected in Q3. We also initiated enrollment of two Phase 2 trials in what we believe are promising mTOR-driven cancer targets, endometrial cancer and neuroendocrine tumors, as we further characterize the potential of *nab*-sirolimus. With a commercial foundation, bold development vision and solid cash runway in to Q4 2025, we believe we are well-positioned to realize our ambition of becoming a multi-indication precision oncology company.”

Recent Operational Highlights

- **FYARRO net product sales were \$6.3 million** in the fourth quarter, or 21% growth over the prior year period, and \$24.4 million for full-year 2023, representing 60% growth year-over-year.
- **PRECISION1 on track to complete enrollment by May 2024**, with the two-thirds interim analysis expected in Q3 2024. Early data presented in December 2023 demonstrated sustained tumor reductions in heavily pre-treated population from investigator-assessed responses in first 40 patients across both arms. The safety profile was consistent with the nab-sirolimus label and the mTOR inhibitor drug class.
- **Enrollment of two single-indication Phase 2 trials underway** to investigate the potential of *nab*-sirolimus for difficult-to-treat mTOR-driven cancers: neuroendocrine tumors (NETs), and advanced or recurrent endometrioid-type endometrial cancer (EEC) in combination with letrozole.
 - NETs are rare, ~3,500 cases a year, with low response rates to existing recommended treatments. Preclinical models indicate improved target suppression relative to other mTORs in the NETS population.
 - Endometrial cancer is the most common cancer of the female reproductive organs and one of the few cancers with increasing mortality. There are an estimated 10,000 cases of EEC diagnosed annually. Prior clinical studies with mTOR inhibitors and letrozole have yielded promising results in EEC.

Fourth Quarter and Full-year 2023 Financial Results

- Cash, cash equivalents and short-term investments as of December 31, 2023, were \$108.8 million as compared to \$172.6 million as of December 31, 2022, which is expected to fund operations into Q4 2025 based on current plans.
- Total revenue for the quarter ended December 31, 2023, was \$6.3 million, and \$24.4 million for the full-year ended December 31, 2023, resulting from sales of FYARRO.
- Net loss for the three months ended December 31, 2023, was \$16.3 million as compared to \$13.9 million for the three months ended December 31, 2022. Net loss for the full-year ended December 31, 2023, was \$65.8 million, as compared to \$60.5 million for the same period in 2022.

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 fourth quarter and full-year 2023.

Participants may access a live webcast of the call 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-directed trial in mTOR inhibitor-naïve malignant solid tumors harboring TSC1 or TSC2 inactivating alterations. Aadi is also exploring *nab*-sirolimus in two single-indication Phase 2 trials for difficult-to-treat mTOR-driven cancers: neuroendocrine tumors (NETs), 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 full enrollment of the PRECISION 1 trial by May 2024 and the expected PRECISION 1 two-thirds interim analysis in 3Q 2024; the Company's anticipated 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 NETs and EEC; 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; failure to demonstrate the efficacy of FYARRO in clinical trials for additional indications; risks related to the release of interim, topline and preliminary data from clinical trials; the risk that unforeseen adverse reactions or side effects may occur in the course of commercializing, developing and testing FYARRO; risks associated with the failure to realize any

value from FYARRO in light of inherent risks and difficulties involved in successfully bringing product candidates to market; risks relating to the Company's reliance on third party suppliers, some of which are sole suppliers; 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, 2022, 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:

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

	December 31, 2023	December 31, 2022
Current assets:		
Cash and cash equivalents	\$ 62,888	\$ 39,019
Short-term investments	45,957	133,541
Accounts receivable, net	5,488	1,862
Inventory	6,427	1,861
Prepaid expenses and other current assets	3,826	3,746
Total current assets	124,586	180,029
Property and equipment, net	4,802	508
Operating lease right-of-use assets	1,169	1,522
Intangible asset, net	—	—
Other assets	1,866	2,178
Total assets	\$ 132,423	\$ 184,237
Liabilities and stockholders' equity		
Current liabilities:		
Accounts payable	\$ 5,898	\$ 3,519
Accrued liabilities	14,306	14,922
Operating lease liabilities, current portion	434	394
Due to licensor payable (Note 8)	5,757	—
Total current liabilities	26,395	18,835
Operating lease liabilities, net of current portion	833	1,267
Due to licensor	—	5,757
Total liabilities	27,228	25,859
Stockholders' equity:		
Preferred stock	—	—
Common stock	2	2
Additional paid-in capital	374,129	361,689
Accumulated other comprehensive income (loss)	27	(115)
Accumulated deficit	(268,963)	(203,198)
Total stockholders' equity	105,195	158,378
Total liabilities and stockholders' equity	\$ 132,423	\$ 184,237



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

	Three Months Ended December 31,		Year Ended December 31,	
	2023	2022	2023	2022
Revenue				
Product sales, net	\$ 6,326	\$ 5,227	\$ 24,354	\$ 15,216
Total revenue	6,326	5,227	24,354	15,216
Operating expenses				
Selling, general and administrative	10,345	11,106	44,549	40,176
Research and development	12,768	9,369	48,929	32,662
Cost of goods sold	927	222	2,809	1,335
Impairment of acquired contract intangible asset	—	—	—	3,724
Total operating expenses	24,040	20,697	96,287	77,897
Loss from operations	(17,714)	(15,470)	(71,933)	(62,681)
Foreign exchange (loss) gain	2	—	(1)	—
Interest income	1,500	1,606	6,400	2,398
Interest expense	(57)	(57)	(231)	(230)
Other income (expense), net	1,445	1,549	6,168	2,168
Loss before income tax expense	(16,269)	(13,921)	(65,765)	(60,513)
Income tax benefit (expense)	—	9	—	—
Net loss	\$ (16,269)	\$ (13,912)	\$ (65,765)	\$ (60,513)
Other comprehensive loss				
Change in unrealize loss on short-term investments	43	\$ (16)	142	\$ (115)
Comprehensive loss	\$ (16,226)	\$ (13,928)	\$ (65,623)	\$ (60,628)
Net loss per share, basic and diluted	\$ (0.60)	\$ (0.52)	\$ (2.44)	\$ (2.69)
Weighted average number of common shares outstanding, basic and diluted	26,965,909	26,839,033	26,917,967	22,511,237